

*MOVING TOWARD GREATER
ACCOUNTABILITY
IN
EVIDENCED-BASED MEDICINE*

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Examination of Conflicts of Interest in Evidenced-Based Medicine

I. Evidence-Based Medicine; Generally

A. Evidence-Based Medicine Dates Back To Mid-19th Century Paris (And Earlier).

B. What Is Evidence-Based Medicine?

1. “Conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.”
2. Translation -- using individual clinical expertise and the best available external evidence, in an integrated fashion, to make clinical decisions about the care of an individual patient.

Source:

D. L. Sachett; W. M. Rosenberg; J. J. Gray; R. B. Haynes; and W. S. Richardson
“Evidence Based Medicine: What it is and What it isn’t.” Vo. 312. British Medical
Journal p. 22 (January 13, 1996).

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II. The Process; Generally

- A. Formulate A Clear Clinical Question From A Patient's Problem.**
- B. Search Relevant Clinical Literature For Articles.**
- C. Evaluate The Evidence For Validity And Usefulness.**
- D. Implement Useful Findings For Specific Patients Based On Patient's Particular Circumstances And Preferences.**

Source:

Introduction to Evidence-Based Practice

www.hsl.umc.edu (Rev. July 2010)

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III. The Process; What it is not

A. “Cookbook Medicine”

1. Focus is on particular patient’s state, predicament and preferences.
2. Not applied to all patients without appropriate considerations.

B. Cost Cutting Exercise

1. Objective is to identify and apply the most efficient interventions to maximize the quality and quantity of life for individual patients.
2. Cost Effectiveness Research or Comparative Effectiveness accurately depicts the process.

Source:

From D. L. Sachett; W. M. Rosenberg; J. J. Gray; R. B. Haynes; and W. S. Richardson
“Evidence Based Medicine: What it is and What it isn’t,”
Vol. 312. British Medical Journal p. 22 (January 13, 1996)

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IV. *How do Conflicts of Interest Relate to Evidence-Based Medicine?*

- A. Randomized Controlled Trials (“RCTs”) universally accepted as the most useful form of analysis and comparison for evidence-based medicine.**
- B. RCT’s published in medical journals is the most common way to demonstrate efficacy and safety.**
- C. The process, when done appropriately, is a meticulous, scientific analysis that provides patients and their providers comfort in the treatment selected.**
- D. Conversely, where conflicts of interests exist, the value and integrity of the evidence is less compelling.**

Source:

“From Evidence-Based Medicine to Marketing-Based Medicine: Evidence from Internal Industry Documents”
G. T. Spielmans, P. I. Parry, Bioethical Inquiry (January 21, 2010)

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V. Commentators Have Described the System of Scientific Research and Publication as “Broken”

- A. **Suppression Of Negative Data;**
- B. **Ghostwriting;**
- C. **Disease Mongering;**
- D. **Market Segmentation; and**
- E. **Lack Of Accountability.**

** This is not to say that: (i) ties among physicians and researchers and industry are not common or that (ii) widespread relationships with industry have improved individual and public health.

Source:

G.I. Spielmans, P.I. Parry, “From Evidence-Based Medicine to Marketing-Based Medicine: Evidence from Internal Industry Documents,” Bioethical Inquiry (January 21, 2010).

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VI. Media Has Focused Negative Attention on High Profile Instances of Conflicts

- A. Lack Of Transparency In Financial Relationships And Ties Among Researchers; Sponsors.
- B. Conflicts of Interests Among Authors Of Research Studies And Articles In Peer-Reviewed Journals.
- C. Illegal Payments Or Gifts.
- D. Failure To Disclose Substantial Payments As Required Under COI Rules.
- E. Not Publishing Or Delaying Publication Of Negative Results Of A Clinical Trial.
- F. Conflicted Researchers Overstating Benefits And Understating Product Risks.

Source:

Institute of Medicine, Committee on Conflict of Interest in Medical Research, Education and Practice;
Lo B, Field, MJ, editors, National Academies Press (2009).

