Evidence, Evaluation, and Ethical Obligations: Looking at Evidence Based Medicine

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- James Giordano, Ph.D., M.Phil., is a Bioethicist with the Department of Defense (DoD) Medical Ethics Center (DMEC), Chief of the Neuroethics Studies Program, Scholar-in-Residence, leads the Sub-Program in Military Medical Ethics, and Co-director of the O'Neill-Pellegrino Program in Brain Science and Global Health Law and Policy in the Pellegrino Center for Clinical Bioethics.
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- Dr. Giordano currently serves as Chair of the Neuroethics Program of the Institute of Electrical Electronic Engineers (IEEE) Brain Project, and an appointed member of the Neuroethics, Legal and Social Issues (NELSI) Advisory Panel of the Defense Advanced Research Projects' Agency (DARPA). He has previously served as Research Fellow and Task Leader of the EU Human Brain Project Sub-Project on Dual-Use Brain Science; an appointed member of United States Department of Health and Human Services Secretary's Advisory Council on Human Research Protections (SACHRP); and as Senior Science Advisory Fellow of the Strategic Multilayer Assessment Branch of the Joint Staff of the Pentagon.
- The author of over 290 publications in neuroscience and neuroethics, seven books, and 15 government whitepapers on neurotechnology, ethics and biosecurity, he is an Editor-in-Chief of the international journal Philosophy, Ethics and Humanities in Medicine; Associate Editor of the Cambridge Quarterly of Health Care Ethics; and Contributing Editor of Frontiers in Human Neuroscience.
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- Mr. Procaccino has served as the Legal Advisor to the Surgeon General, United States Air Force, and Senior Counsel for Health Affairs for the Air Force Judge Advocate General from 1993 until his retirement from Civil Service in that position in 2017. Prior to that, he was the Senior Medical Law Counsel for the Tort Claims and Litigation Branch of the Air Force Legal Operations Agency, beginning his Air Force tenure with that office in 1978. He also served as the legal representative to the Surgeon General's Medical Practice Review Board and Clinical Investigation Review Committee, and participated in the Department of Defense Health Affairs Committee for Risk Management and Quality Assurance.
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Learning Objectives

At the end of the presentation, participants will be able to:

1. **Define evidence-based medicine (EBM).**
2. **Differentiate EBM and "medicine-based evidence" (MBE).**
3. **Discuss the core criteria of any/all EBM/MBE.**
4. **Describe how EBM/MBE ethically enable the clinician.**
5. **Outline how EBM/MBE ethically empower the patient.**

Does Evidence Support Utility?

- ***"Choose your errors carefully, lest you are nigh to repeat them"***
- **Critical evaluation of specific research approaches**
  - **Based on levels/ lines of evidence**
  - **All are not equal or effective**

What Paradigms Facilitate Best Evidence-Based Medicine (EBM)?

General Approach

Pragmatic results that can be used to validate outcomes, elucidate mechanisms or both to demonstrate utility of a technique or paradigm as relevant to a specific domain of medicine.

EBM or *Medicine-Based Evidence*?

- **Studies of outcomes**
  - **What works, what doesn't?**
- **Studies of mechanisms**
  - **What are substrates of effect?**
- **Studies of proposed utility**
  - **How might effective use occur?**
  - **Parametric effects in numerous domains:**
    - **Medical**
    - **Economic**
    - **Administrative / Legal**
    - **Social / Philosophical**

EBM and MBE Must…

- **Maintain validity**
- **Maintain reliability**
- **Be elucidative**
- **Be applicable**
- ***"How we gain evidence is often more critical than what evidence we gain"***

Assessing the Evidence

- **What level(s) of evidence necessary?**
- **Acknowledge hierarchical evidence:**
  - **Preclinical studies**
  - **n=1 studies**
  - **Case series**
  - **Controlled studies**
  - **Randomized controlled trial (RCT)**

