



## Mechanistic Evidence in Evidence-Based Medicine: A Conceptual Framework

By U. S. Department of Health and Human Services

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0.3in. Interest has increased in recent years in comparative effectiveness, that is, assessing the efficacy of new or established medical interventions, with particular emphasis on head to head comparisons of established therapies, or understanding their real-world performance. Randomized controlled trials (RCTs), while the ostensible gold standard for establishing efficacy and sometimes effectiveness, have well recognized liabilities, most notably the time and expense it often takes to mount them, as well as the sometimes limited scope of the questions they address. Alternatives to RCTs include a variety of observational designs. Those attracting considerable attention are typically derived from very large databases, often assembled for non-research purposes, such as hospital billing, reimbursement, prescription data, electronic patient records, etc. Studies derived from such data sources promise real-world relevance, and relatively rapid results, compared to some RCTs. The middle ground is occupied by observational designs with original data gathering and RCTs that utilize surrogate endpoints for example, death versus tumor progression, elevated LDL or coronary artery narrowing versus MI or death. A dilemma facing patients, physicians, regulatory entities, insurance providers, guideline developers and others...

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