Changing Physician Behavior - When To Do It, How To Do It, When Not To Do It

Roy M. Poses, MD, Wally R. Smith, MD

COMBINED BIBLIOGRAPHY
Bibliography - When To Do It

Evidence Based Quality Assessment
Bibliography—How To Do It—Cognitive Psychology Approaches


Recent Studies on Decision Making for Congestive Heart Failure

Overviews and Editorials About Changing Physician Behavior

Systematic Reviews of Original Studies of Interventions to Change Physician Behavior


Judgment and Decision Making


Useful Texts on Judgment and Decision Psychology


Bibliography - How Not to Do It

Core Values

Health Care Dysfunction

Large, Bureaucratic Organizations

Incompetent, Self-Interested, Corrupt Leadership

Allegheny Case
Duffy SP. Federal judge lets RICO civil claims against Allegheny executives continue. Legal Intelligencer, December 17, 1999.

Managed Care Practices, Perverse Incentives, Intimidation

Advertising

Stealth Marketing Campaigns
Elliott C. Pharma goes to the laundry: public relations and the business of medical education. Hastings Center Rep 2004; 34: 18-
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**Manipulation and Suppression of Research**

*Suppression of Research: Dr. David Kern Flock Lung Case*

*Manipulation of Research Design*

*Ghost Writing*

*Vioxx Case*

*Ghost Writing of Reviews and Editorials*

**Special Pleadings: The Nuclear Freeze Example**

**Post-Modernism**
Changing Physician Behavior - When To Do It, How To Do It, When Not To Do It

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Bibliography – How To Do It

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Changing Physician Behavior – When to Do It? How to Do It? When Not to Do It?

Wally R Smith MD, Virginia Commonwealth University; Roy M. Poses MD, Foundation for Integrity and Responsibility in Medicine;
(Moral) Sponsorship by:

• Professionalism Sub-Committee of the SGIM Clinical Practice Committee
When to Change Physicians’ Behavior?

• Our approach is based on the principles and processes of evidence-based medicine (EBM)
Evidence Based Medicine

• Medicine based on the systematic search for and systematic, critical review of the best available evidence

• The integration of best research evidence with clinical expertise and patient values

• The underlying goal is to maximize the likelihood of benefit and minimize the likelihood of harm for each patient, according to the patient’s values
The Evidence Based Medicine Process

- Define clinical question
- Perform systematic search for and systematic, critical review of best available evidence relevant to that question
- Answer question as best you can based on the above
Rationale for Evidence-Based Medicine

• It’s better for patients
• It’s logical
• It crystallizes the intellectual basis of medicine
• It empowers doctors, nurses, patients
• It makes medicine more professional
AN EDUCATIONAL PROGRAM TO IMPROVE PHYSICIANS' DIAGNOSTIC JUDGMENTS FOR PHARYNGITIS

- Roy M. Poses MD, Robert S. Wigton MD,
- Randall D. Cebul MD, Robert M. Centor MD,
- Marjeanne Collins MD, Gerald Fleischli MD
  - Medical College of Virginia, University of Nebraska, Case-Western Reserve University, University of Pennsylvania
An Educational Program to Improve Physicians’ Diagnostic Judgments for Pharyngitis

- Our first effort to change physicians’ behavior
- Based on judgment/decision psychology
Decision analyses suggest that decision to use antibiotics for sore throat should be based on judgment of probability of streptococcal pharyngitis

Preliminary study:
- Probability judgments predicted decisions
- Physicians overestimated probability
Study Design

- Controlled trial
- Practice site as unit of analysis
- Practice sites: 2 university student health centers in different states
- Practitioners: generalist physicians and nurse practitioners
Interventions

● Experimental:
  – Feedback based on judgments of probability made in response to computerized patient vignettes
  – Monthly prevalence feedback
  – Lecture

● Control:
  – Lecture
Outcome Measurements

- Judgments of probability of streptococcal pharyngitis
  - Accuracy via calibration curves
  - Discrimination via ROC curves
- Rates of antibiotic usage
Calibration: Pre-Experimental Intervention

Judged Probability (%) vs. Actual Rate (%)

- Data
- Ideal

Graph showing the relationship between judged probability and actual rate.
Calibration: Post-Experimental Intervention

- Judged Probability (%)
- Actual Rate (%)

Graph showing the relationship between judged probability and actual rate post-experimental intervention.
Antibiotic Usage

Proportion Receiving Antibiotics

Pre-Intervention

Post-Intervention
Results

- Calibration improved more in experimental intervention group
- Discrimination improved in both groups
- No change in antibiotic use (!)
Discussion

- Intervention could improve judgments of probability of streptococcal pharyngitis.
- Although judgments of this outcome are associated with treatment decisions, they do not drive decision making.
- Other judgments correlated with judgment of disease probability drove decisions?
  - clinical improvement were antibiotics to be given?
  - adverse effects of antibiotics?
- Next study should be of judgments of outcomes conditional on treatment.
The Challenge

• How can we educate physicians to make decisions more according to the principles of Evidence-Based Medicine?
  – Our first attempt showed it would not be as simple as we thought
  – Meanwhile, more and more examples appeared of physicians apparently failing to make decisions according to these principles
Doctors Often Don’t Do What the Evidence Says They Should Do

• Failure to use treatments whose benefits clearly outweigh harms
  – ASA, beta-blocker post MI
  – Angiotensin converting enzyme inhibitors (ACEI’s) for CHF with systolic dysfunction
  – Rapid administration of antibiotics for pneumonia
  – Flu and pneumonia vaccines

• Use of treatments whose benefits do not clearly outweigh harms
  – Calcium channel blockers for congestive heart failure (CHF) with systolic dysfunction
Use of Antibiotics for Sore Throats

Linder JA. JAMA 2001; 1181-1186.

Proportion of Patients Receiving Antibiotics

Linder JA. JAMA 2001; 1181-1186.
Examples for the 21st Century? – With a Nod to the Emphasis on Outcomes

• Failure to treat type 2 diabetes mellitus aggressively to lower HgBA1C < 7%?
• Failure to treat hyperlipidemia with statins to lower LDL for primary prevention?
• Failure to treat anemia in chronic renal failure aggressively with epoetin?
Examples for the 21\textsuperscript{st} Century? – Maybe Not

- Failure to treat type 2 diabetes mellitus aggressively to lower HgBA1C < 7%?
  - But this raises risk of hypoglycemia
- Failure to treat hyperlipidemia with statins to lower LDL for primary prevention?
  - But no mortality improvement demonstrated
- Failure to treat anemia in chronic renal failure aggressively with epoetin?
  - And thereby hangs a tale – per Dr Smith’s slides
Changing Physician Behavior: How, and How Not to Do It

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Case Study: Epoetin Overuse in Renal Dialysis

- Epoetin can treat anemia of renal failure.
- Epoetin usually dosed to achieve a given target level of Hct or Hb.
More aggressive treatment attempting to achieve a nearly normal hemoglobin *not clearly supported by RCTs*

- no significant difference in the risk of death for low Hb(<133 g/L).

Lower Hb targets significantly associated with an increased risk for seizures but a reduced risk of hypertension.

Meanwhile, Medicare pays for higher and higher hemoglobin targets

- Despite lack of evidence for more aggressive use of epoetin
  - No evidence from RCTs, no FDA suggested targets
  - (Medicare pays for chronic dialysis in the US)

Spending for Epoetin largest Medicare drug expenditure

- $1.75 billion in 2005
  - Epoetin second-largest source of dialysis facility income
    - 22 percent
  - Epogen made Amgen global powerhouse
    - In 2005, $3.7 billion earned, on $12.4 billion in revenue
Epoetin use Evidence-based?

Defense of Epoetin by Cotter et al

- Medicare based its decisions on published practice guidelines
  - the Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines, written by National Kidney Foundation (NKF)
Did Amgen Sponsorship Influence How Evidence was Assembled and Disseminated?

Amgen Sponsored the Kidney Disease Outcomes Quality Initiative

Review of the evidence supporting KDOQI’s Target Hb rec’s yielded major deficiencies.