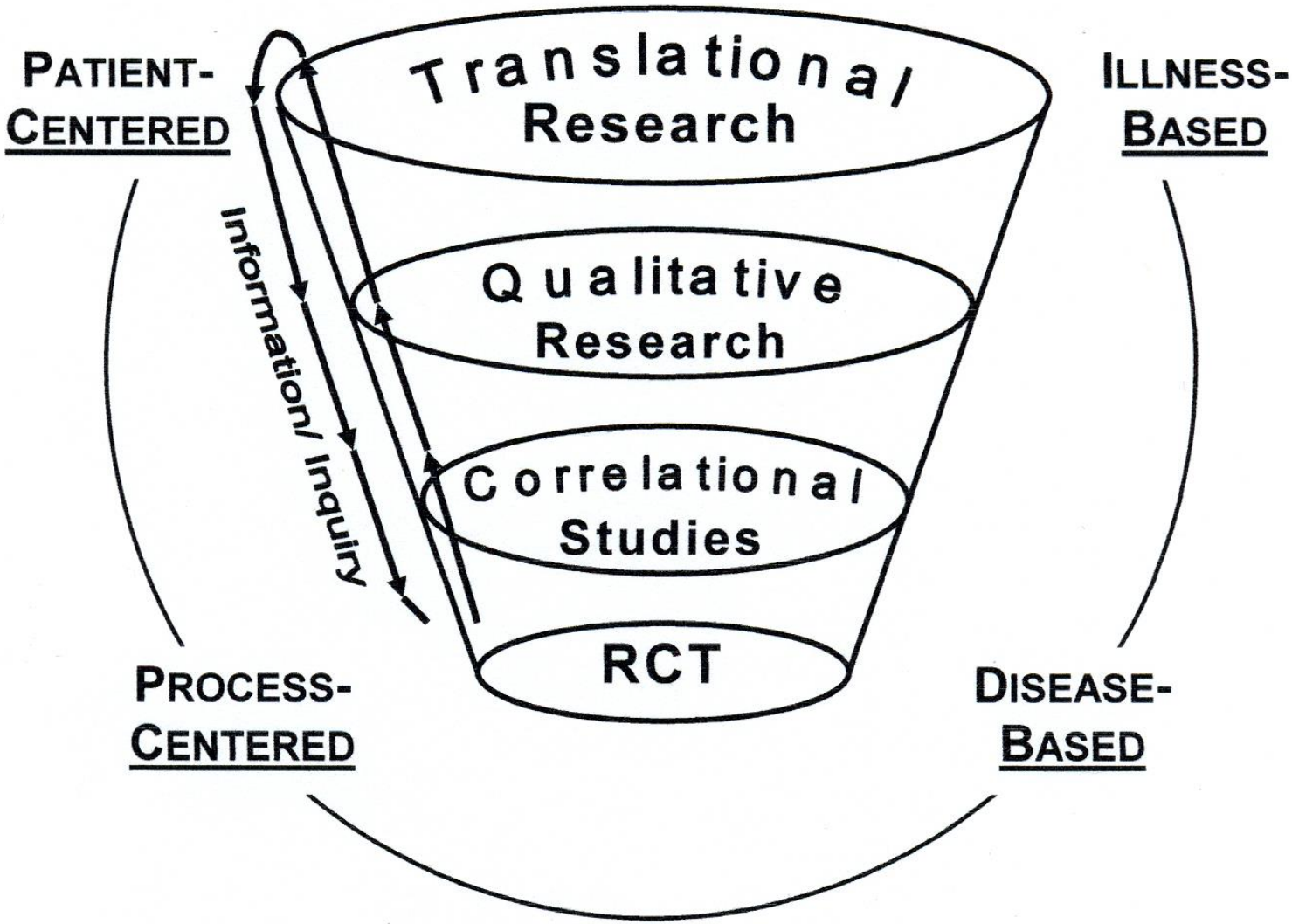
Issues in EBM

- **Current knowledge base suggests need to expand research paradigms**
  - **As appropriate to enhanced knowledge of mechanisms**
  - **To meet changes in interactive "needs" of patient and clinician (as well as other stakeholders)**