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VII. Research Is Inconclusive As To The Impact Of Financial Relationships Between Physicians And Industry

- A. Empirical Evidence About Financial Relationships And Conflicts Of Interest Is Limited.**
- B. No Systematic Studies.**
- C. Data Is Suggestive And Not Definitive.**
- D. Studies Are Observational And Not Interventional.**
- E. No RCT On The Topic.**
- F. COI Policies Are Enforced Unevenly Among Institutions And No Data To Evaluate Consequences.**
- G. Prominent Researchers And Physicians Contend That COI Concerns Have Been Blown Out Of Proportion.**

Source:

Institute of Medicine, Committee on Conflict of Interest in Medical Research, Education and Practice; Lo B, Field, MJ, Editors, National Academies Press (2009).

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VIII. Decentralized Research and Dissemination of Research Impact Proliferation of Evidenced-Based Medicine

- A. No One Organization Interprets Or Disseminates Research Findings.**
- B. New Research Rarely Goes From Journal Article To Clinical Practice Overnight.**
- C. Intermediary Organizations Play A Big Role In Research Interpretation And Dissemination Through Care Protocols, Pathways And Medical Guidelines.**
- D. There Is Often A Divide Between Research Methodology And Study Design And Relevancy To Patients (i.e., Not Patient Centered).**

Source:

“From Evidence to Practice: A National Strategy for CER Dissemination.” NEHI, The National Network for Health Innovation; White Paper (February 2011)

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IX. Consumer Beliefs About Evidence-Based Medicine Add An Additional Wrinkle

- A. Studies Confirm That Consumer Beliefs Are At Odds With Evidenced-Based Medicine Approaches.**
- B. Little Concern That Care Does Not Meet Quality Standards.**
- C. Medical Guidelines Are Inflexible And Not Appropriate To Impose.**
- D. More Care And Newer Care Is Better.**
- E. More Expensive Care Is Better.**
- F. Reluctance To Challenge Physician Or Raise Concerns About Unnecessary Care.**

Source:

“Evidence That Consumers Are Skeptical About Evidence-Based Health Care,” K.L. Carman; M. Maurer; J.M. Yegian, P. Dardess; J. McGee, M. Evers and K.O. Marlo; Health Affairs, online publication, June 3, 2010.

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X. Over the Past 15 Years, COI Policies have Proliferated

- A. Academic Medical Centers**
- B. Research Organizations**
- C. Medical Societies**
- D. Medical Journals**
- E. Pharmaceutical Industry**
- F. Device Industry**
- G. GPO Industry**
- H. State Legislatures**

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XI. *The Concerns Remain And The Stakes Have Increased With Health Reform (Specifically, “Physician Sunshine Act”)*

- A. **Section 6002 Of PPACA - Transparency Reports And Reporting Of Physician Ownership Or Investment.**
- B. **Applies To Manufacturers And GPO’s That Transfer Value To Covered Recipients Or Designees.**
- C. **Covered Recipients Are Defined As Physicians And Teaching Hospitals.**
- D. **Disclosure Reports Are Due Each March 31st Beginning In 2013, But Cover Prior Years’ Payments.**
 - **Data Collection Begins In January 2012**
- E. **Reports Are Comprehensive And Must Cover Payments And Certain Investments By Physicians And Academic Medical Centers.**

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F. Reports Must Include:

1. Charitable giving;
2. Consulting fees;
3. Compensation for non-consulting services;
4. Education;
5. Entertainment;
6. Food;
7. Gifts;
8. Grants;
9. Honoraria;
10. Investment interests;
11. License fee revenue;
12. Research;
13. Royalty revenue;
14. Speaker/faculty fees for educational programs; and
15. Travel.

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G. Physician Sunshine Act Reports Are Not Required To Cover The Following:

1. Payments under \$10; unless aggregated exceeds \$100 per year;
2. Product samples and educational materials for the benefit of Patients; **
3. Loan of a covered device for a 90-day trial (or less);
4. In-kind items provided for use in charity case;
5. Item or services provided under a warranty;
6. Discounts (including rebates); and
7. Expert witness fees.

H. Federal Law Provides for Limited Pre-Emption Of State Conflict Disclosure Laws.

**Under Section 6004 of PPACA, prescription drug manufacturers and authorized distributors of record must report to the Secretary of HHS the identity and quantity of drug samples requested and the identity and quantity of drug samples distributed as aggregated by practitioner or by signatory making the request or signing on behalf of the practitioner). Reports are due beginning April 1, 2012. Report must cover the preceding year.