- Weights for cited studies never published
- Evaluation techniques did not elicit 'linkages in the causal pathway between intervention and outcome.'
- Evidence- a few RCTs, expert opinion, and numerous industry-sponsored observational studies based on administrative data
  - But for any given snapshot of the treated population, higher Hct tended to have better clinical outcomes.
Both researchers and guideline developers interpreted evidence of an *association* between treating the anemia of renal disease with higher Epoetin doses and improved clinical outcomes as an indicator of causality.
CHOIR Trial

- Ortho Biotech Products LP
- 1,432 subjects

Do patients have lower death rates and fewer cardiovascular events if Rx ↑ RBC counts to 13.5 g/dL?
CHOIR Trial (cont’d)

- Intended to document the benefits of larger Procrit doses (Procrit virtually identical to Epogen)
- Instead, safety reviewers halted testing
  - participants dying at an unexpectedly high rate
- Highest doses of Epogen suffered 16 more deaths than those treated within FDA guidelines
  - -- 72 out of about 700 patients vs 56 deaths
- Results not published in an academic journal
Other Results Indicating Epogen Risks

- Fatal heart attacks, strokes, and other problems forced clinical investigators to suspend at least seven other similar trials.

- Unfavorable Epoetin science results published, but editorial piece critical of National Kidney Foundation and guidelines rejected by N Engl J Med
  - Author was senior N Engl J Med writer
  - A less critical editorial was published, written by a National Kidney Foundation associate who works for N Engl J Med

- Critical, rejected editorial piece was published by Lancet
  - Editor: 'I was surprised [the author] came to us because I have admired his work for the New England Journal of Medicine.'
  - 'We thought it extremely important -- because of the significant clinical implications and because of the questions it raised about the propriety of the arrangements over funding and guideline development.'
The FDA just issued a black box warning for erythropoetin in chronic renal failure, suggesting use of the minimum dose required to reduce the need for transfusions. This is the sort of behavior change that we should not be doing.
Changing Physician Behavior – the Old and New Challenges

The Old Challenge involved teaching physicians:

- about the evidence-based medicine and medical decision making paradigms
- about their own human psychological limitations as decision-makers
- to be critical of the current dogma

The New Challenge involves teaching physicians:

- to recognize that most behavior change efforts promote vested economic or ideologic interests
Features of MD Behavior

- >20 years of prior education/training
- Highly ethical, professional
- Some behavior cognitive and not habitual
- Some behavior reflex and habitual
- Abundant educational materials competing for attention
- Limited time for interventions
- Motivated by multiple interests: patients, own, society
- Opinion leaders are local, national
HOW TO CHANGE?
Four steps of Evidence-based Quality Assessment

Set priorities (Plan)

Set guidelines (Do)
- Evidence-based care: 2. Setting guidelines: how should we manage this problem? CMAJ 1994 May 1;150(9):1417-23.

Measure performance (Check)

Improve performance (Act)
Changing Physician Behavior-
When to Do It?

Roy M. Poses MD
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Evidence-Based Quality Assessment

• EBM ideally provides an unbiased determination of whether there is are preferred management options for populations of patients with particular characteristics and particular problems

• Preferred management options here means those which clearly provide benefits that outweigh their harms for these patient population, taking into account the patients’ values (utilities)
The EBQA Process

- Set priorities – find important clinical problems that affect defined populations
- Set guidelines – determine if there are preferred management options for those patients with those clinical problems
- Measure performance – determine if physicians are using the preferred management options
- Improve performance – if not, persuade physicians to do so
Current Quality Improvement and Pay for Performance Schemes

• Sort of look like EBQA
  – For example, principles used to develop the AQA Starter Set of P4P measures include:
    • Measures should be reliable, valid and based on sound scientific evidence.
    • Measures should focus on areas which have the greatest impact in making care safe, effective, patient-centered, timely, efficient or equitable (IOM’s six aims for improvement), and primarily, but not exclusively, where the most improvement can be made (“80/20 rule”).
    • Measures should be selected based on where there has been strong consensus among stakeholders and predictive of overall quality performance.
  – But do not explicitly include all relevant parts of EBQA process
The EBQA Process

- Set priorities – find important clinical problems that affect defined populations
- **Set guidelines** – determine if there are preferred management options for those patients with those clinical problems
- Measure performance – determine if physicians are using the preferred management options
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Set Guidelines

• Systematic search for the best possible evidence
• Critical review of each study
• Clear determination that benefits of preferred management option out-weighed harms
  – Which may require formal assessment of expected utilities of that option versus other options
Was the Search Really Systematic?

• Thorough search using multiple search strategies for all relevant published literature?

• Attempt to assess unpublished studies?
  – “Negative” studies often unpublished
  – Studies that are contrary to vested interests sometimes actively suppressed
Was the Review Really Critical?

• Clear, rigorous methodologic criteria pre-specified (e.g., in the “Users Guides” format)?

• Methods of the study assessed in detail, not just whether it was an RCT?
Clear Methodologic Criteria: Example – Users Guides for Articles about Therapy

- Was the assignment of patients to treatments randomized?
- Were all patients who entered the trial properly accounted for and attributed at its conclusion?
- Was follow-up complete?
- Were patients analyzed in the groups to which they were randomized?
- Were patients, health workers, and study personnel “blind” to treatment?
- Were the groups similar at the start of the trial?
- Aside from the experimental intervention, were the groups treated equally?
Clear Methodologic Criteria: Example – Users Guides for Articles about Therapy II

• How large was the treatment effect?
• How precise was the estimate of treatment effect?
• Can the results be applied to my patient care?
• Were all clinically important outcomes considered?
• Are the treatment benefits worth the potential harms and costs?
Did the Benefits Really Out-Weigh the Risks?

- Benefits really were outcomes important to patients?
  - Not just intermediate outcomes, like laboratory test results?
  - Composite outcomes interpretable?
- Evidence of harms really sought?
  - Possible adverse effects of management option measured?
  - Sufficient study power to find differences in adverse effects?
- Patient population really generalizable to practice?
- Comparison treatment (or use of placebo) realistic?
- Balance of benefits and harms clear and not likely to be greatly affected by differences in patients’ values (utilities)?
  - If not, formal assessment of expected utilities done?
Set Guidelines

• My gut feeling:
  – There are a lot of guidelines out there
  – But, it may be very hard to find guidelines that define preferred management options that even approximately fit these proposed criteria
  – Thus, most efforts to change physicians’ behavior may not be based on firm foundations
The EBQA Process

- Set priorities – find important clinical problems that affect defined populations
- Set guidelines – determine if there are preferred management options for those patients with those clinical problems
- **Measure performance – determine if physicians are using the preferred management options**
- Improve performance – if not, persuade physicians to do so
Measuring Performance

- How good is the evidence that physicians are not currently using the preferred management options for the relevant patients?
- The question is about physicians’ decisions
- Methodologic issues are analogous to those arising when studying disease etiology or prognosis
Measuring Performance – Methodologic Issues – a la the Users Guides

• Was there a representative and well-defined sample of patients?
• Was follow-up sufficiently long and complete?
• Was an objective and unbiased ascertainment of the physicians’ decisions made?
• How large was the likelihood of the decision?
• How precise were the estimates of the likelihood?
Representative Patient Sample

- Was there a representative sample (cohort) of patients who were sufficiently similar to those for whom the guideline was set?
  - Did all the patients have the disease or problem of interest?
  - Were patients for whom a management option of interest was contraindicated excluded?
  - Were patients for whom a management option of interest was mandated excluded?
Sufficiently Long, Complete Follow-Up

- Follow-up reasonably complete through the time-period during which the decision could plausibly be made?
Unbiased Ascertainment?

• Were the decisions ascertained directly?
• If decisions were inferred from data about management options received by patients:
  – How were patients who refused, or who vanished or died before the decision could be carried out handled?
  – How were patients who did not receive the option due to system problems or actions by people other than the physician handled?
  – If decisions were inferred from administrative data, how accurate were the inferences?
• Could the decision be attributed to the physicians under study?
  – As opposed to some other physicians, or someone else
Effect Size and Precision

• Was the deviation of the proportion of patients who got the preferred decision from the optimal proportion clinically important?
• Was the estimate of this deviation sufficiently precise to conclude that it was clinically important?
When Should We Try to Change Physicians’ Behavior?

