NAVIGATING SAFELY THE DARK SIDE OF EVIDENCE BASED PRACTICE©

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Objectives

1. Describe the relationship of ethics, evidence, practice in a fluid health care environment.
2. Describe ways to promote an safe evidence based practice.
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.

So what is good about EBP?

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


Evidence Base for 3000 Interventions

The Dark Side of EBP
Assumptions of EBP

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


The Limits of EBP

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

The Limits of EBP

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

  relevance \times validity

  work & resources & benefit

*Mayer D. Evidence based medicine. Epilepsia. 2006; 47:3-5.*
The Unspoken about EBP

✔ EBM is a practical form of rationing
✔ EBM drives use of power in the clinical encounter

✔ 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.

✔ Who has power? clinician, patient or payor?

Hidden 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

The 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.


The Limitations of EBP

- Over reliance on empiricism
- Narrow definitions of what is evidence
- Limited usefulness for individual patient
- Threat to the clinician-patient relationship

The Literature
What has happened to the literature?

**Threats to validity & integrity**

- Design
- Implementation
- Analysis
- Reporting
- Peer review

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

Number of retracted papers has increased 15 fold

Retraction is Becoming 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

Hwang Woo Suk
Jan Hendrikschon
Jon Sudbo
Eric Poehlman
Dark Forces

How to Achieve positive Results without actually Lying to Overcome the Truth  [Harlot]


Fabrication, Falsification, Plagiarism  [FFP]

Dark Forces

• 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

Dark Forces

- **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 Forces

- **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 Forces

- **SHARKS** – Striking Horror & Retreat through Killer Solicitors

Use really good lawyers to threaten drug review boards with frivolous but expensive lawsuits to suppress negative health technology assessments until sales targets are met


Dark Forces

SALAMI—how to Succeed in Academic Life
Advice & Mentoring Institute

Or 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 Forces

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

Release the Clinician

• There is no evidence that EBM provides greater benefit than traditional care.

• Using evidence as the final arbitrator in health care has created new legal, ethical and governmental powers that overshadow practice & has created new consumer needs.


Where do we stand now?

• 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, individualized & compassionate nursing care.

• The “supermarket” model of “best evidence for sale” leads – the public to believe that healing occurs outside the clinician-patient relationship when the reality is – the clinician is the one who makes EBP safe!!!

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 was a tool that required assessment & judgment before application within a therapeutic relationship?
• Since nursing is a human interaction with potentially infinite responses, RCCT were not perceived as the GOLD standard for best evidence in nursing?
• HCOs and consumers were educated to understand the limitations of EBP.
• What if guidelines were used as guidelines and not rules?


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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