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- I. **Keep In Mind, State Disclosure And Reporting Laws Will Not Be Pre-Empted By PPACA Where State Law Covers:**
 1. Entities or persons other than manufacturers;
 2. Entities other than physicians and teaching hospitals;
 3. Transfers of value or expenditures not covered by or carved out of the requirements under PPACA; and
 4. Federal, State or local agency reports for public health surveillance purposes.

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J. State Laws Also Contain Specific Behavioral Requirements Or Prohibitions Which Would Apply To Manufacturers And Which Are Not Covered By PPACA:

1. Adoption, training, auditing, investigation and enforcement of compliance programs and conduct codes (e.g., OIG Compliance Program Guidance for Pharmaceutical Manufacturers, PhRMA Code or AdvaMed Code of Ethics);
2. Bans on gifts, meals and entertainment;
3. Disclosure of spending on promotions or advertising; and
4. Prohibitions on detailing.

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K. There Are Penalties For Failure To Comply With PPACA And State Laws:

1. States usually have civil penalties for each event or occurrence of non-compliance.
 - Range between \$1,000 and \$5,000
2. Some states impose attorney's fees for investigation and enforcement.
3. Federal civil penalties under PPACA include:
 - (a) \$1,000 - \$10,000 for each failure to report a payment or transfer of value (up to \$150,000 per annual submission); and
 - (b) \$10,000 - \$100,000 for each "knowing" failure to report (up to \$1M per annual submission).

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XII. Health Reform Also Attempts To Enable And Disseminate

- A. Conversion From Volume-Based To Quality Value Based Reimbursement.**
- B. Reliance On Electronic Data And Information To Empower Practitioners.**
- C. Mechanism To Seek Disclosure Of Conflicts And Enable Accountability.**
- D. Creates The Need For Reliable, Rigorously Tested, Empirical Evidence That Is Used By Clinicians And Patients:
 - Valid, Relevant, Timely, Feasible And Actionable
 - Well-Grounded Research**
- E. In 2007, The Commonwealth Fund Estimated That Over \$370B Could Be Saved Over 10 Years Through A National Comparative Effectiveness Research (“CER”) Program.**

Source:

C. Schoen, S. Guterman, A. Shih “Bending the Curve: Options for Achieving Savings and Improving Value in US Health Spending,” The Commonwealth Fund (2007).

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XIII. Comparative Effectiveness Research

- A. First Received Attention In The 2009 Economic Stimulus Package**
 - \$1.1B allocated for research grants and investment in research tools, methodologies, and infrastructure (e.g., patient data bases) to support reliable research.

- B. Subtitle D; Section 6301 of PPACA Made Permanent A National Comparative Effectiveness Research Program**
 - Patient Centered Outcomes Research Institute (“PCORI”).

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C. PCORI

1. Independent, not-for-profit organization.
2. Funded with federal stimulus dollars initially and fees imposed by federal law on health insurers and self-funded employer plans.
3. Governed by 21-member board, including 2 members representing federal or state government, 17 members from outside government who are appointed by the U.S. Comptroller General, with 2 seats reserved for the directors of the Agency for Health Care Research and Quality (“AHRQ”) and NIH.
 - Board members are compensated.
 - Federal employees may not be paid.

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4. Empowered to assist patients, clinicians, purchasers and policy-makers in making informed decisions by:
 - (a) Advancing the quality and relevance of evidence about prevention, management and treatment options.
 - (b) Synthesizing research and evidence that considers variations in patient sub-populations.
 - (c) Dissemination of research findings concerning relative health outcomes, clinical effectiveness and appropriateness of treatments, services and items.

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D. PCORI Will:

1. Identify research priorities and establish a national research agenda.
2. Carry out the research project agenda through contracts.
3. Set requirements for publication of research done under the Act.
4. Have access to Medicare data.
5. Appoint expert advisory panels
 - (a) Clinical Trials; and
 - (b) Rare Diseases
6. Establish committees of PCORI
 - Methodology Committee
7. Establish a peer-review process for primary research.