- When they are managing an important clinical problem
- When it is clear, based on the EBM process, that there are preferred management options for that problem for well-defined patient populations
- When it is clear, based on the EBM process, that physicians are failing to use those preferred options for a clinically significant proportion of patients in those populations
Changing Physician Behavior: How, and How Not to Do It

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Features of MD Behavior

- >20 years of prior education/training
- Highly ethical, professional
- Some behavior cognitive and not habitual
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- Limited time for interventions
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- **Measure performance (Check)**

- **Improve performance (Act)**
This Presentation

Discuss improving performance--what we know

- How to intervene to improve practice
- Methodologic issues affecting studies of interventions
- What we know about various interventions’ effectiveness
- How we can use knowledge about physicians’ decision making to develop potentially better interventions
History of Attempts to Change

- Pre 1980s: Continuing Medical Education widely used
- 1980s- : Quality improvement
  - Systems, feedback, CQI/TQM, guidelines
- 1985- : Managed care
  - Coercive (effective but unpalatable)
- Early Reviews
  - Eisenberg 1985--some success, medium vs. message, studies weak
  - Woolf, 1990, 1993--guidelines not successful
How to Change: Conventional wisdom

- CME conferences
- feedback of performance
- guidelines
- profiling
- economic incentives and disincentives
- administrative approval
- paper-based and computer-based reminders
  - each technique works independently and effectively
Characteristics of Interventions to improve physician behavior

- expensive
- often difficult
- time-consuming
- sometimes carry risks to patient outcomes
Evidence for the Effectiveness of Techniques To Change Physician Behavior*

Wally R. Smith, MD

**Study objectives:** To understand the theory and results of how to improve physician performance, as part of overall health-care quality improvement. In particular, to study whether and how guideline production and dissemination affects physician performance.

**Design:** Review of meta-analyses and structured reviews; review of behavior change theories implicit in interventions to change physician performance.

**Setting:** Primarily the United States.

**Patients or participants:** Various patients and physicians, determined by reviews.

**Interventions:** None.

**Measurements and results:** There is no unifying theory of physician behavior change tested among physicians in practice. Attempts to affect individual physicians’ performance have often met with failure. Mixed results are found for almost all interventions reviewed. Multiple interventions yield better results.

**Conclusions:** The answer to the question of what works to improve an individual physician’s clinical performance is not simple. Emerging theory and evidence suggests that applications of behavior-change methods should not be focused on which tools (don’t) always work. Instead, guideline development and implementation methods should be theory driven and evidence based (supported by evidence that proves the theory correct). In particular, the framework of evidence-based quality assessment offers some insight into past failures and offers hope for organizing attempts at guideline implementation.

(FOREST 2000; 118:88–178)

**Key words:** changing physician behavior; evidence-based medicine; guidelines; meta-analyses; quality improvement

**Abbreviations:** CME = continuing medical education; EBQA = evidence-based quality assessment
Trials, Meta-analyses, and review results

- Cast doubt upon conventional wisdom
- Demonstrate no consistent behavioral and positive patient outcome effects
  - CME and other techniques must be combined
  - even then the effects are variable
Thesis statements

- Application of behavior change method(s) to a situation ought not be focused on which tools (don't) always work.
- Instead, method(s) application should be theory-driven and evidence-based (supported by evidence that proves the theory correct).
- We must diagnose the lesion (why change is not adopted) before prescribing therapy (a change strategy).
- In practical implementations of physician behavior change, multiple tools will be necessary.
Key Points

- Different players in health care use different approaches to changing clinical practice
- Most of these approaches are more based on beliefs than on scientific evidence
- Implementing change seldom entails a single action, but instead good planning and a combination of approaches
- Before a strategy to implement change is selected, the obstacles to change should be identified
- Evidence-based medicine should be complemented by evidence based implementation

Can We Learn from Approaches to Improve “patient performance”?

- **Patient performance**
  - =improve patients’ adherence to treatment regimens
  - and/or self-management of their chronic diseases.

- **Pure “continuing patient education”**
  - providing information to patients in order to improve adherence
  - found inconsistently effective
Enabling strategies more effective

- Simplifying regimens
- Assessing patients’ skills to comply
- Environmental and belief modification
- Modifying deeply-held beliefs
- Employing written treatment contracts
  - That involve patients in decision making
- Enlisting family and social support
Maintenance of change

- Relapse prevention for unwanted or harmful habits
- Based on empirical data on relapse episodes
  - Taxonomy of high-risk relapse situations or characteristics
  - Techniques are offered to teach patients to anticipate and intervene in these situations
- A research agenda for this field
<table>
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<th>Approach</th>
<th>Theories</th>
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<td><strong>Focus on internal processes</strong></td>
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| Educational | Adult Learning Theories | Intrinsic motivation of professionals | • Bottom up, local consensus development  
• Small group interactive learning  
• Problem based learning |
| Epidemiological | Cognitive theories | Rational information seeking and decision making | • Evidence based guideline development  
• Disseminating research findings through courses, mailing, journals |
| Marketing | Health promotion, innovation and social marketing theories | Attractive product adapted to needs of target audience | • Needs assessment, adapting change proposal to local needs  
• Stepwise approach  
• Various channels for dissemination (mass media and personal) |
| **Focus on external influences** | | | |
| Behavioral | Learning theory | Controlling performance by external stimuli | • Audit and feedback  
• Reminder systems, monitoring  
• Economic incentives, sanctions |
| Social interaction | Social learning and innovation theories, social influence/power theories | Social influence of significant peers/role models | • Peer review in local networks  
• Outreach visits (academic detailing), individual instruction  
• Opinion leaders  
• Influencing key people in social networks  
• Patient mediated interventions |
| Organizational | Management theories, system theories | Creating structural and organizational conditions to improve care | • Re-engineering care process  
• Total quality management/continuous quality improvement approaches  
• Team building  
• Enhancing leadership  
• Changing structures, tasks |
| Coercive | Economic, power, and learning theories | Control and pressure, external motivation | • Regulations, laws  
• Budgeting, contracting  
• Licensing, accreditation  
• Complaints/legal procedures |

Adapted from Grol, BMJ, 1997.
Overlap of Theories

Cognitive

Behavioral

Behavioral-Social-Organizational

Psychological

Economic
Popular Theories

- for behavior change and most importantly maintenance of change.
  - Andersen’s Behavioral Model of Health Service Use
  - the Health Belief Model
  - the Theory of Reasoned Action
  - the Theory of Planned Behavior
  - the Health Decision Model
  - the Model of Illness Behavior
  - the Self-Regulation Model
  - Bandura’s and others’ social cognitive theories
  - Behavior modification.
Prochaska’s “Transtheoretical” Model of Behavior Change

- Approach might be adapted and used in a CME format for physicians contemplating adopting new practice behaviors.
- Litany of Transtheoretical model research applications in patients
  - designed to test the model
    - mostly smoking cessation
    - other empirical research
(also apply to physician behavior change)

no single theory can account for all the complexities of behavior change

behavior change unfolds over time

planned interventions (plural) are necessary to move persons along the behavior change journey

the majority of persons needing change are not yet prepared to make it
  - despite typical interventions that are designed to promote it

specific types of interventions work either worse or better at various stages of change;

biological social and personal factors dictate (the lack of) change
Termination is defined as complete self-efficacy with regard to the new previously contemplated and now adopted behavior.
TECHNIQUES, UNDERLYING THEORIES, AND RESULTS OF APPLICATIONS TO DATE
EDUCATION

Historical Perspective

- CME widely used
  - every medical school with department
  - conferences generate income
  - pleasure element
  - alumni relations element
Learning theory

- physicians contemplating and/or adopting behavior change go to CME conferences to validate and test the reliability of their learning and behavior either that of new information and innovations or that of what they are already doing in practice.


EDUCATION

Theoretic underpinnings

Learning theory

- (1) PRACTICALITY--learners (changers) whether physicians-in-training or practicing physicians seek to solve problems they recognize they have
- (2) PARTICIPATION--learners want to be involved in their own learning
- (3) MULTIPLE DEMANDS--instruction must both be time-efficient and also demonstrate the range of ways in which students can apply what they learn

Theoretic underpinnings

**Transtheoretical Model**

- Changing MOTIVATION - Moving from precontemplation to Preparation

Trans-Theoretical Model

Stages of Change

- Precontemplation
- Contemplation
- Preparation
- Action
- Maintenance
- Termination
EDUCATION

Evidence From Literature

- **Eisenberg 1985 Med Care review**
  - some success educating physicians re: cost of care
  - medium of education as important as its message
  - studies methodologically weak

- **Davis 1995 JAMA meta-analysis**
  - 99 RCT studies 29 on education
  - Effective were: reminders patient-mediated interventions
    outreach visits opinion leaders and multifaceted activities
  - Formal CME without enablers or practice-reinforcement had
    little impact
Cochrane: printed materials vs. none
- benefit from -3% to 243.4% provider outcomes
- benefit from -16.1% to 175.6% pt outcomes
  practical importance small at best

Cochrane: printed materials vs. printed plus other
- attrib. benefits -11.8% to 92.7% behaviour
- attrib. benefits -24.4% to 74.5% pt outcomes
- stat sign: 2/14 prof behavior 2/11 pt outcomes
Implications for efficacy trials of approaches to behavior change

- The value of CME will not be measured using end-stage behavior change as an outcome but rather number and strength of change contemplations.