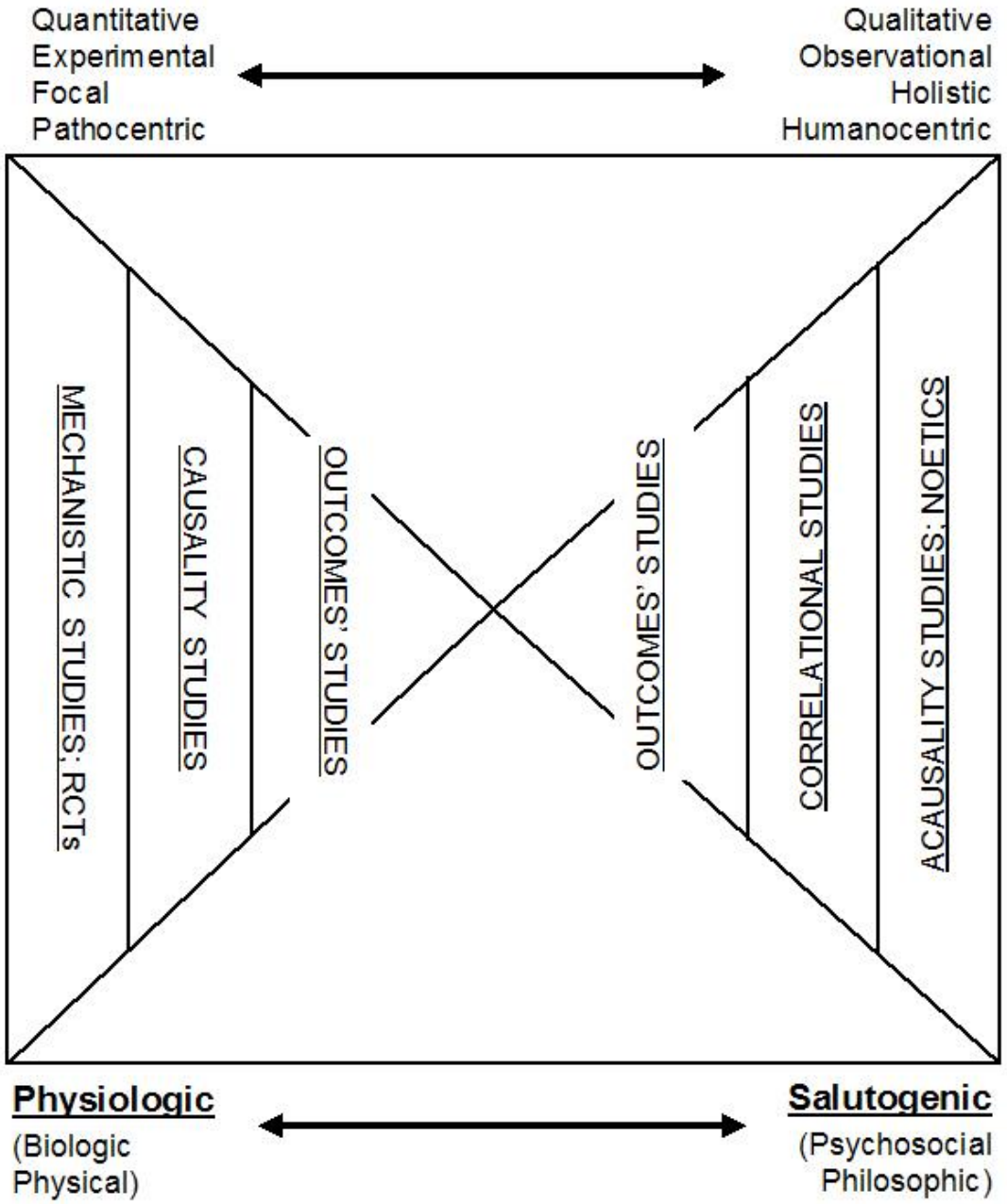
Paradigmatic Revision

- **EBM/MBE paradigms may need to:**
  - **Expand the Randomized Controlled Trial (RCT)**
    - **Attribute based randomization**
    - **Attribute-treatment interaction analyses**
  - **Utilize mixed (quantitative/qualitative) methodologies**
  - **Go beyond/outside use of RCT where indicated by level of evidence**
  - **Maintain a translational framework**

