

**EBDM GLOSSARY**  
**EVIDENCE-BASED DECISION MAKING**

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**A**

**ABSOLUTE RISK (AR)** *(Calculations, Study Design)*

- The observed or calculated probability of an event in the population under study

**ABSOLUTE RISK DIFFERENCE** *(Calculations, Study Design)*

- Difference in the risk for disease or death between exposed and unexposed populations

**ABSOLUTE RISK REDUCTION (ARR)** *(Calculations, Study Design)*

- Difference in the absolute risk (rates of adverse events) between study and control populations
- Difference in the proportion of subjects with the outcome of interest in each group
- $ARR = EER - CER$

*Syn: Risk Difference*

*See also: Absolute Risk (AR), Control Event Rate (CER), Experimental Event Rate (EER), Number Needed to Treat (NNT), Treatment Effect*

**ACTION RESEARCH** *(Qualitative)*

- A general term for a variety of approaches that aim to resolve social problems by improving existing conditions for oppressed groups or communities

**ACTIVE TREATMENT** *(Therapy)*

- In a clinical trial, treatment that is intended to reduce or eliminate the disease in the patient

**ADJUSTMENT** *(Calculations, Study Design)*

- A summarizing procedure for a statistical measure in which the effects of differences in composition of the populations being compared have been minimized by statistical methods

**ADJUVANT TREATMENT** *(Therapy)*

- Additional treatment given with the main treatment to improve the overall effects of treatment

**ADOPTION OF RESEARCH EVIDENCE** *(EBP)*

- A process that occurs across five stages of innovation (i.e., knowledge persuasion, decision, implementation, and confirmation).

**ADVERSE EVENT** *(Study Design, Therapy)*

- An undesirable health event that occurs in a participant during a clinical trial
- May or may not be related to the treatment itself
- More severe adverse events may be life threatening, require hospitalization, result in disability, cause birth defects, or result in death.

*See also: Adverse Reaction, Side Effects*

## EBDM GLOSSARY

### **ADVERSE REACTION**

*(Study Design, Therapy)*

- An unwanted effect caused by the administration of drugs or a harmful response to a medicine
- Onset may be sudden or develop over time

*Syn: Adverse Drug Reaction (ADR)*

*See also: Side Effects*

### **AESTHETICAL INQUIRY**

*(Qualitative, Study Design)*

- A qualitative study design that uses subjective expression to recognize patterns in phenomena.

### **AIM JOURNALS**

*(MEDLINE)*

- Core clinical medical journals indexed for *Abridged Index Medicus* and available in most medium sized hospital or medical center libraries.

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### **ALLOCATION CONCEALMENT**

*(Study Design)*

- Occurs when the person who is enrolling a participant into a clinical trial is unaware whether the next participant to be enrolled will be allocated to the intervention or control group

*See also: Randomized Controlled Trial*

### **ANECDOTAL EVIDENCE**

*(EBP)*

- Informal observations of treatment results in individual patients
- Doctors make such observations in their day-to-day practice of medicine

*See also: Case Report*

### **APPLICABILITY OF STUDY FINDINGS**

*(Study Design)*

- Whether or not the effects of the study are appropriate for a particular patient situation

### **ARM**

*(Study Design, Therapy)*

- Any of the treatment groups in a randomized trial
- Most randomized trials have two "arms," but some have three "arms," or even more

*See also: Randomized Controlled Trial*

### **ASSOCIATION**

*(Study Design)*

- Statistical dependence between two or more events, characteristics, or other variables
- An association may be fortuitous or may be produced by various other circumstances.
- The presence of an association does not necessarily imply a causal relationship.

### **ATTRITION**

*(Study Design)*

- When subjects are lost from or drop their participation in a study

*See also: Lost to Follow Up (Loss of Subjects to Follow Up)*

### **AUDITABILITY**

*(Qualitative, Study Design)*

- A criterion for measuring the trustworthiness of qualitative research that describes a trail of the raw data is made available for review by peer reviewers and other interested investigators.

## EBDM GLOSSARY

### AUDIO-VISUAL

*(Qualitative, Study Design)*

- A qualitative study design that uses audiovisual media to document and study healthcare and nursing phenomena.

### AXIAL CODING

*(Qualitative)*

- A process used in grounded theory to relate categories of information by using a coding paradigm with predetermined subcategories

*See also: Paradigm*

## B

### BACKGROUND QUESTIONS

*(EBP)*

- Questions that need to be answered as a foundation for asking the searchable, answerable foreground question.
- Questions that ask for general information about a clinical issue
- Consist of two components:
  - the starting place of the question (e.g., what, where, when, why and how)
  - the outcome of interest (e.g., the clinical diagnosis)

*See also: Foreground Questions*

### BASELINE

*(Study Design, Therapy)*

- As a reference point, information gathered at the beginning of a study from which variations found in the study are measured
- A known value or quantity with which an unknown is compared when measured or assessed
- The initial time point in a clinical trial, just before a participant starts to receive the experimental treatment which is being tested
- Safety and efficacy of a drug are often determined by monitoring changes from the baseline values.

### BASELINE DATA

*(Calculations, Study Design)*

- Information that describes the patients at the start of the trial

*See also: Data, Demographic Data, Objective Data, Quality-of-Life Data, Raw Data, Subjective Data, Survival Data*

### BENCHMARKING

*(EBP)*

- The process of looking outward to identify, understand, and adapt outstanding best practices and high performance to help improve performance.

### BIAS

*(EBP, Study Design)*

- Deviation of results or inferences from the truth, or processes leading to such deviation
- Divergence of results from the true values or the process that leads to such divergence
- Any factor or idea that distorts observations, results, and conclusions jeopardizing the validity of the study and/or its results.
- When a point of view prevents impartial judgment on issues relating to the subject of that point of view
- In a clinical trial, bias is controlled by blinding and randomization.

*Syn: Systematic Error*

*See also: Blinding, Randomization, Referral Bias, Selection Bias, Random Error*

## EBDM GLOSSARY

### **BIOGRAPHY**

*(Qualitative)*

- An approach that produces an in-depth report of a person's life.
- Life histories and oral histories also involve gathering of biographical information and recording of personal recollections of one or more individuals.

### **BIOSKETCH**

*(Qualitative)*

- A 2-3 page document, similar to a resume or brief curriculum vitae that captures an individual's educational and professional work experience, honors, prior research grants, and publications.

### **BLIND REVIEW**

*(Study Design)*

- A review process in which identification of the author/creator/researcher is removed and, likewise, the identity of the reviewers so that anonymity of both parties is assured.

### **BLINDING / BLIND(ED) STUDY**

*(Study Design, Therapy)*

- A study in which observer/researcher and/or subjects/participants are kept ignorant of the group to which the subjects are assigned (as in an experimental study) or of the population from which the subjects come (as in a non-experimental or observational study)
- A randomized trial is "blind" if the participant is not told which arm of the trial s/he is on.
- A clinical trial is "blind" if participants are unaware of whether they are in the experimental or control arm of the study.
- The purpose of "blinding" is to eliminate sources of bias.

**SINGLE BLIND** – One party, investigator or participant, is unaware of what medication the participant is taking.

**DOUBLE BLIND** – Neither the participating individuals nor the study staff knows which participants are receiving the experimental drug and which are receiving the placebo (or another therapy). The expectations of the doctor and the participant about the experimental drug do not affect the outcome.

**TRIPLE BLIND** – Statistical analysis is also done in ignorance of the group to which subjects belong.

*Syn: Masking / Masked Study*

*See also: Bias, Masking, Clinical Trial, Controlled Clinical Trial, Randomized Controlled Trial*

### **BLOCKING**

*(Study Design)*

- A strategy introduced into a study that entails deliberately including a potential extraneous intrinsic or confounding variable in a study's design in order to control its effects on the dependent or outcome variable.

*See also: Dependent Variable*

### **BOOLEAN SEARCH**

*(MEDLINE)*

- Means of combining search statements or sets using the logical operators "OR" to expand a search, "AND" to restrict a search to articles that contain two or more specified elements together, and "NOT" to restrict the search to articles that do not contain specified terms.

*See also: Keywords, Restrict to Focus, Text words*

### **BOOSTER INTERVENTIONS**

*(Therapy)*

- Interventions that are delivered after the initial intervention or treatment in a study for the purpose of enhancing the effects of the intervention.

### **BRACKETING**

*(Qualitative)*

- Identifying and suspending previously acquired knowledge, beliefs, and opinions about a phenomenon.

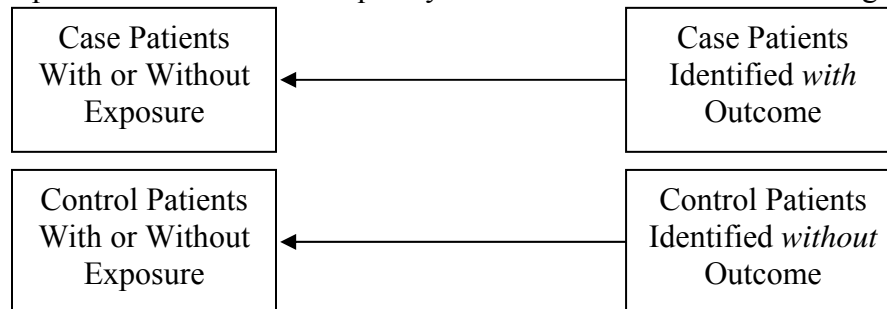
## C

**CARE DELIVERY OUTCOMES***(EBP)*

- The outcomes that are influenced by the delivery of clinical care.