- Current trials showing “no effect” of traditional CME have measured the wrong outcome.
Widely used methods such as conferences have little direct impact on improving professional practice.

- Practical importance

Effects small at best

- Effects small at best
- No additional impact of adding conferences/workshops
- Educational outreach visits and opinion leaders larger additive effect
- A small subset w/ estimates of effectiveness

No full economic analyses

Are we measuring the wrong outcome?
ACADEMIC DETAILING

Historical Perspective

Definition: A face-to-face educational meeting with office-based physicians by specially trained clinical pharmacists usually about drug prescribing.

- But does not involve full range of interventions used by drug reps (per Fugh-Berman, PLoS Med, 2007)

Opinion leaders often deliver message.

A combination method:
- High dose of education
- Advertising/feedback
- Opinion leaders
Theoretic underpinnings

Pharmaceutical advertising techniques (sort of, simplified, without other interventions)

Learning theory, social learning innovation, and social influence/power theories such as Diffusion of Innovation

- Change disseminates through networks of early adopters then later adopters

ACADEMIC DETAILING

Theoretic underpinnings

Self-directed learning theory

- Stage 1—understand and estimate personal levels of need to adopt a change in practice
- Stage 2—learn new competencies to practice differently
- Stage 3—solve problems of using new skills alter the practice environment or adapt new practice to increase goodness of fit

ACADEMIC DETAILING

Theoretic underpinnings

Transtheoretical Model

- Moving from Preparation to Maintenance

Trans-Theoretical Model

Precontemplation Contemplation Preparation Action Maintenance Termination
ACADEMIC DETAILING

Implications of Theories

Effect of (academic) detailing may be to move change contemplaters from one stage to another but not completely through all stages.

Again are we measuring the wrong outcome?
ACADEMIC DETAILING

Summary Recommendation

- When combined with social marketing promising especially for prescribing
- Can be expensive
- Key characteristics of intervention that are important?
- Cost-effectiveness not well evaluated
REMINDES

Theoretic underpinnings

Learning theory

Behavioral/affective theories (Social Cognitive Theory Health Belief Model)

- External controlling stimuli
- Change is governed by goals and perceptions
- These are manipulated by internal and external forces which may be malleable

Theoretic underpinnings

- Transtheoretical model
  - Moving from action to termination
REMINDERS
Summary Recommendation

- Cochrane best evidence of effectiveness
- Effective on processes of care
- Effective on improving performance
- Patient outcomes not measured or improved
- Computer-based reminders improve prevention services in the ambulatory care setting.
- Trials may only be done for behaviors physicians agree with
- Electronic methods expensive
- Paper methods cheap
- Stimulus must continue to maintain response
AUDIT AND FEEDBACK

Methodologic issues

Feedback types

- level of aggregation: physician and patient
- kind of data: diagnosis outcome utility decision cognition
- population of interest: all patients patients with specific characteristics
- comparison group: average doctor other doctors norms previous time periods
AUDIT AND FEEDBACK

Theoretic underpinnings

- Same as for Reminders when behavioral data is fed back
- Also uses cognitive theories when behavioral diagnosis and/or rationales strategies for change are fed back
AUDIT AND FEEDBACK

Theoretic underpinnings

- Transtheoretical Model
  - Moving from preparation to maintenance
AUDIT AND FEEDBACK

Historical Perspective

Feedback types

- level of aggregation: physician and patient
- kind of data: diagnosis, outcome, utility, decision, cognition
- population of interest: all patients, patients with specific characteristics
- comparison group: average doctor, other doctors, norms, previous time periods
<table>
<thead>
<tr>
<th>Hospital</th>
<th>City</th>
<th># of Medicare Cases (96-98)</th>
<th>Deaths/Mortality Inhospital +1 Month</th>
<th>Deaths/Mortality Inhospital +6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHIPPENHAM MEDICAL CENTER</td>
<td>Richmond</td>
<td>1711</td>
<td>★★★★★</td>
<td>★★★★★</td>
</tr>
<tr>
<td>MEDICAL COLLEGE OF VIRGINIA HOSPITALS</td>
<td>Richmond</td>
<td>819</td>
<td>★★★★★</td>
<td>★★★★</td>
</tr>
<tr>
<td>ST MARYS HOSPITAL OF RICHMOND</td>
<td>Richmond</td>
<td>1041</td>
<td>★★★★</td>
<td>★★★★</td>
</tr>
<tr>
<td>MARY WASHINGTON HOSPITAL</td>
<td>Fredericksburg</td>
<td>1147</td>
<td>★★★</td>
<td>★★★</td>
</tr>
<tr>
<td>BON SECOURS-MEMORIAL REGIONAL MEDICAL</td>
<td>Richmond</td>
<td>848</td>
<td>★★★</td>
<td>★★★</td>
</tr>
<tr>
<td>COLUMBIA HENRICO DOCTORS' HOSPITAL</td>
<td>Richmond</td>
<td>1185</td>
<td>★★★</td>
<td>★★★</td>
</tr>
</tbody>
</table>
Results of Report Cards for Patients with Congestive Heart Failure Depend on the Method Used To Adjust for Severity

Roy M. Poses, MD; Donna K. McClish, PhD; Wally R. Smith, MD; Elizabeth C. Huber, MD; F. Lynne W. Clemo, MD; Brian P. Schmitt, MD; Donna Alexander, PhD; Edward M. Racht, MD; and Christopher C. Colenda III, MD

Background: The validity of outcome report cards may depend on the ways in which they are adjusted for risk.

Objectives: To compare the predictive ability of generic and disease-specific survival prediction models appropriate for use in patients with heart failure, to simulate outcome report cards by comparing survival across hospitals and adjusting for severity of illness using these models, and to assess the ways in which the results of these comparisons depend on the adjustment method.

Design: Analysis of data from a prospective cohort study.

Setting: A university hospital, a Veterans Affairs (VA) medical center, and a community hospital.

Patients: Sequential patients presenting in the emergency department with acute congestive heart failure.

Measurements: Unadjusted 30-day and 1-year mortality across hospitals and 30-day and 1-year mortality adjusted by using disease-specific survival prediction models (two sickness-at-admission models, the Cleveland Health Quality Choice model, the Congestive Heart Failure Mortality Time-Independent Predictive Instrument) and generic models (Acute Physiology and Chronic Health Evaluation [APACHE] II, APACHE III, the mortality prediction model, and the Charlson comorbidity index).

Results: The community hospital's unadjusted 30-day survival rate (85.0%) and the VA medical center's unadjusted 1-year survival rate (60.9%) were significantly lower than corresponding rates at the university hospital (92.7% and 67.5%, respectively). No severity model had excellent ability to discriminate patients by survival rates (all areas under the receiver-operating characteristic curve < 0.73). Whether the VA medical center, the community hospital, both, or neither had worse survival rates on simulated report cards than the university hospital depended on the prediction model used for adjustment.

Conclusions: Results of simulated outcome report cards for survival in patients with congestive heart failure depend on the method used to adjust for severity.

For author affiliations, current addresses, and contributions, see end of text.
AUDIT AND FEEDBACK

Summary Recommendation

- A & F Sometimes effective (for prescribing and diagnostic test ordering)
- Small to moderate but potentially worthwhile effect
- Don’t rely solely on this approach
- Complementary intervention didn’t enhance effectiveness
- Reminders might be more effective to improve preventive services but not striking.
- More study needed on what and how to feed back
  - (modify important characteristics such as the content source timing, recipient and format of feedback)
GUIDELINES

Historical Perspective

- being developed by
  - government agencies (NIH AHCPR)
  - professional organizations
  - care providers

- acceptance varies by
  - type of physician
  - source of guidelines
  - strength of supporting evidence
GUIDELINES
Theoretic underpinnings

Transtheoretical Model

- Changing MOTIVATION - Moving from precontemplation to Preparation
Explicit guidelines do improve clinical practice when introduced in the context of rigorous evaluations. However, the size of the improvements in performance varied considerably. Necessary but not sufficient. May be impossible to apply. Require customization for local use.
ECONOMIC INCENTIVES

Historical Perspective

- Not many trials
- Several incentive typologies
- Unpalatable to physicians
ECONOMIC INCENTIVES

Theoretic underpinnings

- Transtheoretical Model
  - Moving from precontemplation to action

Trans-Theoretical Model

Stages of Change

Precontemplation | Contemplation | Preparation | Action | Maintenance | Termination
Incentives work according to non-randomized studies.