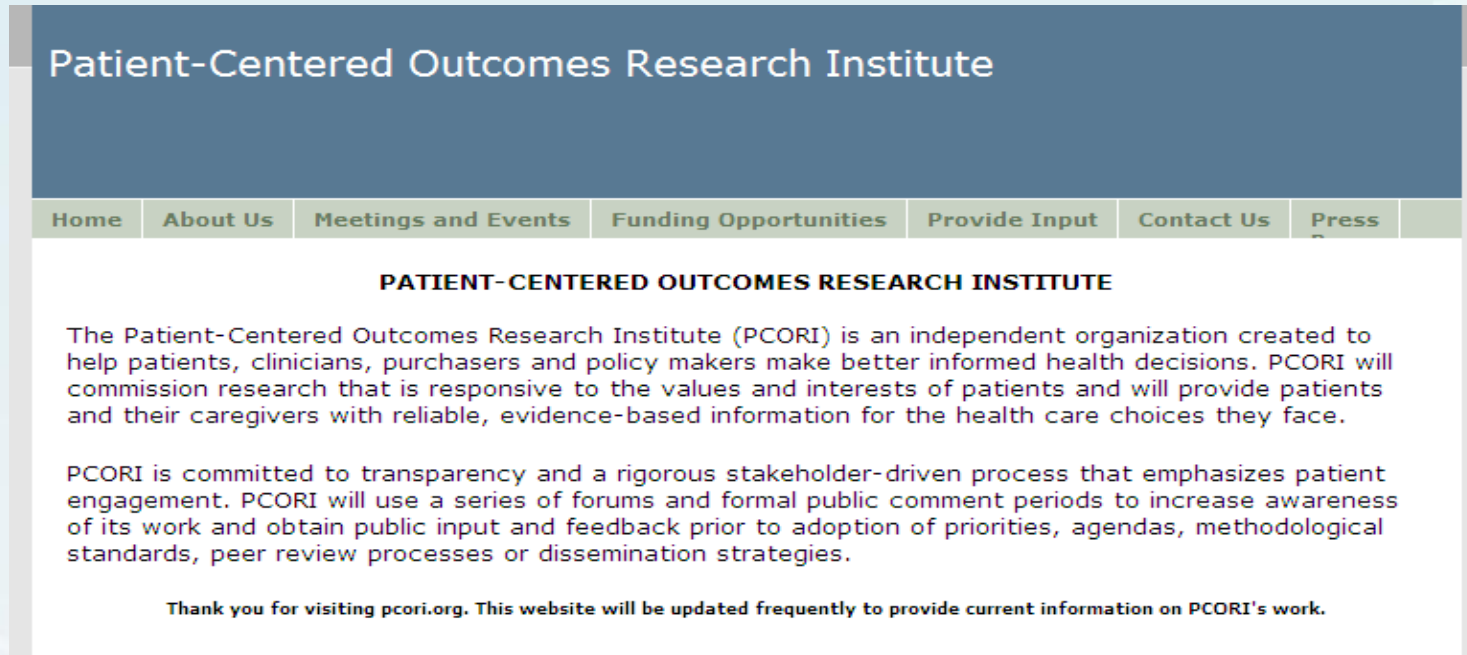
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E. PCORI Is Obligated To Ensure Transparency, Creditability And Access

1. Provide for public comment on:
 - (a) national agendas and priorities;
 - (b) methodological standards;
 - (c) peer-review processes; and
 - (d) drafts of systematic reviews of research.

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2. Public Availability of Findings and Initiatives



Patient-Centered Outcomes Research Institute

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PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

The Patient-Centered Outcomes Research Institute (PCORI) is an independent organization created to help patients, clinicians, purchasers and policy makers make better informed health decisions. PCORI will commission research that is responsive to the values and interests of patients and will provide patients and their caregivers with reliable, evidence-based information for the health care choices they face.

PCORI is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI will use a series of forums and formal public comment periods to increase awareness of its work and obtain public input and feedback prior to adoption of priorities, agendas, methodological standards, peer review processes or dissemination strategies.

Thank you for visiting pcori.org. This website will be updated frequently to provide current information on PCORI's work.

<http://pcori.org/>

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3. Disclosure of conflicts.
4. Dissemination of studies through AHRQ.