**CASE–CONTROL STUDY***(Study Design)*

- A study with retrospective comparison of persons with a disease or outcome of interest (*cases*) with persons without the disease or outcome of interest (*controls*), looking back to see if they had the exposure of interest; attempting to relate an effect or outcome to a probable cause.
- Type of research that retrospectively compares characteristics of an individual who has a certain condition (e.g., hypertension) with one who does not (i.e., a matched control or similar person without hypertension)
- Often conducted for the purpose of identifying variables that might predict the condition (e.g., stressful lifestyle, sodium intake)
- Groups are followed as:
  - Patients with a disease are identified who have suffered a bad outcome such as death or recurrence; Compared with patients who have the disease but have not suffered the bad outcome.
  - Patients are identified with a disease of interest compared to a control group without the disease.
  - The relationship of an attribute to the disease is examined by comparing these diseased and non-diseased persons related to the frequency or levels of the attribute in each group.



*See also: Control, Recall Bias, Retrospective Study, Selection Bias*

**CASE REPORTS***(Study Design)*

- Anecdotal evidence
- Reports that describe the history of a single patient, or a small group of patients, usually in the form of a story
- A description of a single case, typically describing the manifestations, clinical course, and prognosis of that case
- Due to the wide range of natural biologic variability in these aspects, a single case report provides little empirical evidence to the clinician. They do describe how others diagnosed and treated the condition and what the clinical outcome was.

*See also: Anecdotal Evidence, Case Series, Case Study*

**CASE SERIES***(Study Design)*

- Report of a number of cases of disease.
- A descriptive, observational study of a series of cases, typically describing the manifestations, clinical course, and prognosis of a condition.
- Provides weak empirical evidence because of the lack of comparability unless the findings are dramatically different from expectations. No control group is involved.
- Best used as a source of hypotheses for investigation by stronger study designs, leading some to suggest that the case series should be regarded as clinicians talking to researchers.
- The most common study type in the clinical literature.

*See also: Case Reports, Case Study*

## EBDM GLOSSARY

### **CASE STUDY**

*(Study Design)*

- An intensive investigation of a case involving a person or small group of persons, an issue, or an event.  
*See also: Case Reports, Case Series*

### **CAT (CRITICALLY APPRAISED TOPICS)**

*(Systematic Review)*

- A means of teaching the principles of evidence-based medicine  
*See also: Review, Systematic Review*

### **CATEGORICAL DATA**

*(Calculations, Study Design)*

- Data that is classified into categories (e.g., gender, hair color) instead of being numerically ordered.

### **CAUSALITY**

*(Etiology)*

- The relating of causes to the effects they produce.
- Epidemiological evidence by itself is insufficient to establish causality, although it can provide powerful circumstantial evidence.

### **CEILING EFFECTS**

*(EBP)*

- Participants scores that cluster toward the high end of a measure  
*See also: Floor Effects*

### **CLINICAL**

*(EBP)*

- Pertaining to or founded on observation and treatment of participants, as distinguished from theoretical or basic science

### **CLINICAL FORETHOUGHT**

*(EBP)*

- All the anticipated actions and plans relevant to a particular patient's possible trends and trajectories that a clinician prepares for in caring for the patient.

### **CLINICAL GRASP**

*(EBP)*

- Clinical inquiry in action, including problem identification and clinical judgment across time about the particular transitions of particular patient/family clinical situations.
- Four aspects of clinical grasp include making qualitative distinctions, engaging in detective work, recognizing changing relevance, developing clinical knowledge about specific patient populations

### **CLINICAL INQUIRY**

*(EBP)*

- A process in which clinicians gather data together using narrowly defined clinical parameters
- Allows for an appraisal of the available choices of treatment for the purpose of finding the most appropriate choice of action.

### **CLINICAL INVESTIGATOR**

*(Study Design)*

- A medical researcher in charge of carrying out a clinical trial's protocol

*Syn: Principal Investigator (PI)*

*See also: Clinical Research Coordinator, Investigator, Principal Investigator*

## EBDM GLOSSARY

### CLINICAL PRACTICE GUIDELINE (EVIDENCE-BASED) (EBP)

- A systematically developed statement designed to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.
- Ideally the guidelines consist of a systematic review of the literature, in conjunction with consensus of a group of expert decision-makers, including administrators, policy-makers, clinicians and consumers who consider the evidence and make recommendations.

*See also: Evidence-Based Practice*

### CLINICAL RESEARCH (Study Design)

- Studies performed in humans that are intended to increase knowledge about how well a diagnostic test or treatment works in a particular patient population

### CLINICAL RESEARCH COORDINATOR (Study Design)

- A person who handles the administrative responsibilities in a clinical trial
- Coordinates communication between the trial site(s), the sponsor, other agencies, and reviews all data before visits from anyone monitoring the trial

*Syn: Clinical Coordinator, Protocol Nurse, Research Coordinator, Research Nurse, Study Coordinator, Trial Coordinator*

*See also: Clinical Investigator*

### CLINICAL SIGNIFICANCE (EBP)

- Study findings that will directly influence clinical practice, whether they are statistically significant or not.

*Syn: Clinically Significant*

*See also: Statistical Significance*

### CLINICAL TRIAL (Diagnosis, Study Design, Therapy)

- Prospectively planned studies of the safety, efficacy, quality of life, or optimum dosage schedule of one or more diagnostic, therapeutic, or prophylactic drugs, devices or techniques, selected according to predetermined criteria of eligibility and observed for predefined evidence of favorable and unfavorable effects.
- A research study to answer specific questions about vaccines or new therapies or new ways of using known treatments in humans - investigational new devices, drugs, biologics, or procedures
- Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people.
- Trials are in four phases:
  - PHASE I TRIAL** – Initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; Tests a new drug or treatment in a small group; May include healthy participants and/or patients; Studies safety and toxicity in a small group of healthy volunteers or patients with the disease of interest
  - PHASE II TRIAL** – Controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks; Studies safety and efficacy, typically in 50 to 300 patients with the condition or disease that the investigational treatment is intended to treat; Trial may take up to two years
  - PHASE III TRIAL** – Expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained; Intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling; Studies safety and efficacy in a larger group, perhaps in a 1,000 or more patients to demonstrate safety and efficacy in a larger population and to look for uncommon adverse reactions; This phase trial may last several years
  - PHASE IV TRIAL** – Post-marketing studies to delineate additional information including the drug's risks, benefits, and optimal use; Takes place after the drug or treatment has been licensed and marketed; Studies the use of a drug or device after it has been approved for marketing to determine longer-term effectiveness and identify rarer adverse reactions

*See also: Controlled Clinical Trial, Effectiveness, Efficacy, Randomized Controlled Trial*

**THE COCHRANE DATABASES***(EBP, Therapy)***CENTRAL REGISTER OF CONTROLLED TRIALS**

- A bibliography of controlled trials identified by contributors to the Cochrane Collaboration and others
- Comprises a merge of Specialized Registers submitted by Cochrane Review Groups and Fields, a hand-search results register, relevant records retrieved from MEDLINE, and EMBASE
- Includes references to clinical trials compiled by the Cochrane Review Groups and to other studies that may be relevant for inclusion in Cochrane reviews.
- Records include their MEDLINE or EMBASE accession numbers, where available. MeSH keywords have also been included for many of the records.

**DATABASE OF ABSTRACTS OF REVIEWS OF EFFECTS (DARE)**

- An international register of quality assessed published research reviews of the effectiveness of health interventions, and the management and organization of health services.
- Complements the Cochrane Database of Systematic Reviews with further structured abstracts of quality appraised systematic reviews.

**QUALITY ASSESSED REVIEWS (CRITICALLY APPRAISED REVIEWS)**

- Structured abstracts assessing the quality of previously published systematic reviews and summarizing the findings.

**DATABASE OF METHODOLOGY REVIEWS**

- Contains structured reports of systematic reviews of research methodology – full text of systematic reviews of empirical methodological studies prepared by The Cochrane Empirical Methodological Studies Methods Group

**DATABASE OF SYSTEMATIC REVIEWS**

- Database of structured reports of systematic reviews of the effects of health care interventions
- Contains reviews that are highly structured and systematic with evidence included or excluded on the basis of explicit quality criteria, to minimize bias.

**METHODOLOGY REGISTER**

- Bibliography of articles and books on the science of research synthesis
- Intended to help those who are new to the science of reviewing to find additional material of interest, and those who are already immersed in it to find something new, including all published reports of empirical studies of methods used in reviews, as well as methodological studies that are directly relevant to doing a review, such as empirical studies of the association between research methods and bias in Randomized Controlled Trials.

*See also: Meta-Analysis, Systematic Review*

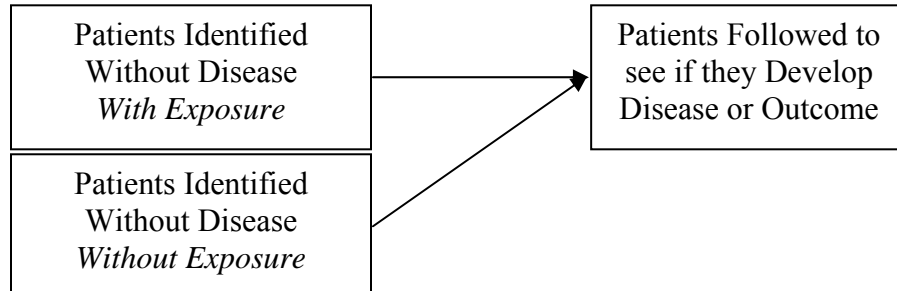
**COHORT STUDY***(Study Design)*

- Two groups of individuals/patients (*cohorts*), one that received the exposure (e.g., to a disease) and one that does not, are followed *prospectively* over time to see if they develop a disease or outcome of interest – including follow-up of exposed and non-exposed defined groups, with a comparison of disease rates during the time covered.
- By comparing the characteristics of patients with and without disease, risk factors can be identified; relating exposure to possible factor(s) of interest to later incidence of disease or outcome.