Bonuses sharply and rapidly increased immunization coverage in medical records.
- However much of the increase was the result of better documentation.

A bonus is a powerful incentive but more structure or education may be necessary to achieve desired results.

Financial incentives and feedback did not improve physician compliance with cancer screening guidelines for women 50 years of age and older in a Medicaid HMO.

Several incentive typologies
Methodologic Problems with Reviews to Date

- 1139 references
- 18 reviews that met the inclusion criteria
- No common classification approach between reviews
- Few linked findings to theories of behavioral change
- Passive dissemination of information is generally ineffective
- Use strategies to ensure changes in practice
- Further research required

SUMMARY RESULTS

- Education (small dose) ineffective
- Guideline dissemination effective but passive
- Multiple tools more effective
- Disparate results for any single tool
- Attempted Comparisons of effectiveness done to date may be invalid
  - target audience target behaviors nomenclature for techniques and combinations of methods dissimilar
- Reminders may have best evidence of effectiveness though narrowest range of tested behaviors
NO UNIFYING THEORY OF MD BEHAVIOR CHANGE

- Attempts to change physician behavior often atheoretically applied
- Theories assumptions about changing patient behavior testable among MDs
- Many patient health behavior change theories untested in physicians
Can We Learn...? Perhaps.

Several readily adaptable theories and approaches to behavior change in physicians

- now being and should be tested among physicians and health care workers
  - sometimes in order to improve their performance
  - sometimes with goals of cost savings etc.
Changing Physician Behavior- How Not to Do It?, or Defense Against the Dark Arts

Roy M. Poses MD
President, the Foundation for Integrity and Responsibility in Medicine (FIRM)
Associate Clinical Professor of Medicine
Brown University
Evidence Based Medicine

• Medicine based on the systematic search for and systematic, critical review of the best available evidence

• The integration of best research evidence with clinical expertise and patient values

• The underlying goal is to maximize the likelihood of benefit and minimize the likelihood of harm for each patient, according to the patient’s values
The EBQA Process

• Set priorities – find important clinical problems that affect defined populations
• Set guidelines – determine if there are preferred management options for those patients with those clinical problems
• Measure performance – determine if physicians are using the preferred management options
• Improve performance – if not, persuade physicians to do so
Changing Physician Behavior – the Old and New Challenges

• The Old Challenge involved teaching physicians:
  – about the evidence-based medicine and medical decision making paradigms
  – about their own human psychological limitations as decision-makers
  – to be critical of the current dogma

• The New Challenge involves teaching physicians
  – to recognize that most behavior change efforts promote vested economic or ideologic interests
Background: A Qualitative Study of Physicians’ Concerns about Health Care

• Asked physicians open-ended questions about their concerns
• Compiled and described their major themes in “A Cautionary Tale: The Dysfunction of American Health Care”
• The over-riding concern was that a dysfunctional health care system was threatening physicians’ core values

Echoed the Introduction to the ABIM/ ACP-ASIM/ ESIM New Physician Charter

• “Physicians today are experiencing frustration as changes in the health care delivery systems in virtually all industrialized countries threaten the very nature and values of medical professionalism.”

• “We share the view that medicine’s commitment to the patient is being challenged by external forces of change within our societies.”

Our New Assumptions

• An increasingly dysfunctional health care system externally threatens physicians’ core values,
  – Reducing their ability to make the best possible decisions for each patient, based EBM and medical decision making principles

• Physicians are increasingly distrustful of attempts to change their behavior which they suspect may arise out of this dysfunctionality, and may threaten their core values
Hypothesis About Causes of Health Care Dysfunction

• Health care is increasingly dominated by large organizations whose goals may not be aligned with physicians’ professional values
• Such organizations may be lead by the ill-informed, the incompetent, the conflicted, and even the corrupt
Large Organizations

• Health care now dominated by large organizations that may not share physicians’ and patients’ values
  – Providers: hospitals, health systems, IPA’s
  – Industry: pharmaceutical and device manufacturers, medical information technology vendors
  – Insurers and managed care organizations
  – Payers: employers, government agencies
  – Middlemen: brokers, consultants, malpractice insurers, etc.
  – Non-profits: universities, professional organizations, advocacy groups, accrediting agencies, etc.
Historical Background of the Growing Health Care Bureaucracy

• Enthoven, the architect of “managed competition,” one of the leaders of Jackson Hole, published a book in Europe in which he
  – identified physicians as members of a tightly-knit guild that was responsible for high health care costs
  – so to control health care costs, his main goal was “to break up the guild,” and transfer physicians’ supposed power to managers
**Bureaucracy in Large Organizations**

- “Tens of thousands of well-meaning people work throughout the health care system, none of whom ever see a patient or deliver any actual medical care. They preside over an infinity of rules, regulations, forms, processes, contract outsourcing, financial brokering, benefit plan tinkering, analytical processes, incompatible data systems, and dead forests of paperwork. Health care administration in America is a Tower of Babel that reaches to the moon....”

Bureaucracy and its Discontents

• Ignorance of context
• Unintended consequences
• Diffused responsibility
• Bureaucratic imperative:
  – "work expands so as to fill the time available for its completion." (Cyril Northcote Patterson)
Table 1.13
Health Care Employment by Occupation, 1983-2000

Health care employment growth exceeded that of the general economy.

Percent Change 1990-02

<table>
<thead>
<tr>
<th>Occupation</th>
<th>1983</th>
<th>1990</th>
<th>2000</th>
<th>Percent Change 1990-02</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiologic Technicians</td>
<td></td>
<td></td>
<td></td>
<td>32.0%</td>
</tr>
<tr>
<td>Health Record Technologists &amp; Technicians</td>
<td></td>
<td></td>
<td></td>
<td>-75.4%</td>
</tr>
<tr>
<td>Dental Hygienists</td>
<td></td>
<td></td>
<td></td>
<td>28.7%</td>
</tr>
<tr>
<td>Clinical Laboratory Technologists &amp; Technicians</td>
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<td></td>
<td></td>
<td>14.8%</td>
</tr>
<tr>
<td>Physicians’ Assistants</td>
<td></td>
<td></td>
<td></td>
<td>7.5%</td>
</tr>
<tr>
<td>Speech Therapists</td>
<td></td>
<td></td>
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<td>39.4%</td>
</tr>
<tr>
<td>Physical Therapists</td>
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<td></td>
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<td>61.9%</td>
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<tr>
<td>Occupational Therapists</td>
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<td>56.5%</td>
</tr>
<tr>
<td>Respiratory Therapists</td>
<td></td>
<td></td>
<td></td>
<td>48.6%</td>
</tr>
<tr>
<td>Dietitians</td>
<td></td>
<td></td>
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<td>23.8%</td>
</tr>
<tr>
<td>Pharmacists</td>
<td></td>
<td></td>
<td></td>
<td>16.9%</td>
</tr>
<tr>
<td>Registered Nurses</td>
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<td>21.6%</td>
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<tr>
<td>Licensed Practical Nurses</td>
<td></td>
<td></td>
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<td>26.6%</td>
</tr>
<tr>
<td>Health Diagnosing Practitioners</td>
<td></td>
<td></td>
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<td>-15.2%</td>
</tr>
<tr>
<td>Optometrists</td>
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<td>30.4%</td>
</tr>
<tr>
<td>Dentists</td>
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<td></td>
<td></td>
<td>5.0%</td>
</tr>
<tr>
<td>Physicians</td>
<td></td>
<td></td>
<td></td>
<td>24.6%</td>
</tr>
<tr>
<td>Medical Scientists</td>
<td></td>
<td></td>
<td></td>
<td>95.3%</td>
</tr>
<tr>
<td>Managers, Medicine &amp; Health</td>
<td></td>
<td></td>
<td></td>
<td>332.2%</td>
</tr>
<tr>
<td><strong>Total Employment</strong></td>
<td></td>
<td></td>
<td></td>
<td>13.8%</td>
</tr>
</tbody>
</table>

A Plague of Managers

- Physicians
- Nurses
- Managers

in K

- 1983
- 1990
- 2000
Ludmerer’s History of Bad Governance: Academic Health Centers Become Like Businesses

- Academic health centers (AHCs) became dependent on huge cash inflows from Medicare and commercial insurance
- Cost rises lead to cost containment
- In response, medical schools and AHCs “were content to go where the money was....”
- So, “financial success, the measure of the marketplace, has become the dominant standard of measurement of ‘value’ for most academic medical centers.”
Academic Medical Centers: “Show Me the Money”