F. Limitations On Use Of CER

1. Centers for Medicare and Medicaid Services (“CMS”) is prohibited from using research to make Medicare coverage decisions unless through “an interactive and transparent process.”
 - (a) Must include public comments;
 - (b) Cannot deny coverage of items or services under Medicare solely based on CER; and
 - (c) Similar to NCD approach today.

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2. “Death Panel” Protections
 - (a) CER evidence cannot be used to determine coverage, reimbursement or incentives under Medicare that favor extending the life of younger, non-disabled and not terminally ill individuals as opposed to older, disabled or terminally ill individuals.
 - (b) But can use CER’s evidence to determine coverage, reimbursement or incentives under Medicare based on differences in the effectiveness of an alternative treatment in extending an individual’s life due to the individual’s age, disability or terminal illness.
 - (c) CMS cannot use CER in a manner that precludes or discourages an individual from choosing a health care treatment based on his/her individual values.
 - But differential co-payments are permitted;
 - Also, CMS can use CER to determine Medicare coverage, reimbursement, or incentives based on comparison of the difference in effectiveness of alternative treatments in extending an individual’s life.

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G. Take-Aways For Industry Members

1. Conflict of interest disclosure and reporting will require intensive focus and commitment to compliance, training and technology.
2. Behavior will need to change to accommodate business and strategic concerns over disclosure.
3. Health reform will highlight the need for reliable and high quality medical evidence.
 - PCORI, as a non-governmental, board-run organization, will have broad authority to impact industry.
 - Still too early to know what to make of PCORI.

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4. Industry members will need to decide how aggressive or passive they will be with the national CER program.
 - (a) Other traditional means of research and publication will continue;
 - (b) How much involvement from industry members is necessary will be determined on an individual basis;
 - (c) Monitoring PCORI meetings, attending hearings, coordinating with industry and patient advocacy groups on advocacy initiatives, and providing public comments including research supportive of specific treatments, products, devices or process;
 - (d) Continue to develop and promote supportive research studies; and
 - (e) Evaluate and monitor PCORI board members for potential opportunities to educate through group or individual encounters.

ADDITIONAL RESOURCES TO MONITOR

INSTITUTE OF MEDICINE

<http://iom.edu/>



The screenshot shows the homepage of the Institute of Medicine of the National Academies. At the top right, there are navigation links for Media Room, Directory, Meetings and Events, Videos, and Member Login. The main header features the IOM logo and the text "INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES" on the left, and the tagline "Advising the Nation. Improving Health." on the right. Below the header is a dark green navigation bar with "ABOUT THE IOM", "REPORTS", and "ACTIVITIES" tabs. To the right of these tabs are buttons for "Explore by Topic" and "Keyword Search". Below the navigation bar, there are links for "Sign up for E-mail Updates", "RSS", and "Text Size". The main content area is divided into two columns. The left column has a "Browse History" section and a featured report titled "Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research" dated 6/29/2011. The report text states: "Chronic pain affects 116 million American adults—more than those affected by heart disease, cancer, and diabetes combined. The IOM recommends that healthcare professionals tailor treatment to each patient to ensure that everyone receives the appropriate care." Below the text is a "Read More" button. The right column features a photograph of three people: a woman in a pink top, a man in a patterned shirt, and a doctor in a white coat with a stethoscope, looking at a document together.

ADDITIONAL RESOURCES TO MONITOR

NEHI

<http://www.nehi.net/>

The screenshot shows the NEHI website homepage. At the top right, there are navigation links for Home, News, and Member Log In, along with social media icons for Twitter and Facebook, and a search bar. The NEHI logo is on the left. Below the navigation bar is a menu with six items: PROGRAMS & INITIATIVES, IMPACT & OUTCOMES, PUBLICATIONS, MEMBERS & PARTNERS, EVENTS, and ABOUT. The main content area features a large banner with the text "CATALYST FOR CHANGE." and three buttons: COLLABORATE, RESEARCH, and TRANSFORM. The TRANSFORM button includes the text "The power of change". To the right of the buttons is a large image of the U.S. Capitol building with the text "Collaboration and research empower NEHI to educate policy makers and drive change in health care."

ADDITIONAL RESOURCES TO MONITOR

ECRI Institute

<https://www.ecri.org>

