



## Pathology & Biology Section – 2005

### G98 The Evidence-Based Medicine Paradigm Shift and Forensic Pathology

M.G.F. Gilliland, MD\*, Brody School of Medicine at East Carolina, Department Pathology and Laboratory Medicine, Brody 7 S 10, Greenville, NC 27834

Attendees will learn that the concepts of Evidence-Based Medicine are not being used in forensic pathology writings, although some of the terminology is being applied in polemics about the Shaken Baby Syndrome.

This presentation will impact the forensic community and/or humanity by assisting forensic pathologists in being better able to judge the validity of assertions about Abusive Head Injury and/or Shaken Baby Syndrome couched in terms of Evidence Based Medicine.

**Hypothesis:** The term Evidence-Based Medicine (EBM) has, so far, been utilized in the Forensic Pathology context to gain entry to the current literature for an editorial, an opinion paper, and a single case report, all attempting to discredit the concept of Shaken Baby Syndrome. Such papers might not be given as much consideration without the appearance of fluency with the issues raised by EBM.

**Synopsis:** Evidence-Based Medicine (EBM) is an approach to scientific decision-making in selecting treatments for well-defined diseases. Prospective, double-blinded, randomized controlled trials (RCTs) of therapies are given the highest weight, while other forms of comparing health interventions are ranked lower in the EBM hierarchy. The term Evidence-Based as used in the forensic pathology literature to date asserts that no evidence exists, or only weak evidence exists, for what is called Shaken Baby Syndrome. EBM nomenclature has not been used in other contexts to establish or refute other diagnoses in health-related papers, whether in medicine, respiratory care, or dentistry.

Evidence-Based Medicine (EBM) concepts were introduced to a broad readership in a publication in the Journal of the American Medical Association in 1992. The then editor of the JAMA, George Lundberg, referred to the JAMA itself as "The Journal of Physician Behavior Change." He was describing his vision for the impact of the articles presented in the Journal. EBM has rapidly achieved widespread acceptance and is achieving "Physician Behavior Change." Print and electronic journals have sprung up to publish articles using the term, and at times even applying the concepts.

Use of the term "Evidence-Based Medicine" has not been uniformly associated with appropriate appreciation of EBM's goals nor application of its techniques. Reviewing the actual EBM literature reveals multiple articles complaining that others use their terminology but not their concepts. Still other articles discuss the phenomenon of EBM and urge further study of the validity of its assumptions. Much of the literature dealing with the results from applying EBM describe large studies (called mega-studies) and substitutes for mega-studies by literature analyses (called meta-analyses), both seeking to achieve more "Statistical Power" (statistical significance) by comparisons of treatment in similar, large groups. Additionally, other articles call for Evidence-Based comparisons of various forms of intervention from toilet-training to cancer treatments.

A review of the literature accessed through PubMed (<http://www.ncbi.nlm.nih.gov/PubMed>) searching for the terms "EvidenceBased Medicine" and "Shaken Baby" reveals only three papers: one is a literature review, the second is a single case report with a brief literature review, and the third is a comment published in the same issue as the case report. Both of the literature reviews fail to provide a citation to describe the classifications used to assert the weakness(es) of existing "Evidence."

Determining whether the terminology from EBM is used accurately or not requires the reader to review the goals and techniques of EBM. Such a review leads one to realize that the terms and techniques of EBM are misapplied in these three publications. Abusive Head Injury is not a "treatment" applied prospectively and randomly with case-controls (RCTs) in a mega-study.

The published reports of cases, case series, or studies involving Abusive Head Injuries or Shaken Babies are not legitimate subjects for meta-analyses: Those studies which support statistical inference (have sufficient "Statistical Power" on their own) gain no benefit from having their populations and selection criteria diluted. Those studies which do not support statistical inference are too dissimilar both in their populations and selection criteria to be legitimately combined. When such heterogeneous populations are combined for analysis, the result is at best an admixture, not the blend meta-analysis seeks. It is a priori apparent that every attempted meta-analyses of such disparate groupings must lack all true "Statistical Power," whether for or against any given hypothesis.

**Evidence-Based Medicine, Abusive Head Injury, Shaken Baby Syndrome**