• Lee Goldman (interview in April, 2007, SGIM Forum) divided faculty into:
  – “Taxpayers” who generate more than they cost
  – “Hired workers” who get paid to do a job
  – “Loss leaders” who get short-term investments in the expectations they will become taxpayers
  – “Welfare recipients”

• The primary criterion of success in academic medicine is now how much money faculty bring in, from clinical practice or external grants
The Allegheny Health Education and Research Foundation (AHERF) Case: Background

- From Allegheny General Hospital in Pittsburgh (1968) to largest health care system in Pennsylvania (1997)
- CEO was Sherif Abdelhak, called a “visionary,” “genius,”
- By 1995, Abdelhak earned $1.2 M, 3 times the median for a health system CEO
- Abdelhak gave John D. Cooper Lecture at AAMC (1996)
  - “We will need to create new forms of organization that are more flexible, more adaptive, and more agile than before”
  - “Unleash the creativity and productive potential of every individual and provide an environment that encourages teamwork”
- Abdelhak actually ruled by intimidation:
  - Dominated board, forced admission of his wife to medical school and had dean who protested fired
  - Speech to faculty, “Don’t cross me or you’ll live to regret it.”
  - “Most faculty realized this was a dictatorship…. It was an organization run by fear and reprisal.”
The Allegheny Health Education and Research Foundation (AHERF) Case: Events

- In 1997, although Abdelhak was still publicly announcing expansion plans, debt was soaring
- Losing $1 M / day, Abdelhak raided restricted endowments
- In 1998, Abdelhak fired, AHERF declared Chapter 11 bankruptcy, $1.2 billion in debt
  - second largest bankruptcy in US at that time
- Allegheny University of Health Sciences downsized, multiple hospitals closed, multiple lay-offs
- Multiple lawsuits filed
  - Securities and Exchange Commission settled civil fraud charges against AHERF ex-CFO McConnell and two Vice Presidents
  - SEC filed suit against AHERF auditors
- McConnell, Abdelhak sought plea bargain, Abdelhak sentenced to 11-23 months
The Allegheny Health Education and Research Foundation (AHERF) Case: Responses

- Outrage by ex-AHERF Doctors:
  - “colossal disaster that could have been avoided”
  - “obscene,” “an atrocity,” “repugnant”
  - Abdelhak was “an evil person” who “never took responsibility for bringing the system down”

- Uwe Reinhardt, health economist: “the lunacy that is acceptable would make you throw up”

- Tepid response of national organizations:
  - CEO of AAMC: “unprecedented for a medical school to be caught up in this type of bankruptcy”
  - LCME: would help place students if AUHS bankrupt
  - JCAHO: Hahnemann Hospital “not cited for any deficiencies”
  - AMA, ACP, AAFP, other specialty organizations - ?
  - ACGME, ABIM, other boards, DHHS - ?
The Allegheny Health Education and Research Foundation (AHERF) Case: in the Literature

- Burns et al. article in Health Affairs, covered events through mid-1999, but not outcome of most legal proceedings, and concentrated on debt financing issues[1]
- Nothing in any large-circulation journal (including news sections)
- Nothing in Academic Medicine since Abdelhak’s paper
  - which has never been cited

AHERF Key Points

• Small group of insulated leaders, largely unaccountable
  – put their self-interest first
  – intimidated professionals, suppressed dissent
• Leaders focused on self-interest don’t manage well
• Why did everyone believe the hype?
• Where was the outrage?
• Why is there still silence?
Bad Governance: A Catalog of Scandals

• Old
  – Hermann Hospital’s managers convicted of theft
  – Seven convicted for embezzling >$20 M from Cooper Hospital/UMC
  – AMA endorsed Sunbeam, AMA endorsed alteplase for cash

• New
  – NIH leaders got six-figure consulting fees from pharma, one plead guilty to federal conflict of interest so far
  – Hospital CEOs fired for ethical lapses: Fletcher Allen (convicted of conspiracy), Bellevue, Jacobi, Staten Island University (EVP), Roger Williams (operating under deferred prosecution agreement), UC- Irvine, Caritas Christi, University Medical Center of Southern Nevada
  – UMDNJ President, board members, other leaders resign, now operating under deferred prosecution agreement
  – UnitedHealth CEO quit after amassing >$1.5 BILLION in stock options, some apparently back-dated
  – Pfizer plead guilty and is under a deferred prosecution agreement for marketing of human growth hormone, Bristol-Myers-Squibb under deferred prosecution for manipulating inventory
  – Etc, etc, etc

• Have you heard of them?
American College of Physician Executives Survey

How concerned are you about:

- Gifts to executives
- Conflicted executives
- Gifts to board members
- Conflicted board members
- Unethical business practices

Slightly  Moderately  Very

American College of Physician Executives Survey

Who is Involved in Unethical Business Practices in Your Organization?

- Physician: 35%
- Executive: 15%
- Board member: 10%
American College of Physician Executives Survey

- 53.8% thought that a health care organization in their community was involved in unethical business practices
- 80.8% agreed that large professional organizations should take a tougher stand against unethical business practices
Corruption - alongside poverty, inequity, civil conflict, discrimination and violence - is a major issue that has not been adequately addressed. It leads to the skewing of health spending priorities and the leaching of health budgets, resulting in the neglect of diseases and those communities affected by them; it also means that poor people often decide against life-saving treatment, because they cannot afford the fees charged for health services that should be free. Corruption in the health care sector affects people all over the world.

Corruption might mean the difference between life and death for those in need of urgent care. It is invariably the poor in society who are affected most by corruption.
Transparency International’s Global Corruption Report II

• But the scale of corruption is vast in both rich and poor countries. Corruption deprives people of access to health care and can lead to the wrong treatments being administered.

• Corruption in the health sector is not exclusive to any kind of health system. It occurs in systems whether they are predominantly public or private, well funded or poorly funded, and technically simple or sophisticated. No other sector has the specific mix of uncertainty, asymmetric information and large numbers of dispersed actors that characterise the health sector. As a result, susceptibility to corruption is a systemic feature of health systems.
The Premise

• Badly governed health care organizations may forsake their missions, and endeavor to change physicians’ behavior so as to further the economic or ideologic interests of the organizations’ leaders
What are the External Threats to the EBQA Process? – at Each Step

• Set priorities – find important clinical problems that affect defined populations
• Set guidelines – determine if there are preferred management options for those patients with those clinical problems
  – Systematic search for the best possible evidence
  – Critical review of each study
  – Clear determination that benefits of preferred management option out-weighed harms
    • Identify possible management options
    • Identify outcomes of options
    • Assess outcome probabilities (for each option)
    • Assess outcome values (that is, utilities, for each option)
    • Combine probabilities and values to determine option with most favorable benefit vs harm, or highest expected utility
• Measure performance – determine if physicians are using the preferred management options
• Improve performance – if not, persuade physicians to do so
External Threats to the EBQA Process

• Set priorities – find important clinical problems that affect defined populations
  – *Stealth marketing*
  – *Special pleading*

• Set guidelines – determine if there are preferred management options for those patients with those clinical problems
  – Systematic search for the best possible evidence
  – Critical review of each study
  – Clear determination that benefits of preferred management option out-weighed harms
    • Identify possible management options
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    • Combine probabilities and values to determine option with most favorable benefit vs harm, or highest expected utility

• Measure performance – determine if physicians are using the preferred management options

• Improve performance – if not, persuade physicians to do so
Questions to Keep in Mind About Depression and Obesity

- How prevalent are they?
- How serious are they?
- Why do you think so?
Stealth Marketing Campaigns

- Pharma and other organizations orchestrate elaborate marketing campaigns to sell products or services
- Goals include:
  - Increasing awareness of the relevant disease or problem
  - Making that problem appear more salient or more important
  - Emphasizing short-comings of existing approaches and treatments
  - Then, emphasizing advantages of the new product or service
- Often executed by medical education and communication, or medical information companies (MECCs or MICs)
- Elements of these campaigns *may be covert, failing to identify the sponsoring organization*
  - These may be distinct from traditional advertising, detailing, etc.
Pfizer Sertaline (Zoloft) Stealth Marketing Campaign Case

• Pfizer engaged Current Medical Directions (CMD) to orchestrate marketing of sertaline (Zoloft)

• CMD drafted 85 articles by 1998, of which 55 were published
  – Topics included depression, dysthymia, panic disorder, post-traumatic stress disorder, differentiation between selective serotonin reuptake inhibitors (SSRIs), use of sertaline in children, etc
  – Appeared in J Clin Psychiatr, J Psychopharmacology, Am J Psych, JAMA, Arch Gen Psych, etc
  – CMD ghost-written articles outnumbered conventionally written articles in medical literature, and had five times as many citations