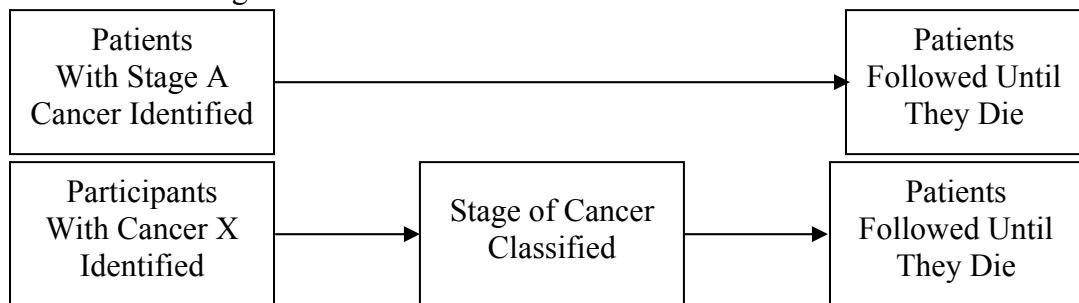
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## EBDM GLOSSARY

- Ideally patients are assembled without the disease in question, and then followed until they develop the disease. Subsets of a defined population are identified. These groups may or may not be exposed to factors hypothesized to influence the probability of the occurrence of a particular disease/outcome.



- In a cohort study of prognosis, patients continue to be followed *after* they develop the disease in question to see how they do regarding mortality, disease progression, and other important outcomes.
  - Patients may or may not begin as a group of disease-free patients. If they *do not*, it is important that patients either are at the same stage of the disease at the start of the study or are able to be precisely characterized in the stage of the disease.



- Cohort studies provide very valuable information, but are very expensive and time-consuming.  
*See also: Follow Up Study, Prospective Study, Risk Factor*

### CO-INTERVENTIONS

*(Therapy)*

- Interventions other than the treatment under study applied differently to the treatment and control groups
- A serious problem when double blinding is absent or when the use of very effective non-study treatments is permitted

### COMMUNITY-BASED CLINICAL TRIAL

*(Study Design, Therapy)*

- A clinical trial conducted primarily through primary-care physicians rather than academic research facilities  
*See also: Clinical Trial, Controlled Clinical Trial, Randomized Controlled [Clinical] Trial*

### CO-MORBIDITY

*(Etiology)*

- Coexistence of a disease(s) in a study participant in addition to the index condition, the subject of study

### COMPLEMENTARY AND ALTERNATIVE THERAPY

*(EBP)*

- Broad range of healing philosophies, approaches, and therapies that Western (conventional) medicine does not commonly use to promote well-being or treat health conditions
- Examples include acupuncture, herbs, etc. (<http://www.nccam.nih.gov>)

*Syn: Complementary and Alternative Medicine (CAM)*

### COMPUTER ASSISTED QUALITATIVE DATA ANALYSIS

*(Qualitative)*

- An area of technological innovation that, in qualitative research, has resulted in uses of word processing and software packages to support data management.

## EBDM GLOSSARY

### CONFIDENCE INTERVAL (CI)

(Calculations, Study Design)

- Indicates the strength of evidence or quantifies the uncertainty of a measurement; affected by sample size
  - *Wide CI* – less precise estimates of effect; *Narrow CI* – “precision” is increased
  - Larger trial sample size yields larger number of outcome events and greater confidence that the true relative risk reduction is close to the value stated.
- 95% CI = Point Estimate +/- 1.96 (square root of SE)
- The range of numerical values, for whatever effect being measured, in which we can be confident (to a computed probability, such as 90 or 95%) that the population value being estimated is “true” or will be found. Results may reveal both magnitude of effect and precision.
- In a *positive finding* study, the lower boundary of the confidence interval (lower confidence limit) should still remain important or clinically significant if the results are to be accepted. In a *negative finding* study, the upper boundary of the confidence interval should not be clinically significant if you are to confidently accept this result.
- When comparing the confidence intervals of different treatment groups, look for overlap. If the confidence intervals don’t overlap, the difference is statistically significant. To see if the difference is clinically meaningful, compare the closest extremes. If the upper limit of the treatment effect for the control group is very close to the lower limit of the treatment group, it is possible the results are not clinically important.

See also: *Precision, Standard Error*

### CONFIDENTIALITY

(Study Design)

- Refers to maintaining the confidentiality of trial participants including their personal identity and all personal medical or health information (PHI)
- The trial participants' consent to the use of records for data verification purposes should be obtained prior to the trial and assurance must be given that confidentiality will be maintained.

### CONFIRMABILITY

(Qualitative)

- Repeated descriptions from participants, which confirm the researcher’s observations, participation, and reflections throughout the study
- This is considered a neutral criterion for measuring the trustworthiness of qualitative research. If a study demonstrates credibility, auditability, and fittingness, the study is also said to possess confirmability. This criterion for evaluation of a qualitative study asks the question: are the findings verified within the context?

### CONFLICT OF INTEREST

(Study Design)

- In a clinical trial, a situation in which the interests of the researcher or research institution are at odds with patient welfare
  - FINANCIAL** – The conflict between a researcher’s or research institution’s financial interests in a company sponsoring the research and their obligation to patient welfare
  - INTELLECTUAL** – The conflict between a researcher’s self-interests (achieving positive results and personal recognition, maintaining his or her reputation, advancing career) and his or her obligation to uphold the integrity of the research
  - POTENTIAL** – Conflict of interest that could affect patient welfare or the integrity of research results due to conflicting interests of the researcher or research institution

### CONFOUNDING

(Study Design)

- Occurs when two factors are closely associated and the effects of one confuses or distorts the effects of the other factor on an outcome. The distorting factor is a confounding variable.

## EBDM GLOSSARY

### **CONFOUNDING VARIABLE**

*(Study Design)*

- Those factors that interfere with the relationship between the independent and dependent variables.
- A variable that can cause or prevent the outcome of interest, is not an intermediate variable, is associated with the factor under investigation, and may be due to chance or bias.
- Unless it is possible to adjust for confounding variables, their effects cannot be distinguished from those of factor(s) being studied.

*Syn: Confounder*

### **CONSTANT COMPARISON**

*(Study Design)*

- A systematic approach to analysis that is a search for patterns in data as they are coded, sorted into categories, and examined in different contexts.

### **CONTRAINDICATION**

*(Therapy)*

- A specific circumstance or condition when the use of certain treatments could be harmful to the patient

### **CONSTRUCT VALIDITY**

*(Study Design)*

- The degree to which an instrument measures the construct it is supposed to be measuring.

*See also: Control, Placebo, Standard Treatment*

### **CONTAMINATION**

*(Study Design, Therapy)*

- The inadvertent and undesirable influence of an experimental intervention on another intervention.

### **CONTENT ANALYSIS**

*(Qualitative)*

- Refers to processes of breaking down narrative data (coding, comparing, contrasting, and categorizing bits of information) and reconstituting them in some new form (e.g., description, interpretation, theory).

### **CONTENT VALIDITY**

*(Qualitative)*

- The degree to which the items in an instrument are tapping the content they are supposed to measure.

### **CONTROL**

*(Study Design)*

- The standard by which experimental or intervention observations are evaluated.

*Syn: Comparison*

*See also: Control Group, Placebo, Standard Treatment*

### **CONTROL EVENT RATE (CER)**

*(Study Design)*

- Percentage of the control or non-exposed group who experienced outcome in question

*See also: Event Rate, Experimental Event Rate*

### **CONTROL GROUP**

*(Study Design)*

- Any group to which the index group is compared; the standard by which experimental observations are evaluated; this group does not receive the experimental intervention or treatment
- In many clinical trials, one group of patients will be given an experimental drug or treatment, while the control group is given either a standard treatment for the illness, a placebo, or no treatment.

*Syn: Comparison Group*

*See also: Control, Placebo, Standard Treatment*

## EBDM GLOSSARY

### **CONTROLLED CLINICAL TRIAL (CCT)** *(Study Design)*

- A prospective clinical trial that does not employ truly randomized techniques for patient assignment, but rather base allocation on coin flips, odd-even numbers, patient social security numbers, days of the week, or other pseudo- or quasi-random processes
- One group of participants is given an experimental drug, while another group (i.e., the control group) is given either a standard treatment for the disease or a placebo.
- A controlled trial may or may not use randomization to assign patients to groups and it may or may not use blinding to prevent them from knowing which treatment they get – comparing two or more treatments, or placebo and treatment(s) in similar groups of patients or within patients.

*Syn: Controlled Trial, Quasi-Experimental Trial*

*See also: Placebo, Randomized Controlled Trial, Standard Treatment*

### **CONTROLLED VOCABULARY OR THESAURUS** *(EBP, Study Design)*

- A hierarchical arrangement of descriptive terms that serve as mapping agents for searches
- Often unique to each database

### **CONVENIENCE SAMPLING** *(Qualitative, Study Design)*

- Drawing readily available subjects to participate in a study.

### **CORRELATIONAL PREDICTIVE STUDY** *(Etiology, Study Design)*

- A study that is conducted for the purpose of describing what variables predict a certain outcome.

### **COST–BENEFIT ANALYSIS (CBA)** *(Economic Analysis)*

- Used to compare interventions for two different conditions
- Costs and outcomes measured in monetary terms – assesses whether the cost of an intervention is worth the benefit by measuring both in the same units

### **COST–EFFECTIVENESS ANALYSIS (CEA)** *(Economic Analysis)*

- Used when the effect of the interventions can be expressed in terms of one main outcome measurable in natural units, such as improvement
- Measures the net cost of providing an intervention as well as the outcomes obtained

### **COST–MINIMIZATION ANALYSIS (CMA)** *(Economic Analysis)*

- Used when the effect of both interventions is identical (true or assumption).
- Only costs, not outcomes, are accounted – the least costly alternative is chosen.