Paradigmatic Revision



Paradigmatic Revision



Ethical Value of EBM/MBE

Grounded in moral obligation of **maximizing good**

Upholding fiduciary nature of the clinical encounter:

- **Physician**
  - **Allows for effective evaluation of benefit:burden (risk) ratio**
  - **Enhances knowledge on all levels necessary for adequate prudence in resolving equipoise/decision-making**
  - **Affords information available to provide patient in respect for patients' autonomy**
- **Patient**
  - **Allows adequate informational basis to consent to treatment**
  - **Affords equity in disparity of vulnerability**
  - **Allows for participation in resolution of equipoise**

Ethical Imperative for Translational Research

- **Normative**
  - Grounded in moral obligation of **non-harm**
  - How?
    - "Harm by ***commission***"
      - ie.- a Tx is "bad" and is not identified as such
    - "Harm by ***omission***"
      - ie.- a Tx has potential "good" that is not recognized
    - "Harm by ***interference***"
      - ie.- a Tx interferes with use of more effective Tx
    - Harm through failure to acknowledge the social good of new knowledge to provide epistemic revision thereby enhancing both the therapeutic and moral agency of medicine

Ethical Obligations

- **What works/what doesn't?**
  - **Addressing the non-harm imperative**
- **In whom does it work?**
  - **Addresses the prudential question of what should be done for a particular patient**
- **In what domains?**
  - **Addresses the need for intellectual virtue to apprehend nature of patient effects**
- **Mechanisms of effect**
  - **Addresses types and levels of knowledge applicable to medicine, fortifying both art and skill**
- **Need to study how we study**
  - **Addresses intellectual honesty and epistemic capital**

Ethical Obligations

"Every branch of medicine involves moral considerations, both as regards to the practitioner and the patient…all contain a moral element…which cannot be neglected without injury to the doctor, to the individual and to society."

Elizabeth Blackwell, 1889

LOOKING AT EVIDENCE BASED MEDICINE: AN "*ADVOCATUS DIABOLI*" VIEW

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EVIDENCE BASED MEDICINE

THE MELDING OF:

- BEST EVIDENCE
- CLINICAL EXPERTISE
- PATIENT VALUES AND PREFERENCES

- GOOD IN THEORY, **BUT**: ARE THESE OF EQUAL VALUE AND CONSIDERATION, OR DOES THE WORD "EVIDENCE" ALLOW "BEST EVIDENCE" TO SUPERSEDE THE OTHER FACTORS IN CONSIDERATION?

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ISSUES WITH EVIDENCE BASED MEDICINE

- **MEDICINE: IS IT A SCIENCE, AN ART, OR BOTH?**
  - **IF BOTH, WHERE DOES THE PROVIDER'S OWN EXPERIENCE, CONTEXT, UNDERSTANDING OF A PATIENT'S UNIQUENESS, FIT IN?**
  - **RECOGNITION OF PROVIDER DISCRETION**
    - **FORCING PROVIDERS TO BE "BOXED IN" TO FOLLOWING ONE "PREFERRED" PATH FOR CARE**
    - **NOT JUST PATIENT PREFERENCES, BUT WHAT ABOUT PATIENT'S CIRCUMSTANCES?**
      - **AUTONOMY/CONSENT**
- **EVIDENCE BASED MEDICINE IS PREMISED ON EVOLVING FINDINGS AND STANDARDS**
  - **DOES NOT CREATE A STABLE "TEXTBOOK" STANDARD, BUT IS A RESULT OF CONTINUALLY CHANGING FINDINGS**
  - **DOES NOT ALLOW FOR VARIANCE OF SPECIALIZATION OR PROFESSIONAL TRAINING DIFFERENCES**
  - **MAY NOT PROVIDE FOR PRACTICAL DIFFERENCES RECOGNIZED IN CONVENTIONAL "REASONABLE AND PRUDENT PROVIDER IN SAME OR SIMILAR CIRCUMSTANCES"**
  - **NEED TO SEARCH FOR "GOLD STANDARD"?**