Wyeth Fenfluramine-Phenteramine (Fen-Phen) Stealth Marketing Campaign Case

• Marketed obesity as a serious health issue using slogans like:
  – “Obesity – the Public Health Crisis”
  – “Obesity – a Chronic Disease”
• Gave grants to American Academy of Family Physicians, American Diabetes Association, North American Society for the Study of Obesity, American Society of Bariatric Physicians, Shape Up America
• Established Key Opinion Leaders and an advisory board, whose members wrote favorable opinion articles that did not reveal their conflicts of interest[2]
• Hired Excerpta Medica, a subsidiary of Reed Elsevier, to ghost-write 10 articles in Reed Elsevier journals
  – Only two published before Fen-Phen withdrawn, did not reveal true authors
• After fen-phen withdrawn, spent another $100 million to minimize the fallout
  – “Very Important Visiting Professor” program
  – Studies to suggest adverse effects were minimal

Questions to Keep in Mind About Depression and Obesity

• How prevalent are they?
• How serious are they?
• Why do you think so?
  – Were your answers influenced by Pfizer’s and Wyeth’s stealth marketing campaign?
• The effects on physicians’ and the public’s perceptions of the prevalence, severity, and importance of various diseases of stealth marketing campaigns is unstudied and unknown
Special Pleadings About Politically Correct Problems, Diseases, and Patient Groups

• Focus attention on areas that may be outside traditional medical practice, not obviously amenable to medical solutions
• Suggest ideologically, rather than evidence-based approaches
• Intentions may vary, as may source of funding
• May distract physicians into areas in which they have little expertise, or ability to influence outcomes
Special Pleading: Nuclear Freeze Example (1985)

• In the 1980s, there was a major campaign for a nuclear freeze in major medical journals, lead by the International Physicians for the Prevention of Nuclear War (IPPNW) founded by Bernard Lown and “Eugene” Chazov

• Articles appeared in Lancet, NEJM, arguing
  – “Physicians must respond to the moral imperative of their commitment to life and health rather than worry about crossing the ill-defined boundary of the political realm.”

• Nuclear freeze was the official policy of the USSR at the time

• Physicians have no direct control over military or foreign policy, did their role here cross into “the political realm?”
Nuclear Freeze Example: Yevgeny Chazov’s Conflict of Interest

- Member of the Central Committee of the Communist Part of the USSR (after 1982)
- Lenin Prize (3x), Hero of Socialist Labor
- Personal physician to Communist Party leader Leonid Brezhnev, possibly Yuri Andropov
- Never criticized USSR foreign or nuclear policy
- Signed letter in Izvestia discrediting dissident Andrei Sakharov, for “grossly distorting the realities of [Soviet] life”
- Elena Bonner, Sakharov’s wife, alleged that Chazov participated in Sakharov’s torture
- British Foreign office charged that IPPNW “probably has working links with the KGB.”
External Threats to the EBQA Process

- Set priorities – find important clinical problems that affect defined populations
- Set guidelines – determine if there are preferred management options for those patients with those clinical problems
  - Systematic search for the best possible evidence
  - Critical review of each study
- Suppression of research
- Manipulation of study design
- Manipulation of study reporting
  - Clear determination that benefits of preferred management option out-weighed harms
    - Identify possible management options
    - Identify outcomes of options
    - Assess outcome probabilities (for each option)
    - Assess outcome values (that is, utilities, for each option)
    - Combine probabilities and values to determine option with most favorable benefit vs harm, or highest expected utility
- Measure performance – determine if physicians are using the preferred management options
- Improve performance – if not, persuade physicians to do so
Unspoken Assumptions of Evidence-Based Medicine

- Evidence-based medicine involves making decisions using the best possible evidence, as assessed by critical review of the best studies obtained by a systematic search.

- Unspoken assumptions:
  - Most of the most relevant studies will be published,
    - so systematic search will find nearly all of them
  - Investigators honestly attempt to design the best possible studies, and to report them honestly,
    - so critical review will adequately assess their validity and generalizability
PseudoEvidence-Based Medicine

• Suppression of research: some studies may be purposefully suppressed because of results that are unfavorable to vested interests

• Manipulation of study design: some studies may be purposefully designed to enhance likelihood of favorable results

• Manipulation of reporting: studies and reviews may be purposefully manipulated to make them appear more favorable
Suppression of Research: Dr. David Kern “Flock Lung” Case

- Dr. David Kern (Brown and Memorial Hospital of Rhode Island) discovered new interstitial lung disease, “flock lung,” at Microfibres Inc. factory
- When Kern prepared to present a case series at a conference, Microfibres threatened to sue
  - based on trade secrets protection agreement Kern signed 1 year before he started investigating factory, on a previous routine teaching visit to Microfibres facility with medical students
- Kern presented abstract
- Memorial Hospital CEO Francis Dietz:
  - removed Kern from his Chief of GIM and Occupational Medicine position
  - shut down Occupational Medicine service
  - failed to renew Kern’s contract
Dr. David Kern “Flock Lung” Case II

• Brown officials blamed the victim
  – Medical School Dean Donald Marsh: “Dr. Kern persisted in working at the company without a written contract, leaving him with no prior understanding about the right to publish....”
  – Physician-in-Chief H. Denman Scott: “The only person who compromised his academic freedom was Dr. Kern himself, by virtue of his conduct and his failure to get assurances from the company.”

• They hadn’t heard of the First Amendment, which protects free speech and free press even for people without contracts?

• Brown officials more concerned about hospital’s finances than academic freedom:
  – Dean Marsh’s “greater fear was for the hospital’s financial well-being in the face of a threatened lawsuit”

• Kern left Memorial Hospital and went into private practice
• Microfibres never filed a lawsuit
Suppression of Research: Other Examples

• 6% of faculty admitted delaying publication of undesirable results[1]

• Anonymous cases of articles withdrawn because results “ran counter to financial interests and strong beliefs.”[2]

• Other older famous cases
  – Betty Dong, UCSF, “thyroid storm
  – Nancy Olivieri, U of Toronto, defirapone

• Recent pharmaceutical cases
  – Cox-2 inhibitors
  – Selective serotonin reuptake inhibitors

Manipulation of Research: Tactics to Increase Likelihood of Favorable Results

• **Study Population**
  – Select a study population unlikely to have adverse outcomes, but unrepresentative of patients who might use the treatment
  – Keep the trial too small to detect adverse effects of treatment

• **Alternative Treatment**
  – Compare the treatment to one known to be inferior
  – Use a dosage of the comparison treatment that is too low (so it won't work), or too high (so it will have side effects)

Manipulation of Research: Tactics II

• Measurement
  – Use multiple endpoints in the trial, but pick the one that shows a favorable result
  – Use composite endpoints related to possible benefits to increase the likelihood of finding a statistically significant effect
  – Use individual endpoints related to possible harms to decrease the likelihood of finding a statistically significant effect
  – Use intermediate outcomes (e.g., laboratory tests) rather than clinical outcomes

• Analysis
  – Do multi-centre trials, but use only results from the centers with favorable outcomes for the product
  – Do multiple sub-group analysis, but only publish those with favorable results

The Contractual Basis for Manipulation and Suppression of Evidence: the Mello Study

• Surveyed 107/122 medical school research administrators

• Asked about acceptability of a variety of research contract provisions, especially about control of the sponsor (external funding organization, including industry, pharma, device manufacturing, biotech etc) over aspects of the research

Contract confidential
Investigators cannot discuss while ongoing
Sponsor writes up results
Sponsor may do statistical analysis
Sponsor can alter study design
Investigators cannot alter study design
Sponsor will own the data
Manipulation of Research Reporting: Ghost Writing of Reviews and Editorials

• Reports going back to 1993 that pharmaceutical companies may pay for medical education companies to ghost write review articles which favor their products, or disfavor competitors, then lure academics to be front authors

AstraZeneca RxComm Ximelagatran Case

- Adriane Fugh-Berman approached by RxComm to author a review of herb-warfarin interactions, sponsored by AstraZeneca
- RxComm sent her complete draft of article, with title page stating Dr. Fugh-Berman was author
- RxComm said “whilst there is no promotion of any drug within this paper, AstraZeneca is keen to set the scene for new anticoagulants that are not subject to the numerous limitations of warfarin”
- A new oral anticoagulant, ximelagatran, made by AstraZeneca, had been licensed in France, and a US New Drug Application was pending
- Fugh-Berman refused to “author” the article
- The same article, somewhat revised, with a new “author,” was submitted to the Journal of General Internal Medicine, and sent to Fugh-Berman for review, who then blew the whistle

AstraZeneca RxComm Ximelagatran Case: Fugh-Berman’s Comments

• “Companies regularly fund articles and talks that never mention the target drug, but are meant to disadvantage the competition.”