### **COST–UTILITY ANALYSIS (CUA)** *(Economic Analysis)*

- Used when the effect of the interventions on health status has two or more important dimensions (benefit and side effects of treatment)
- Outcome is a utility unit (e.g., QALY) which combines a quantitative and qualitative measure

*See also: Quality-Adjusted Life-Year, Side Effects*

### **COVARIATE** *(Study Design)*

- A confounding or extraneous variable that is controlled for in statistical analyses (e.g., analysis of covariance) that may influence the outcome.

*See also: Confounding Variable*

## EBDM GLOSSARY

### **CREDIBILITY**

*(Qualitative)*

- The truth of the findings
- A criterion for evaluation of qualitative research that relates to the trustworthiness of findings. Credibility is demonstrated when participants recognize the reported research findings as their own experiences. This criterion for evaluation of a qualitative study asks the question: are the findings credible?
- Comes largely from the insider/participant findings, through observation, participation, and reflection phases of the study

### **CRITICAL INQUIRY**

*(Qualitative)*

- Theoretical perspectives that are ideologically oriented toward critique of and emancipation from oppressive social arrangements or false ideas.

### **CRITICAL THEORY**

*(Qualitative)*

- A blend of ideology (based on a critical theory of society) and a form of social analysis and critique that aims to liberate people from unrecognized myths and oppression in order to bring about enlightenment and radical social change.
- A qualitative study design that is a blend of ideology (based on a critical theory of society) and a form of social analysis and critique that aims to liberate people from unrecognized myths and oppression in order to bring about enlightenment and radical social change.

### **CRONBACH'S ALPHA**

*(Calculations, Study Design)*

- An estimate of internal consistency or homogeneity of an instrument that is comprised of several subparts or scales.

*See also: Construct Validity, Internal Consistency Reliability*

### **CROSS-CONTAMINATION**

*(Therapy)*

- Diffusion of the treatment or intervention across study groups.

*See also: Contamination*

### **CROSSOVER TRIAL**

*(Study Design)*

- A trial in which patients first receive either the treatment or control (placebo or standard treatment) and after a predetermined amount of time, are given the other intervention.
- Patients serve as their own controls because treatment and control effects are compared within the patient.

*Syn: "On/Off" Design*

### **CROSS-SECTIONAL STUDY**

*(Study Design)*

- A study designed to observe an outcome or variable at a single point in time, usually for the purpose of inferring trends over time.
- Exposure and Outcome are determined simultaneously – cross-sectional studies lack any information on timing of exposure and outcome relationships and include only prevalent cases.
- Examines the relationship between disease (or other health-related characteristics) and other variables of interest as they exist in a defined population at a single point in time.

*See also: Prevalence*

### **CULTURE**

*(EBP)*

- Shared knowledge and behavior of people who interact within distinct social settings and subsystems

## EBDM GLOSSARY

### D

#### **DATA** *(Calculations, Study Design)*

- Recorded observations about patients in a trial

*See also: Baseline Data, Demographic Data, Objective Data, Quality-of-Life Data, Raw Data, Subjective Data, Survival Data*

#### **DATA AND SAFETY MONITORING BOARD (DSMB)** *(Study Design)*

- An independent committee composed of community representatives and clinical research experts that reviews data while a clinical trial is in progress to ensure that participants are not exposed to undue risk
- May recommend that a trial be stopped if there are safety concerns or if the trial objectives have been achieved

*See also: Data and Safety Monitoring Plan*

#### **DATA AND SAFETY MONITORING PLAN** *(Study Design)*

- A detailed plan for how adverse effects will be assessed and managed.

*See also: Data and Safety Monitoring Board (DSMB)*

#### **DECISION ANALYSIS** *(Decision Analysis)*

- The application of explicit, quantitative methods that quantify prognoses, treatment effects, and patient values in order to analyze a decision under conditions of uncertainty
- A decision analysis model must compare at least two decision options. The process involves identifying all the relevant and available management options (including all alternatives), and the potential outcomes of each, in a series of decisions that have to be made about patient care.
- Uses probabilities and utilities to analyze what actions may be preferred
- Range of choices plotted on a Decision Tree

*See also: Decision Tree*

#### **DECISION TREE** *(Decision Analysis)*

- Illustrates all the potential choices and subsequent outcomes in diagrammatic form.
- Decisions and outcomes are presented in the order in which they are likely to occur (hierarchical structure)

*See also: Decision Analysis*

#### **DEDUCTIVE THEORY** *(Qualitative, Study Design)*

- A theory that is used to guide data collection and analysis. It is the process of moving from generalizations to specific conclusions. It includes variables, concepts, constructs and hypotheses that are derived from previous research and relationships are tested during the research process.

#### **DEMOGRAPHIC DATA** *(Calculations, Study Design)*

- Information about patient sex, age, race, geographic location, etc.

*Syn: Descriptive Data*

*See also: Baseline Data, Data, Objective Data, Quality-of-Life Data, Raw Data, Subjective Data, Survival Data*

#### **DEPENDENT VARIABLE** *(Study Design)*

- The variable or outcome that is influenced or caused by the independent variable.

*Syn: Outcome Variable*

*See also: Independent Variable*

## EBDM GLOSSARY

### DESCRIPTIVE STATISTICS

*(Calculations, Study Design)*

- Means and standard deviations for quantitative data; Absolute or relative frequencies for qualitative data
- Statistical parameters describe the distribution characteristics of the variable(s) being examined in samples derived from the study populations

*See also: Inferential Statistics*

### DESCRIPTIVE STUDY

*(Study Design)*

- Studies conducted for the purpose of describing the characteristics of certain phenomena or selected variables
- The objective is to describe the distribution of variables in a group.
- Statistics serve only to describe the precision of those measurements or to make statistical inferences about the values in the population from which the sample was taken

### DESIGN

*(Study Design)*

- The overall plan for a study that includes strategies for controlling confounding variables, strategies for when the intervention will be delivered (in experimental studies) and how often and when the data will be collected.

*Syn: Study Design*

### DETERMINANT

*(Etiology, Study Design)*

- Any definable factor that effects a change in a health condition or other characteristic.

### DIAGNOSTIC TRIALS

*(Diagnosis, Study Design)*

- Trials that are conducted to find better tests or procedures for diagnosing a particular disease or condition
- Usually include people who have signs or symptoms of the disease or condition being studied

### DIALOGICAL ENGAGEMENT

*(Qualitative, Study Design)*

- Thinking that is like a thoughtful dialogue or conversation.

### DIMENSIONAL ANALYSIS

*(Qualitative)*

- A method for generating grounded theory using an explanatory matrix.

### DIRECT COSTS

*(Economic Analysis, Study Design)*

- Actual costs required to conduct a study (e.g., personnel, subject honoraria, instruments).

*See also: Indirect Costs*

### DISCOUNTING

*(Economic Analysis)*

- Makes current costs and benefits worth more than those occurring in the future. An opportunity cost to spending money now and a desire to enjoy benefits now exists versus the future (e.g., if money is invested wisely now, it will be worth more in a year).

*See also: Opportunity Cost*

### DISCOURSE ANALYSIS

*(Qualitative, Study Design)*

- A general term for approaches to analyzing recorded talk and patterns of communication.

## EBDM GLOSSARY

### DOMAIN

(EBP, PubMed, MEDLINE)

- Main categories or types (domains) into which clinical questions may fall:
  - THERAPY** (may include Harm)
    - How to select treatments for patients that do more good than harm and that are worth the efforts and costs of using them
  - DIAGNOSIS**
    - How to select and interpret diagnostic tests, in order to confirm or exclude a diagnosis, based on considering their precision, accuracy, acceptability, expense, safety, etc.
  - PROGNOSIS**
    - How to estimate our patient's likely clinical course over time and anticipate likely complications of the disorder
  - ETIOLOGY** (may include Harm)
    - How to identify causes for disease
  - QUALITATIVE**
    - How to observe or describe persons or groups and variables of interest

### DOMAIN OF INQUIRY

(Qualitative, Study Design)

- A general category of qualitative study and its boundaries. An area of study with similar intents, functions and meanings.

### DOSE

(Therapy)

- A measured amount of a therapeutic substance
  - EFFECTIVE DOSE** – the dose that produces the desired clinical result
  - MAXIMUM-TOLERATED DOSE** – The highest dose that can be administered without having toxic or lethal effects in humans

### DOSE-RANGING STUDY

(Study Design, Therapy)

- A clinical trial in which two or more doses of an agent (such as a drug) are tested against each other to determine which dose works best and is least harmful

*See also: Clinical Trial*

### DOSE-RESPONSE RELATIONSHIP

(Harm, Therapy)

- A relationship in which change in amount, intensity, or duration of exposure is associated with a change, either an increase or decrease, in risk of a specified outcome.

### DRUG-DRUG INTERACTION

(Harm, Therapy)

- A modification of the effect of a drug when administered with another drug
- The effect may be an increase or a decrease in the action of either substance, or it may be an adverse effect that is not normally associated with either drug.

*See also: Adverse Reaction*

## E

### ECONOMIC EVALUATION / ANALYSIS

(Economic Analysis)

- An explicit measurement and valuation of resource consumption or cost and health outcomes (consequences or benefits) which are related to the costs of the alternative treatment strategies.
- Should be set in the context of overall quality and relevance of the study from appraisal of the study – if the randomized controlled trial is of poor quality, the appraisal of the economic evaluation is unnecessary.

*See also: Sensitivity Analysis*

## EBDM GLOSSARY

### ECOLOGIC STUDY

(*Etiology, Study Design*)

- An observational analytical study based on aggregated secondary data.
- Aggregate data on risk factors and disease prevalence from different population groups is compared to identify associations. Because all data are aggregate at the group level, relationships at the individual level cannot be empirically determined but are rather inferred from the group level. Thus, because of the likelihood of an ecologic fallacy, this type of study provides weak empirical evidence.