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SETTING THE "TRADITIONAL STANDARD OF CARE"

- ***THE* MEASUREMENT *OF DUTY OWED THE PATIENT BY THE PROVIDER OF CARE, THE BREACH OF WHICH WILL RESULT IN LIABILITY FOR ANY INJURIES WHICH MAY BE CAUSED.***

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GENERAL RULE

- **THE STANDARD OF CARE IS:**
  - **THAT OF ANOTHER REASONABLE PROVIDER OF THE SAME SPECIALTY IN SAME OR SIMILAR CIRCUMSTANCES**
- **STANDARDS MAY BE AN EVOLUTIONARY PROCESS**

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TANGIBLE FACTORS

- **WRITTEN POLICIES AND GUIDANCE**
  - **STATUTES**
  - **REGULATIONS**
  - **CODES OF CONDUCT**
  - **PROFESSIONAL POLICY POSITIONS**
  - **OPERATING INSTRUCTIONS**
  - **CLINICAL PRACTICE "GUIDELINES" ???**

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INTANGIBLE FACTORS

- **CUSTOMARY AND ACCEPTED PRACTICE**
- **DEGREE AND LEVEL OF SPECIALTY**
- **ADVANCES IN PROFESSION**
- **PROXIMITY OF SPECIALISTS**
- **AVAILABILITY OF FACILITIES**
- **GEOGRAPHY**

- ***UNIQUE MILITARY REQUIREMENTS***
  - **ISSUE OF SYSTEMIC NEGLIGENCE**
  - **DISCRETIONARY FUNCTION AND FEDERAL SUPREMACY**

- **ALLOWANCE FOR STANDARDS BASED ON TIME OF INCIDENT**

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HOW DOES AN EVIDENCE BASED STANDARD AFFECT THE PROVIDER AND OBJECTIVE PATIENT CARE?

- **MAY CREATE AN INCREASED BURDEN FOR PROVIDERS IN MALPRACTICE LITIGATION**
  - **GUIDELINES VS. STANDARDS***
    - **REVERSING THE BURDEN OF PROOF?**
  - **THE "DAMNED IF YOU DO, DAMNED IF YOU DON'T" RESULT**
  - **DILUTES DEFENSE OF "ACCEPTABLE MINORITY STANDARD"**
  - **PREVENTS INDIVIDUAL DISCRETION BASED ON UNIQUE PATIENT ISSUES**
    - **OFF-LABEL USE DRUGS**
    - **HOLISTIC MEDICINE RECOMMENDATION IN COMBINATION WITH "CONVENTIONAL" MEDICINE**
    - **TAKING ON THE HIGH RISK PATIENT**
- **POTENTIAL CONFLICTS**
  - **CLINICAL EVIDENCE STANDARDS BASED ON LABORATORY ANALYSES WITH CAPTURED STAFF OF EXPERTS**
  - **FINANCIAL INCENTIVE FOR SETTING STANDARDS**
    - **APPROPRIATION BY THE PHARMACEUTICAL INDUSTRY?**

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FROM OXFORD ONLINE DICTIONARY

- **Dictionary**

guideline

[ˈgīdˌlīn]

NOUN

- a general rule, principle, or piece of advice.
- *synonyms:*
- recommendation · instruction · direction · suggestion · advice · regulation · rule · requirement · specification · prescription · precept · principle · guiding principle

standard · criterion · measure · gage · yardstick · benchmark · touchstone · procedure · parameter · constraint · limit

Oxford Online Dictionary

Oxford University Press 2021

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Key Takeaways

- Analyze legal and ethical complexities utilizing evidence based medicine.
- Outline standard of care criteria in determining efficacy of practice.
- Identify arguable deficiencies using a pure evidence based medicine approach.
- Demonstrate how human factors/preferences as well as the uncertainties in the evolution of medicine affect the determination of the propriety of care given.

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4. Follow the onscreen prompts to complete the post-activity assessments:
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   b. Complete the Evaluation
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5. After completing the posttest at 80% or above, your certificate will be available for print or download.
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