ETHICS OF EVIDENCE-BASED PRACTICE

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The OPANA 2014 Fall Seminar
Siegel Center, Columbus, Ohio
October 18, 2014
Objectives

1. Describe the relationship of ethics, evidence, practice in a fluid health care environment.
2. Describe ways to promote an ethical environment for research translation and inquiry.
Evidence-Based Practice (EBP)

... a problem solving approach to clinical care using the best evidence from well designed studies, clinician expertise, and patient values and preferences...... provided in a context of caring, EBP leads to the best clinical decision making and outcomes for patients and families....

Change of Emphasis
Nurse Knowing

- Empirical
- Ethical
- Personal
- Aesthetic

Origins of EBP

• Rise of the information age
• Shift from opinion, experience, precedent and pathophysiology to evidence.

Why is EBP good?

- Successful translation of research
- Significant reductions in mortality & morbidity
- The “highway” for nearly ALL drug development since 1950


Evidence Base for 3000 Interventions

Clinical Evidence. British Medical Journal. Available at:
http://clinicalevidence.bmj.com/ceweb/about/knowledge.jsp.
Myths of EBP

• Solves problems **quickly**
• **Safest** option
• Best **value** for the money
• Interventions & outcomes can be **measured**
• Best **path** to solve clinical problems
• A **simple**, logical process for critical thinking & decision making.


Unspoken-EBP Has Limits!

1. Many questions in nursing cannot be answered via experimental design.
2. Patients are not biological machines.
3. Evidence is never free of bias or error.
4. Interventions based on probabilities without accounting for circumstances, pathophysiology, physiology & history is dangerous care.


Unspoken-Limits of EBP continued:

5. Association does not mean causation.
6. Precision is not validity.
7. The usefulness of any evidence is equal to:

\[
\text{relevance} \times \text{validity} \\
\text{work & resources & benefit}
\]

Why practice in an evidence based way?

• Improved health?
• Reduce costs?
• Strengthen informed consent process?
• Promote value-free decision making?
• Improved decisions regarding effectiveness vs. burden?
• Improve reimbursement?
• Meet quality metrics?
What is Unspoken

✔ EBM is a practical form of rationing
✔ EBM drives use of power in the clinical encounter
✔ **Who has power?** clinician, patient or payor?
✔ **Someday??** only clinicians with wealthy patients will be able to follow traditional medical ethics and *choose* what is best practice rather than forced *adherence* - prescribing what is directed & required by an external source with “*the evidence*” for payment and protection from penalty.

*Saarni S & Gylling H. Evidence based medicine guidelines: a solution to rationing or politics disguised as science? J Med Ethics 2004;30: 171-175*
Negative Outcomes of EBP

- Medicalization” of life
- Condition + Intervention= Predictable Outcome
- Evidence is truth & primary marker for quality care
- “Replaced” expert, experienced, relationship based care
- Nurse/Patient relationship has changed to Provider & Consumer
- Declining confidence in provider judgment
- Declining tolerance to adverse or unpredicted natural biological variation which is often labeled as error or incompetence

Risks of EBP

- HCO lack dynamic systems & access to disseminate evidence
- Significant numbers of clinical nurses lack competency to synthesize & evaluate & judge evidence for application (application is not the problem!)
- Applied evidence within poorly structured order sets, policies, procedures & clinical guidelines discourages nurses to think through the consequences of applying evidence in an ethical way.

Limitations of EBP

- Reliance on empiricism
- Narrow definitions of evidence
- Lack of evidence of efficacy
- Limited usefulness for individual patients
- Threat to the clinician-patient relationship

The Literature
What happened to the literature?

**Threats to validity & integrity**
- Design
- Implementation
- Analysis
- Reporting

**New Peer Review:** Data availability & plagiarism monitoring

*Bauchner H. Editorial policies for clinical trials and the continued changes in medical journalism. JAMA. 2013; 310(2). Available at jama.com.*
Erosion of Truth & Trust Since 2001

Number of retracted papers has increased 15 fold

Retraction is Common

There is probably a lot of undiscovered fraudulent research.

Increasing Erosion of Truth & Trust in Science

Andrew Wakefield
Naoyuki Nakao

Naik G. Mistakes in Scientific Studies
Surge. WSJ.com. August 10, 2011

Scott Reuben
O’Malley P. A Case of Scientific Misconduct.