*Syn: Aggregate Study*

*See also: Non-Experimental Study Design*

### EDUCATIONAL PRESCRIPTION (EP)

(*EBP*)

- A written plan (usually self-initiated) for identifying and addressing EBP learning needs.
- The EP contains each step of the EBP process, but may have a primary focus on one or two steps, such as searching or critical appraisal.

*See also: Evidence-Based Practice (EBP)*

### EFFECT

(*Calculations, Study Design*)

- The idea that one variable has an effect on another
- Study results yield the estimate of the effect. Statistics are used to describe the relationship between *two or more* sets of numbers. Main effect statistics are the difference in means, the correlation coefficient, and relative frequency.

*See also: Effect Size, Mean*

### EFFECT MEASURES

(*Study Design*)

- Measures used to compare the differences in occurrences of outcomes between groups.

### EFFECT SIZE

(*Calculations, Therapy*)

- The strength of the effect of an intervention.
- Effect-size is a standardized, scale-free measure of the relative size of the effect of an intervention. It is particularly useful for quantifying effects measured on unfamiliar or arbitrary scales and for comparing the relative sizes of effects from different studies. Represents a family of indices that measure the magnitude of a treatment effect.
- Calculated by the difference in the means between two group divided by the standard deviation
- These indices are independent of sample size, unlike significance tests.
  - For example, unlike the t test of the difference between two population means based on random samples, the Effect Size (*d*) is unaffected by the size of the groups or samples.
  - The most usual interpretation of *d* is to consider:
    - $0.0 < d < 0.2$ : trivial effect size
    - $0.2 < d < 0.5$ : small effect size
    - $0.5 < d < 0.8$ : moderate effect size
    - $0.8 < d$ : strong effect size
- Use of an effect size with a confidence interval conveys the same information as a test of statistical significance, but with the emphasis on the significance of the effect, rather than the sample size.
- Interpretation of effect-size generally depends on the assumptions that 'control' and 'experimental' group values are normally distributed and have the same standard deviations. Effect-sizes can be interpreted in terms of the percentiles or ranks at which two distributions overlap, in terms of the likelihood of identifying the source of a value, or with reference to known effects or outcomes.

## EBDM GLOSSARY

### **EFFECTIVENESS**

*(Harm, Therapy)*

- A measure of the benefit resulting from an intervention for a given health problem under usual conditions of clinical care for a particular group.
- The degree to which a diagnostic test or a treatment produces a desired result in patients in the daily practice of medicine
- Considers both the efficacy of an intervention and its acceptance by those to whom it is offered
- Answers the question, "Does the practice do more good than harm to people to whom it is offered?"

*See also: Intention-to-Treat, Efficacy*

### **EFFICACY**

*(Therapy)*

- A measure of the benefit resulting from an intervention for a given health problem under the ideal conditions of an investigation
- The maximum ability of a drug or treatment to produce a result regardless of dosage
- The degree to which a diagnostic test or a treatment produces a desired result in patients under the idealized circumstances of a clinical trial
- A drug passes efficacy trials if it is effective at the dose tested and against the illness for which it is prescribed. In the procedure mandated by the FDA, Phase II clinical trials gauge efficacy, and Phase III trials confirm it.
- Answers the question, "Does the practice do more good than harm to people who fully comply with the recommendations?"

*See also: Effectiveness*

### **ELIGIBILITY CRITERIA**

*(Study Design)*

- Summary criteria for participant selection (inclusion and exclusion criteria)
- Based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions – the medical or social standards determining whether a person may or may not be allowed to enter a clinical trial
- Not used to reject people personally, but rather to identify appropriate participants and keep them safe.

*See also: Exclusion Criteria, Inclusion Criteria*

### **EMERGENCE**

*(Qualitative)*

- Conceptually–driven (“discovery”) versus procedurally–driven (“forcing”) theory development

### **EMIC AND ETIC**

*(Qualitative)*

- Contrasting “insider” views of informants (*emic*) and the researcher’s “outsider” (*etic*) views

### **EMPIRICAL**

*(EBP)*

- Based on experimental data, not on a theory

### **ENDPOINT**

*(Study Design)*

- Overall outcome that the protocol is designed to evaluate
- In a clinical trial, the designated point that researchers will measure in patients after the completion of treatment within the trial.
- Common endpoints are severe toxicity, disease progression, or death.

*Syn: Clinical Endpoint*

### **ENROLL**

*(Study Design)*

- To register in writing to join a group (e.g., enroll in a clinical trial)

## EBDM GLOSSARY

### EPIDEMIOLOGY

(EBP)

- The branch of medical science that deals with the study of incidence and distribution and control of a disease in a population

### EPISTEMOLOGIES

(EBP, Qualitative, Study Design)

- Ways of knowing and reasoning

### EQUIPOISE

(Study Design)

- A state of true uncertainty on the part of a researcher about which treatment (investigational or standard) will achieve a better result

### EQUITY

(Study Design)

- Fairness in the allocation of resources or treatments among individuals or groups

### ESSENCES

(Qualitative)

- Internal meaning structures of a phenomenon grasped through the study of human lived experience

### ETHNOGRAPHIC STUDIES

(Qualitative, Study Design)

- Studies of a social group's culture through time spent combining participant-observation and in-depth interviews in the informants' natural setting
- Common data collection methods are observation and interviews.

*Syn: Ethnography, Ethnonursing, Ethnoscience*

### ETHNOGRAPHY

(Qualitative, Study Design)

- A qualitative study design that uses a systematic process of observing, detailing, describing, documenting and analyzing the lifeways or patterns of the people in their familiar environment. It is a study of a social group's culture through time spent combining participant-observation and in-depth interviews in the informants' natural setting.

*Syn: Ethnographic Studies, Ethnonursing, Ethnoscience*

### ETHNONURSING

(Qualitative, Study Design)

- A qualitative study design that is the study and analysis of the local or indigenous peoples' viewpoints, beliefs, and practices about nursing care behavior and processes of designated cultures. It is the observation and documentation of interactions with people of how these daily life conditions and patterns are influencing human care, health and nursing care practices.

*Syn: Ethnographic Science, Ethnography, Ethnoscience*

### ETHNOSCIENCE

(Qualitative, Study Design)

- A qualitative study design that uses a rigorous and systematic way of studying and classifying local or inside data of a cultural group's own perceptions, knowledge, and language in terms of how people perceive and interpret their universe.

*Syn: Ethnographic Science, Ethnography, Ethnonursing*

### EVENT RATE

(Study Design)

- The rate at which a specific event occurs
- The proportion of patients in a group in whom the event is observed

*See also: Control Event Rate, Experimental Event Rate, Patient Expected Event Rate*

## EBDM GLOSSARY

### **EVIDENCE-BASED DECISION MAKING (EBDM)** (EBP)

- The integration of best research evidence in making decisions about patient care which should also include the clinician's expertise as well as patient preferences and values

*See also: Evidence-Based Practice*

### **EVIDENCE-BASED PRACTICE (EBP)** (EBP)

- A problem solving approach to practice that involves the conscientious use of current best evidence in making decisions about patient care
- EBP incorporates a systematic search for and critical appraisal of the most relevant evidence to answer a clinical question along with one's own clinical expertise and patient values and preferences.
- A process of life-long, problem-based learning, involving:
  - Converting information needs into focused questions
  - Efficiently tracking down the best evidence with which to answer the question
  - Critically appraising the evidence for validity and clinical usefulness
  - Applying the results in clinical practice
  - Evaluating performance of the evidence in clinical application

*Syn: Evidence-Based Care, Evidence-Based Health Care, Evidence-Based Medicine, Evidence-Based Nursing, Evidence-Based...*

### **EVIDENCE-BASED THEORIES** (EBP)

- A theory that has been tested and supported through accumulation of evidence from several studies.

### **EVIDENCE SUMMARY** (EBP)

- Synthesis of studies

*See also: Systematic Review*

### **EVIDENCE USER** (EBP)

- Anyone who uses valid evidence to support or change practice
- Demonstrating skills in interpreting evidence, not generating evidence

### **EXCLUSION CRITERIA** (Study Design)

- Investigator identified characteristics or conditions that are possessed by individuals that would exclude them from participating in a study, even if the inclusion criteria are met

*See also: Eligibility Criteria, Inclusion Criteria*

### **EXPERIENTIAL LEARNING** (EBP)

- Experience requiring a turning around of preconceptions, expectations, sets, and routines or adding some new insights to a particular practical situation
- A way of knowing that contributes to knowledge production, influencing the development of science

### **EXPERIMENT** (Study Design)

- A study whose purpose is to test the effects of an intervention or treatment on selected outcomes
- This is the strongest design for testing cause and effect relationships.

*Syn: Experimental Design*

### **EXPERIMENTAL DRUG** (Therapy)

- A treatment for a particular condition
- A drug that is not FDA licensed for use in humans

*See also: Adverse Reaction, Side Effect, Standard Treatment*

## EBDM GLOSSARY

### **EXPERIMENTAL EVENT RATE (EER)**

*(Calculations, Study Design)*

- The percentage of intervention or exposed group who experienced outcome in question
- See also: Control Event Rate, Event Rate*

### **EXPLODE**

*(MEDLINE)*

- Permits simultaneous searching of both a broad subject and the narrower subjects classed under it (e.g., searching "Antiviral Agents" will retrieve articles on antiviral agents in general, new antiviral agents not yet assigned a MeSH heading, plus individual drugs such as "Acyclovir" or "Zidovudine" classed as antiviral agents in Medline).
- Because indexing norms require that the most specific subject heading available be applied, normally an article indexed under the specific heading would not also be indexed under the broader heading. Thus, searching only the broad subject would result in lost references which have been indexed under the more specific heading.