• “Message talks … are not obviously advertising…."

• “The talk’s usefulness may lie in convincing doctors that a particular condition is underdiagnosed or undertreated, or that an invented disease exists, or that medical management is a sound alternative to surgery, or that a currently used therapy is fraught with problems.”

• The goal is “to create a receptive atmosphere within the minds of physicians.”
AstraZeneca RxComm Ximelagatran Case: Editorial Comments

• “Publishing biased literature is not simply ‘getting the message out’ for the pharmaceutical client of the medical education company.”
• “It injects bias and untruth into the scientific dialogue in order to enhance corporate profits.”
• “How much is sulllying the medical literature worth in market share?”
• “What are the long-terms effects on scientific discourse and the bond of trust among the scientific and clinical communities, pharmaceutical manufacturers, and the public?”
• “What is the ultimate effect on market share if that trust is breached?”

Flanagin Survey: Ghost Writing in Major Journals

% of Articles Ghostwritten

- Am J Card
- Am J Med
- Am J Ob Gyn
- Ann Int Med
- JAMA
- NEJM

- Green: Total
- Blue: Research
- Light Blue: Review
- Gray: Editorial
External Threats to the EBQA Process

• Set priorities – find important clinical problems that affect defined populations
• Set guidelines – determine if there are preferred management options for those patients with those clinical problems
  – Systematic search for the best possible evidence
  – Critical review of each study
  – Clear determination that benefits of preferred management option out-weighed harms
    • Identify possible management options

• **Stealth Marketing**

• **Direct-to-Consumer Advertising**
  • Identify outcomes of options
  • Assess outcome probabilities (for each option)
  • Assess outcome values (that is, utilities, for each option)
  • Combine probabilities and values to determine option with most favorable benefit vs harm, or highest expected utility

• Measure performance – determine if physicians are using the preferred management options
• Improve performance – if not, persuade physicians to do so
Mis-Identify Options or Outcomes of Options

• Stealth marketing
  – See previous discussion

• Conventional advertising
  – Standard advertising to, detailing of physicians
  – Direct to patient advertising
    • So that, for example, the patient insists on “little purple pill” for dyspepsia, distracting physician from thinking of other options
Deceptive Advertising: the Academic Medical Center Study

• Larson et al studied hospital advertising practices which “seem to place the interests of the medical center before the interests of the patients.”[1]

• The hospitals’ advertisements promoted dubious services:
  – "Of the 21 ads for single [clinical] services,... 19 single-service advertisements were for procedures considered cosmetic ..., having limited (or no) efficacy data, ... or lacking consensus."

• They played on patients' emotions,
  – "Most of the institutions' slogans emphasized cutting-edge care and institution status.... The remaining slogans tended to use emotional themes." "Advertising headlines ... commonly mentioned symptoms or diseases or used strategies that might appeal to patients' emotions or fears."

• They exaggerated benefits while avoiding mention of harms,
  – "While more than three quarters of the single-service ads highlighted potential benefits of the services promoted... none quantified their positive claims. Only 1 ad mentioned or implied potential harms of the service...."

External Threats to the EBQA Process

• Set priorities – find important clinical problems that affect defined populations
• Set guidelines – determine if there are preferred management options for those patients with those clinical problems
  – Systematic search for the best possible evidence
  – Critical review of each study
  – Clear determination that benefits of preferred management option out-weighed harms
    • Identify possible management options
    • Identify outcomes of options
• Force attention to extraneous options
  • Assess outcome probabilities (for each option)
  • Assess outcome values (that is, utilities, for each option)
  • Combine probabilities and values to determine option with most favorable benefit vs harm, or highest expected utility
• Measure performance – determine if physicians are using the preferred management options
• Improve performance – if not, persuade physicians to do so
Attend to Extraneous Outcomes of Option

• For a physician making a decision as an agent for a patient
  – An extraneous outcome is one that might affect the decision maker, but not the patient, and thus should not bear on decisions made as an agent for patient

• Large organizations may seek to influence physicians by inducing physicians to attend to extraneous outcomes in the form of:
  – Perverse bureaucratic and financial incentives
  – Intimidation and coercion
Imaging Pre-Authorization Example

• Ostensibly because of increased costs of imaging, insurers in Pennsylvania and Massachusetts have started requiring onerous pre-authorization for all advanced imaging tests

• However, insurers have not decreased their reimbursements for imaging
  – While hospitals’ profits from CT scan facilities have increased 1030% (298% inflation adjusted) from 1974 to 2004 [1]
Perverse Bureaucratic and Financial Incentives: Other Managed Care Tactics

• “Slowing and controlling use of services and payment for services by impeding, inconveniencing, and confusing providers and consumers alike”[1]

• Gate-keeping

• Utilization review

• Financial disincentives for excess utilization

• Gag rules (now illegal)

• Profiling

• Pay-for-performance

Intimidation and Coercion: Examples

• Threats of malpractice litigation
• Merck’s campaign to “neutralize” physicians it perceived as hostile to Vioxx
• Hospital managers:
  – “Don’t cross me or you will live to regret it” – Sherif Abdelhak, ex-CEO, AHERF, convicted of misusing charitable funds
  – "He controlled those around him and managed those around him by fear and intimidation,” describing William Boettcher, ex-CEO, Fletcher Allen Health Care, convicted of federal conspiracy
Intimidation of Quality of Care Whistleblowers: Examples from the “Cost of Courage” Series

• After cardiovascular-thoracic surgeon at University Hospitals of Cleveland complained about quality issues (e.g., monitor turned off, failure to address post-op bleeding)
  – called “disruptive and abusive,” and lost job

• After surgeon at Roper Hospital (Charleston, SC) complained about quality issues (e.g., failures to give medication, incomplete notes, orders not followed, etc.,)
  – He was labeled “disruptive” and suspended
  – later state investigators confirmed the problems about which he complained
Intimidation of Quality of Care Whistleblowers: Emergency Department Survey

• Doctors may get in trouble for complaining about quality
  – 23% of Emergency Department doctors felt jobs were threatened because they voiced concerns about quality

External Threats to the EBQA Process

- Set priorities – find important clinical problems that affect defined populations
- Set guidelines – determine if there are preferred management options for those patients with those clinical problems
  - Systematic search for the best possible evidence
  - Critical review of each study
  - Clear determination that benefits of preferred management option out-weighed harms
    - Identify possible management options
    - Identify outcomes of options
    - Assess outcome probabilities (for each option)
- Suppression of research
- Manipulation of study design
- Manipulation of study reporting
  - Assess outcome values (that is, utilities, for each option)
  - Combine probabilities and values to determine option with most favorable benefit vs harm, or highest expected utility
- Measure performance – determine if physicians are using the preferred management options
- Improve performance – if not, persuade physicians to do so
Assess Outcome Probabilities

• Data about outcome probabilities can be
  – Suppressed
  – Manipulated

• See previous discussion
What is to be Done?

• Better understand the dysfunctionality of health care, especially as it threatens physicians’ professionalism
• Describe external threats to the evidence-based quality assessment process
  – Threats that act at specific steps
  – Threats that undermine the entire process
• Based on this knowledge, develop defenses against these threats
• Do not accept attempts to change behavior based on corrupted processes
A Start Toward Solutions

- Recognize ill-conceived and ill-intentioned attempts to change physician behavior
  - Stealth marketing
  - Special pleadings
  - Suppression of research
  - Manipulation of study design
  - Manipulation of research reporting
  - Deceptive advertising
  - Perverse bureaucratic and financial incentives
  - Intimidation and coercion
  - Postmodernism
A Start Toward Solutions

• Put core values first
• Empower patients and physicians
• Re-organize, regulate, sometimes disband large organizations
• Improve their governance to make it:
  – Representative
  – Transparent
  – Honest and Ethical
  – Accountable
Possible Solutions: Lancet on Transparency International’s Global Corruption Report

• Any cure should start with maximum transparency.
• Codes of conduct need to be adopted by health workers and private sector companies.
• Any transgressions have to be rigorously prosecuted.
• Whistleblowers from all sectors should be protected.

Better Understanding: A Plug

• Health Care Renewal Blog: http://hcrenewal.blogspot.com/

• Foundation for Integrity and Responsibility in Medicine: http://www.firmfound.org/