Hwang Woo Suk
Jan Hendrikschon
Jon Sudbo
Eric Poehlman

Dark Side of EBP
How to Achieve positive Results without actually Lying to Overcome the Truth


Fabrication, Falsification, Plagiarism

Dark Side of EBP

- Report only the impressive relative risk reduction while **suppressing** the unimpressive **absolute risk reduction** & **actual numbers needed to treat**.
- Provide experimental patients **additional treatments** with known efficacy to treat co-morbidities & improve study results
- **Concoct** invalid inflated event rates especially among control patients

_D. Sackett & A. Oxman. HARLOTplc: an amalgamation of the world’s oldest professions. BMJ. 2003;327:1442._

Dark Side EBP

- **SCUM** - Sick Celebrities for Use in the Media
  - Hire stars, athletes and politicians for talk shows, gossip magazines, to promote the product.
  - Say anything for money (paid experts to generate guidelines, write editorials, be keynote speakers, referee for key journals


Dark Side EBP

- **FYP** - Foundation in Your Pocket
  - build beautiful headquarters & conference centers for health foundations

- **BOSS** - Bureau of Secret Surveillance
  - buy confidential information from pharmacists to know who is prescribing what

- **SOW** - Save/Sacrifice Our Workers
  - threaten to move the product development & production to another country

Dark Side EBP

• **SHARKS** – *Striking Horror & Retreat through Killer Solicitors*
  
  • Really good lawyers to threaten drug review boards with frivolous but expensive lawsuits to suppress negative health technology assessment till sales targets are met


Dark Side EBP

**SALAMI**-how to Succeed in Academic Life
Advice and Mentoring Institute

- how to pad your vitae, exploit your staffs and slice your research findings into a minimum of one paper published per enrolled subject- always overstating the significance of the study findings


Dark Side EBP

GSWS - Ghost Writers in the Sky

- Once the data is “cooked”, write the paper and report only favorable results. Randomize sentence presentation to camouflage plagiarism


The Future of EBP & Nursing
Evidence is a gift with ethical wrappings

Nursing’s Treasures to Navigate EBP

• ANA Code of Ethics

• 5 Nursing Ethics
  • Autonomy
  • Beneficence
  • Non-malfeasance
  • Justice
  • Veracity

ANA Code of Ethics with Interpretive Statements. Available at:
Look at Practice Again

- There is no evidence that EBM provides a greater benefit than traditional care.
- Evidence as the final arbitrator in health care has created new legal, ethical and governmental powers that overshadow practice & has created new consumer needs.


What Have We Gained?
What Have We Lost?

• EBP as the primary model to quantify, cost, govern and evaluate care while efficient has rendered the clinician-patient relationship into a “thing” stripped of all therapeutic power & along with the dynamics of healing & meaning.

• Patient outcomes are becoming a function of enacted probabilities rather than the result of expert & compassionate nursing care.

• The “supermarket” model of “best evidence for sale” leads – the public to believe that healing occurs outside the clinician-patient relationship.

Improving Research Translation & Inquiry within an Ethical Framework

1. Provide evidence of ethical research processes (Human Subjects, COI, Bias, Error)
2. Eliminate unnecessary research!
3. Focus more on education & training in FINDING, READING, INTERPRETING, JUDGING & APPLYING evidence within nursing’s primary ethics.
4. Prospective agreement for publication regardless of findings to stop data concealment
5. Reduce emphasis on volume of projects over quality.


What if?

Health care was **liberated** from probability based statistics which often leads to incorrect diagnosis, the wrong evidence application and increased need for testing to refute or confirm “successful” evidence application?

What If?

- Evidence is a **tool** that requires assessment & judgment **before** application within the nurse-patient relationship.
- Since nursing is a human interaction with potentially infinite responses, RCCT should **not** be perceived as the GOLD standard for evidence in nursing. In fact, No one type of evidence should secure a position of **domination** over another.
- Uniform & transparent processes for evaluation & use of evidence would help clinicians, HCOs and consumers to understand the **limitations** of EBP.
- Guidelines **SHOULD NEVER BE RULES**!


Ethics, Evidence, Practice & Research

• Safe evidence based nursing practice begins with: knowing*, nursing assessment, competency, experience & intuition.

• Use of evidence is a function of the patient & nurse relationship within resources, circumstances, values & goals.

• SAFE evidence-based nursing practice takes place in relationship built on the ANA Code of Ethics.

*Knowing: Anatomy, physiology, pathophysiology, pharmacology, microbiology, & evidence evaluation, aesthetics & personal knowledge
EBP & Ethics Resources


Resources


• **Clinical Practice Guidelines as Legal Standards- The Wrong Cure for Health Care.** Center of Justice & Democracy. [http://centerid.org](http://centerid.org).
Questions?

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