### **EXTERNAL VALIDITY**

*(Study Design)*

- The ability to generalize the findings from a study to the larger population from which the sample was drawn
  - The extent to which a trial's results can be applied to patient populations or settings outside those of the trial
- Syn: Generalizability*  
*See also: Internal Validity, Validity*

### **EXTRANEOUS VARIABLES**

*(Study Design)*

- Those factors that interfere with the relationship between the independent and dependent variables.
- See also: Dependent Variables, Independent Variables*

## **F**

### **FACE VALIDITY**

*(Qualitative, Study Design)*

- The degree to which an instrument appears to be measuring (i.e., tapping) the construct it is intended to measure

### **FACTORIAL DESIGN**

*(Study Design, Therapy)*

- An experimental design that has two or more interventions or treatments

### **FALSE NEGATIVE**

*(Diagnosis, Study Design)*

- A condition where the test indicates that the person does not have the outcome of interest when, in fact, the person does
- See also: False Positive, True Negative, True Positive*

### **FALSE POSITIVE**

*(Study Design)*

- A condition where the test indicates that the person has the outcome of interest when, in fact, the person does not
- See also: False Negative, True Negative, True Positive*

### **FIELD NOTES**

*(Qualitative, Study Design)*

- Self-designed observational protocols for recording notes about field observations

### **FIELD STUDIES**

*(Qualitative, Study Design)*

- Studies involving direct, first-hand observation and interviews in informants' natural settings

## EBDM GLOSSARY

### FIELD WORK

*(Qualitative, Study Design)*

- All research activities carried out in and in relation to the field (informants' natural settings)

### FIELDS

*(MEDLINE)*

- Labeled divisions of a Medline record – Fields include:
  - **AU**=Author
  - **TI**=Title of article
  - **SO**=Journal title, volume, issue, pages and year of publication
  - **AB**=Abstract (present in about 2/3 of Medline references) Note: abstracts are reprinted from the original paper if the original had no abstract, there will be no abstract in Medline)
  - **IN**=Institution
  - **SH**=List of subject headings under which the article is indexed, including subheadings
  - **UI**=Unique Identifier, an accession number applied to each Medline record as it is entered
  - **PT**=Publication Type (e.g., review, randomized controlled trial, clinical trial, meta-analysis, practice guideline, etc.)
  - **RN**=Chemical Abstracts Registry Number (useful for searching new or obscure drugs or toxic agents)
  - **RW**=Registry Number Word (used for searching portions of chemical names, new or obscure drugs)
- Most fields are directly searchable, separately or as specified in an "expert search", set off by periods (e.g., random\$.ti,ab,sh,pt. or alberta.ti,ab,sh,in.).

### FITTINGNESS

*(Study Design, Qualitative)*

- A criterion for measuring the trustworthiness of the qualitative research which means the concepts must evolve to fit the data.

*See also: Transferability*

### FIXED EFFECTS MODELS

*(Qualitative)*

- Traditional assumption that the event rates are fixed in each of the control and treatment groups.
- Considers only within-study variability with assumptions that (1) use identical methods, patients, and measurements; (2) should produce identical results; and (3) differences are only due to within-study variation.
- Fixed effects models are less "conservative" and generate a more narrow confidence interval. They are more likely to show a significant treatment effect than a random effects model. In general, if the studies are homogenous, the researchers should use a fixed effects model.
- Using a fixed effects model, the researcher answers the question, "Did the treatment produce benefit on average in the studies at hand?"
- Peto and Mantel-Haenszel Odds Ratios are both based on a fixed effects model.
- Fixed and random effects models can give very different answers. Differences occur when studies are not homogenous. When heterogeneity is found, one possibility is to do a random effects analysis on all of the studies. However, it may be better to identify an important subgroup difference; then do a fixed effects analysis of each and report all of the results.

*See also: Heterogeneity/Homogeneity, Random Effects Models*

### FLOOR EFFECTS

*(Study Design)*

- Participant scores that cluster toward the low end of a measure

*See also: Ceiling Effects*

## EBDM GLOSSARY

### FOCUS GROUPS

(Qualitative)

- This type of group interview generates data on designated topics through discussion and interaction.
- Focus group research is a distinct type of study when used as the sole research study.
- A qualitative study design that uses group interview to generate data on designated topics through discussion and interaction.

### FOLLOW-UP

(Study Design)

- Observation over a period of time of an individual, group, or initially defined population whose relevant characteristics have been assessed in order to observe changes in health status or health-related variables

### FOLLOW-UP STUDIES

(Study Design)

- Studies in which individuals or populations are followed to assess the outcome of exposures, procedures, or effects of a characteristic

*See also: Cohort Study, Prospective Study*

### FOREGROUND QUESTIONS

(EBP)

- Those questions that can be answered from scientific evidence about diagnosing, treating, and assisting patients with understanding their prognosis, focusing on specific knowledge.

*See also: Background Questions*

### FOREST PLOT

(Calculations, Study Design)

- Diagrammatic representation of the results (i.e., the effects or point estimates) of trials (i.e., squares) along with their confidence intervals (i.e., straight lines through the squares)

### FUNCTIONAL STATUS

(Qualitative, Study Design)

- A person's ability to perform age-appropriate self-care tasks related to social, psychological, and physical functions

### FUNNEL PLOT

(Calculations, Systematic Review)

- The plotting of sample size against the effect size of studies included in a systematic review
- The funnel should be inverted and symmetrical if a representative sample has been obtained.

*See also: Systematic Review*

## G

### GENERALIZABILITY

(Study Design)

- The extent to which the findings from a study can be generalized or applied to patients being treated in routine medical practice outside the trial

*Syn: External Validity*

### GOLD STANDARD

(Diagnosis, Study Design, Therapy)

- A method, procedure, or measurement that is widely accepted as being the best available

### GREY LITERATURE

(EBP)

- Refers to publications such as brochures and conference proceedings

### GROUNDING FORMAL THEORY

(Qualitative)

- A systematic explanation of an area of human/social experience derived through meta-analysis of substantive theory

*See also: Grounded Theory*

## EBDM GLOSSARY

### **GROUNDING SUBSTANTIVE THEORY**

(Qualitative)

- A systematic explanation of a situation-specific human experience/social phenomenon

*See also: Grounded Theory*

### **GROUNDING THEORY**

(Qualitative)

- A qualitative study design that uses data grounded in fact and generates theory from the data. It generates theory about how people deal with life situations that is ‘grounded’ in empirical data and describes the processes by which they move through experiences over time. It is a study design that generates theory developed from the research, which has its roots in the data from which it was derived.
- Studies to generate theory about how people deal with life situations that is ‘grounded’ in empirical data and describes the processes by which they move through experiences over time

*See also: Grounded Formal Theory, Grounded Substantive Theory*

## H

### **HARM**

(Study Design)

- When risks outweigh benefits

### **HEALTH-RELATED QUALITY-OF-LIFE MEASURE**

(Study Design)

- Any of a variety of tools (i.e., questionnaires, rating scales, or surveys) used to assess the effect of an individual’s health on how well he or she performs activities of daily living and fulfills social, familial, and personal roles

### **HEALTH TECHNOLOGY ASSESSMENT DATABASE**

(EBP)

- Database containing information on healthcare technology assessments

### **HERMENEUTICS**

(Qualitative, Study Design)

- A qualitative study design that is the interpretation of cultural contexts and meaningful human action. It describes and studies meaningful human phenomenon in a careful and detailed manner as free as possible from prior theoretical assumptions, based instead on practical understanding.
- Philosophy, theories, and practices of interpretation

### **HETEROGENEITY**

(Systematic Review, Meta-Analysis)

- When subjects in a study are different on the characteristics (demographic, medical) that may affect the outcome variable(s)
- The degree of between-study variability in a group of studies
- Heterogeneous study results are most likely not combined
- When there is significant heterogeneity, the between-study variance becomes much larger than the within-study variance, and studies of different sample size receive relatively similar weight.

*See also: Fixed Effects Models, Homogeneity, Q Statistic, Random Effects Models*

### **HIERARCHY OF EVIDENCE**

(EBP)

- A mechanism for determining which study designs have the most power to predict cause-and-effect
- The highest level of evidence is systematic reviews of RCTs
- The lowest level of evidence is expert opinion and consensus statements

*Syn: Levels/Grades of Evidence*

*See also: Levels of Evidence*

## EBDM GLOSSARY

### HIGH-RISK

(*Study Design*)

- Particularly subject to potential danger or harm

### HISTORY

(*Study Design*)

- A qualitative study design that applies a method or steps to study history systematically. It is a method that studies the interrelationship of social, economic, political, and psychological factors that influence ideas, events, institutions, and people.
- The occurrence of some event or program unrelated to the intervention that might account for the change observed in the dependent variable

### HITS

(*Study Design*)

- Studies obtained from a search that contain the searched word

### HOMOGENEITY

(*Systematic Review, Meta-Analysis*)

- When subjects in a study are similar on the characteristics that may affect the outcome variable(s)
- The degree of between-study variability in a group of studies
- Homogenous study results may be combined
- When there is homogeneity, sample size dominates, and both models give similar results.

*See also: Fixed Effects Models, Heterogeneity, Q Statistic, Random Effects Models*

### HYPERLINK

(*EBP*)

- A connection to organized information that is housed in cyberspace and usually relevant to the site on which it was found

### HYPOTHESIS (HYPOTHETICAL)

(*Study Design*)

- A supposition or assumption advanced as a basis for reasoning or argument – assumed without proof
- A guide to experimental investigation
- Philosophy, theories, and practices of interpretation
- An unproven idea or proposition that is formed and used in clinical research to explain the relationship between or among variables that a researcher intends to study

## I

### INCEPTION COHORT

(*Study Design*)

- Group of patients who are assembled near the onset of the target disorder

*See also: Cohort Study*

### INCIDENCE

(*Calculations, Etiology*)

- New occurrences of the outcome or target disorder within the at-risk population in a specified time frame
- The number of new cases of illness commencing, or of persons falling ill, during a specified time period in a given population
- Probability that a patient without disease develops the disease during an interval of time

*See also: Prevalence*

### INCLUSION CRITERIA

(*Study Design*)

- Essential characteristics of potential participants that must be possessed in order to be considered for a study
- An underlying rationale established by the investigator related to the questions that the researchers are trying to answer by conducting the trial

*See also: Eligibility Criteria, Exclusion Criteria*

## EBDM GLOSSARY

### INCREMENTAL ANALYSIS

*(Economic Analysis)*

- Additional costs that one service or intervention imposes over another compared with the additional benefits it delivers

### INDEPENDENT VARIABLE

*(Study Design, Therapy)*

- The variable that is influencing the dependent variable or outcome
- In experimental studies, it is the intervention or treatment.

*See also: Dependent Variable*

### INDIRECT COSTS

*(Economic Analysis)*

- Costs that are not directly related to the actual conduct of a study, but are associated with the ‘overhead’ in an organization, such as lights, telephones, office space

*See also: Direct Costs*

### INDUCTIVE THEORY

*(Qualitative, Study Design)*

- A theory that is used to guide data collection and analysis. It is the process of moving from specific observations to generalizations. It includes variables, concepts, constructs and hypotheses derived from relationships observed during the process of coding the data. Thus, theory is constructed to explain the observed relationships as they emerge from the data.

### INFERENCE STATISTICS

*(Calculations, Study Design)*

- Testing hypotheses about variables:
  - Associations between two or more variables within a population
  - Differences in the distribution or statistical characteristics of a variable between two or more populations
- An inference (conclusion about a hypothesis) is made based on the outcome of the statistical test being used.
- The type of test used depends on the sample design, data type, and hypothesis being tested.
- Statistical analyses are usually performed on data collected in samples drawn from the study populations.
- Assurances must be made that the samples are either representative of the populations being studied or adequate adjustments must be made in design or data collection to account for inherent biases, not always possible in clinical studies.
- Interpretation of results must be predicated upon intelligent, honest, and subjective considerations of weaknesses in sampling design, etc. and inferences to clinical populations must be made with extreme caution and appropriate qualification.
- There are two major classes of inferential statistical tests available with use dependent on the type of data being analyzed and hypotheses being tested: Nonparametric Tests & Parametric Tests

*See also: Descriptive Statistics, Nonparametric Tests, Parametric Tests*

### INFORMATICS

*(EBP)*

- How data, information, knowledge, and wisdom are collected, stored, processed, communicated, and used to support the process of healthcare delivery to clients, providers, administrators, and organizations involved in healthcare delivery

## EBDM GLOSSARY

### **INFORMED CONSENT**

*(Study Design)*

- The process of learning the key facts about a clinical trial before deciding whether or not to participate
- It is also a continuing process throughout the study to provide information for participants.
- To help someone decide whether or not to participate, the doctors and nurses involved in the trial explain the details of the study.
- A patient's oral and written agreement to participate in a clinical trial. Consent is based on full disclosure about the treatment, its potential risks and benefits, alternative treatments, and any other information the patient needs to make the decision. All patients enrolling in clinical trials must sign a consent document that explains what will happen to them in the trial.

*See also: Informed Consent Document*

### **INFORMED CONSENT DOCUMENT**

*(Study Design)*

- A document that describes the rights of the study participants, and includes details about the study, such as its purpose, duration, required procedures, and key contacts.
- Risks and potential benefits are explained in the informed consent document. The participant then decides whether or not to sign the document.
- Informed consent is not a contract, and the participant may withdraw from the trial at any time.

*See also: Informed Consent*

### **INSTITUTIONAL REVIEW BOARD (IRB)**

*(Study Design)*

- A group of individuals (committee) who review a study before it can be conducted to determine the benefits and risks of conducting the research to study participants and approve or disapprove research protocols, consent forms, and promotional materials for a trial
- A committee of physicians, statisticians, researchers, community advocates, and others that ensures a clinical trial is ethical and that the rights of study participants are protected
- Every institution that conducts or supports biomedical or behavioral research involving human participants must, by federal regulation, have an IRB that initially approves and periodically reviews the research in order to protect the rights of human participants. All clinical trials in the U.S. must be approved by an IRB before they begin. IRBs, in turn, must adhere to federal regulations.

*Syn: Research Subjects Review Board (RSRB)*

*See also: Research Subjects Review Board (RSRB)*

### **INTEGRATIVE REVIEWS**

*(Qualitative, Study Design)*

- Systematic summaries of the accumulated state of knowledge about a concept, including highlights of important issues left unresolved

*See also: Review, Systematic Reviews*

### **INTENTION-TO-TREAT ANALYSIS**

*(Therapy)*

- A method for data analysis in a randomized clinical trial in which individual outcomes are analyzed according to the group to which they have been randomized, even if they never received the treatment they were assigned ("Analyzed as Randomized")
- By simulating practical experience, it provides a better measure of effectiveness (versus efficacy)

*See also: Effectiveness, Efficacy, Randomization*

### **INTERNAL CONSISTENCY RELIABILITY**

*(Study Design)*

- The extent to which an instrument's subparts are measuring the same construct

## EBDM GLOSSARY

### **INTERNAL VALIDITY**

*(Study Design)*

- The integrity of the experimental design
- The extent to which it can be said that the independent variable (i.e., the intervention) causes a change in the dependent variable (i.e., the outcome), and the results are not due to other factors or alternative explanations, such as flaws in the study design
- Allows you to draw valid conclusions about the way one variable affects another in that study
- A study can be internally valid (i.e., the intervention works for the study population or in the setting studied) and yet have no validity for populations or settings outside the study.

*See also: Dependent Variable, External Validity, Independent Variable, Validity*

### **INTERPRETIVE ETHNOGRAPHY**

*(Qualitative)*

- Anthropological movement that generates many hybrid forms of ethnographic work as a result of crossing a variety of theoretical boundaries within social science

### **INTER-RATER RELIABILITY**

*(Study Design)*

- The degree to which two individuals agree on what they observe

*See also: Observer Drift*

### **INTERVAL DATA**

*(Study Design)*

- Data that has quantified intervals and equal distances between points, but without a meaningful zero point (e.g., temperature in Fahrenheit degrees)

*Syn: Continuous Data*

*See also: Ratio Data*

### **INTERVENTION**

*(Study Design, Therapy)*

- Primary interventions/treatments/therapies being studied
- Types of interventions are Drug, Gene Transfer, Vaccine, Behavior, Device, or Procedure.

### **INTERVENTION NAME**

*(Study Design, Therapy)*

- The generic name of the precise intervention being studied.

### **INTERVIEWER BIAS**

*(Study Design)*

- Systematic error due to interviewer's subconscious or conscious gathering of selective data

*See also: Bias*

### **INTROSPECTION**

*(Qualitative)*

- A process of recognizing and examining one's own inner state or feelings

### **INVASIVE**

*(Therapy)*

- In healthcare, the puncture or incision of the skin using a medical device (e.g., needle, scalpel, laser)

### **INVESTIGATIONAL**

*(Study Design)*

- Experimental, Unproven

## EBDM GLOSSARY

### INVESTIGATIONAL NEW DRUG (IND)

(*Diagnosis, Study Design, Therapy*)

- A new drug, antibiotic drug, or biological drug that is used in a clinical investigation to affect the function of the mind or body with the intention of diagnosing, preventing, or treating a disease, a condition, or its symptoms
- It also includes a biological product used *in vitro* for diagnostic purposes.
- Not yet FDA approved for marketing to treat a particular condition, but must be investigated in clinical trials to gather data that FDA will consider for the marketing approval application.

### INVESTIGATOR

(*Study Design*)

- A researcher responsible for conducting a clinical trial at a trial site
- See also: Clinical Research Coordinator, Principal Investigator, Sponsor-Investigator*

## J

## K

### KAB – MEANING

(*Qualitative, Study Design*)

- Knowledge, Attitudes, & Beliefs
- See also: Meaning, Meta-Synthesis, Qualitative Study*

### KEY INFORMANT

(*Qualitative*)

- A select informant/assistant with extensive or specialized knowledge of his/her own culture.

### KEYWORD

(*MEDLINE*)

- A word that is part of the database's controlled vocabulary/thesaurus
- Words found in the title and/or abstract fields; an indexed text word in MEDLINE
- Generally, prefer thesaurus searching (i.e., using the subject or MeSH headings).

*Syn: Text word*

*See also: MEDLINE, MeSH (MeSH Heading), Restrict to Focus*

## L

### LANDMARK STUDY

(*EBP*)

- In clinical research, a study of such importance that it historically marks the discovery of a new way to diagnose or treat a disease or condition

### LEAD-TIME BIAS

(*Prognosis, Study Design*)

- If prognosis study patients are not all enrolled at similar, well-defined points in the course of their disease, differences in outcome over time may merely reflect differences in duration of illness

## EBDM GLOSSARY

### LEVELS OF EVIDENCE

*(Prognosis, Study Design)*

- Evidence is reported within a variety of study designs. These designs are presented at various levels of evidence. How this literature is organized will help the searcher retrieve the highest level of evidence for a particular clinical question.
- High levels of evidence may not exist for all clinical questions, due to the nature of medical problems and research and ethical limitations. Levels of evidence for domains or study designs include:
  - Therapy – Randomized Controlled Trials (RCTs)
  - Diagnosis – Controlled Trials
  - Prognosis – Cohort Studies, Case–Control Studies, Case Series, occasional RCTs
  - Etiology – Cohort Studies
  - Prevention – RCTs, Cohort Studies
  - Quality Improvement – RCTs

*Syn: Hierarchy/Grades of Evidence*

*See also: Hierarchy of Evidence*

### LIFEWAYS

*(Qualitative, Study Design)*

- The ways people live their life

### LIFE HISTORY

*(Qualitative, Study Design)*

- A research method wherein the researcher listens to the telling of their life story for the purpose of understanding a particular aspect of the individual's life

### LIKELIHOOD RATIOS (LR)

*(Calculations, Diagnosis)*

- The likelihood that a given test result would be expected in patients with a disease compared to the likelihood that the same result would be expected in patients without that disease
- Ratio of the probability that a given diagnostic test result will be expected for a patient with the target disorder rather than for a patient without the disorder
- A measure of how much more likely a positive test result is in a patient with the disease compared with a patient without the disease
- Compares pre-test and post-test probabilities using a nomogram with the LR

*See also: Pre-Test Probabilities, Post-Test Probabilities*

### LIMIT(S)

*(MEDLINE)*

- Broad restrictions applicable to existing search sets; includes designations such as:
  - Human, animal (and types of animal)
  - English or other languages
  - Publication types (e.g., randomized controlled trial, clinical trial, meta-analysis, practice guideline, etc.)
  - Age groups
  - Gender
  - Journal subsets (including AIM journals, Nursing Journals, and Dental Journals)
  - Year of publication
  - Latest update

### LIVED EXPERIENCE

*(Qualitative)*

- Everyday experience, not as it is conceptualized, but as it is lived (i.e., how it feels)

### LOST TO FOLLOW UP (LOSS OF SUBJECTS TO FOLLOW UP) *(Study Design)*

- The proportion of people who started the study but do not complete the study, for whatever reason

*Syn: Attrition*

## M

**MACRO LEVEL CHANGE** (EBP)

- Change at a large-scale level (e.g., nation-wide systems or large institutions)

*See also: Micro Level Change*

**MAGNITUDE OF EFFECT** (Study Design)

- Expressing the size of the relationship between two variables or difference between two groups on a given variable/outcome (i.e., the effect size)

*See also: Effect Size*

**MANIPULATION CHECKS** (Study Design, Therapy)

- Assessments verifying that subjects have actually processed the experimental information that they have received or followed through with prescribed intervention activities

**MAPPING** (MEDLINE)

- A computer process whereby the search system matches a term entered to the closest subject headings in the database

**MARGINAL COSTS** (Economic Analysis)

- Change in total costs resulting from a one-unit increase or decrease in the service (For example, the cost of one additional patient)

**MASKING / MASKED** (Study Design)

- Knowledge or lack of knowledge of the intervention assignment

*See also: Blinding, Clinical Trial, Randomized Controlled Trial*

**MATURATION** (Qualitative, Study Design, Therapy)

- Developmental change that occurs, even in the absence of the intervention

**MEAN** (Calculations, Study Design)

- A measure of central tendency
- Derived by summing all scores and dividing by the number of participants

*See also: Confidence Interval, Effect, Effect Size*

**MEANING/KAB** (Qualitative, Study Design)

- Qualitative questions are a part of clinical inquiry. These types of questions often may be asked to determine meaning, to provide insight and scope to a phenomenon, to appreciate a patient's experience, or to help understand the influence of culture on health care.
- May provide insight and scope to a phenomenon, appreciate a patient's experience, or help in understanding the influence of a culture on healthcare

*See also: KAB-Meaning, Meta-Synthesis, Qualitative Study*

**MEANING-IN-CONTEXT** (Qualitative)

- This evaluation criterion for a qualitative research study asks the question: Are the findings reported within the context of the area of study?
- The significance of the findings within the participant's environment

## EBDM GLOSSARY

### MEASUREMENT DATA TYPES

*(Calculations, Study Design)*

#### • **Qualitative Data**

- Categorical, Nominal, Typological (e.g., blood type A, blood type B, etc.; diseased/healthy)
- Ordinal, Ranked (e.g., low birth weight, normal birth weight, high birth weight; cancer staging)
- Binary = Dichotomous; Tertiary (or higher) = Polychotomous

#### • **Quantitative Data**

- Continuous, Metric (e.g., height, weight)
- Discontinuous, Quasicontinuous, Meristic (e.g., blood pressure)

*See also: Statistical Models*

### MEDIATING PROCESSES

*(Study Design)*

- Identifies the expected activities that produce the desired outcome

### MEDIATING VARIABLE

*(Study Design)*

- The variable or mechanism through which an intervention works to impact the outcome in a study

### MEDLINE

*(MEDLINE)*

- An electronic index to the contents of biomedical and health sciences journals published since 1966
- Medline includes Index Medicus, the Index to Dental Literature, and the International Nursing Index.

### MESH / MESH HEADINGS

*(MEDLINE)*

- *Medical Subject Headings*
- MEDLINE's controlled vocabulary, the thesaurus for Medline
- A controlled vocabulary providing consistent terminology for concepts covered by the database

### META-ANALYSIS

*(Systematic Review, Study Design)*

- A statistical technique for assembling the results of several studies in a review, typically a systematic review, into a single numerical estimate, giving more weight to larger studies
- Process of using quantitative methods to summarize the results from the multiple studies, obtained and critically reviewed using a rigorous process (to minimize bias) for identifying, appraising, and synthesizing studies to answer a specific clinical question and draw conclusions about the data gathered, to gain a summary statistic (i.e., a measure of a single effect) that represents the effect of the intervention across the multiple studies

*See also: Funnel Plot, Systematic Review*

### META-SYNTHESIS

*(Qualitative, Study Design)*

- Synthesis of qualitative research involving the critical analysis of primary qualitative studies and synthesis of findings into a new theory or framework for the topic of interest.
- Involves translating single qualitative studies into a synthesis that transforms individual findings into a new conceptualization.

*See also: KAB–Meaning, Meaning/KAB, Qualitative Study*

### METHOD

*(Study Design)*

- The theory of how a certain type of research should be carried out (i.e., strategy, approach, process, overall design, logic of design)
- Researchers often subsume description of techniques under a discussion of method

## EBDM GLOSSARY

### **MICRO LEVEL CHANGE**

*(EBP)*

- Change at a small-scale level (e.g., units within a local healthcare organization or small groups of individuals)

*See also: Macro Level Change*

### **MONITOR**

*(Study Design)*

- An individual employed by a sponsor or contract research organization who helps to plan, conduct, analyze and interpret data from a trial

### **MONITORING**

*(Study Design)*

- Activities to check patients' health status during a trial
- Activities to oversee the progress of a trial to ensure a researcher's compliance with the protocol and regulatory requirements

### **MORBIDITY**

*(Study Design)*

- Rate of sickness often expressed as the ratio of sick to well people in a given population

*See also: Mortality*

### **MORTALITY**

*(Study Design)*

- Death Rate

*See also: Morbidity*

### **MULTI-CENTER TRIAL**

*(Study Design)*

- A clinical trial conducted at multiple sites using a common protocol

*See also: Clinical Trial, Controlled Clinical Trial, Randomized Controlled Trial*

## **N**

### **NARRATIVE**

*(Study Design, Qualitative)*

- A qualitative study design that refers to distinct styles of generating, interpreting, and representing data as stories that provide insights into life experiences. It uses data collection methods whereby participants are asked to imagine or picture an event or sequence of events as a method of describing an experience.

### **NARRATIVE ANALYSIS**

*(Qualitative)*

- A term that refers to distinct styles of generating, interpreting, and representing data as stories that provide insights into life experiences

### **NATIONAL GUIDELINE CLEARINGHOUSE**

*(EBP)*

- A comprehensive database of up-to-date English language evidence-based clinical practice guidelines, developed in partnership with the American Medical Association, the American Association of Health Plans, and the Association for Healthcare Research and Quality

### **NATIONAL INSTITUTES OF HEALTH (NIH)**

*(EBP)*

- A federal agency consisting of many separate research institutions, such as the National Cancer Institute
- Conducts research in its own facilities and funds billions of dollars in research in other facilities in the United States and abroad

### **NATURAL HISTORY STUDY**

*(Etiology, Study Design)*

- Study of the natural development of something (such as an organism or a disease) over a period of time

## EBDM GLOSSARY

### **NATURALISTIC RESEARCH**

*(Etiology, Qualitative, Study Design)*

- Commitment to the study of phenomena in their naturally occurring settings (contexts)

### **NEGATIVE PREDICTIVE VALUE**

*(Calculations, Study Design)*

- Probability of no disease among patients with a negative test (those who test negative and truly do not have the disease)

*See also: Positive Predictive Value, Predictive Value, True Negative, Likelihood Ratio*

### **NEW DRUG APPLICATION (NDA)**

*(Study Design, Therapy)*

- An application submitted by the manufacturer of a drug to the FDA, after clinical trials have been completed, for a license to market the drug for a specified indication

### **NHS ECONOMIC EVALUATION DATABASE**

*(Economic Analysis)*

- A register of published economic evaluations of healthcare interventions

### **N-OF-1 TRIALS**

*(Study Design, Therapy)*

- A patient undergoes pairs of treatment periods organized so that one period involves the use of the experimental treatment and the other involves the use of an alternate or placebo therapy.
- Patient and clinician are blinded, if possible, with outcome monitoring.
- Treatment periods are replicated until the clinician and patient are convinced that the treatment are definitely different or definitely not different.

### **NOMINATED SAMPLE**

*(Study Design)*

- A sample obtained with the help of informants already enrolled in the study

*Syn: Snowball Sample*

### **NON-EXPERIMENTAL STUDY DESIGN**

*(Qualitative, Study Design)*

- A study design in which data are collected but whose purpose is not to test the effects of an intervention or treatment on selected outcomes

*Syn: Observational Study Design*

### **NON-HOMOGENEOUS SAMPLE**

*(Study Design)*

- A sample comprised of individuals with dissimilar characteristics

*See also: Heterogeneity, Homogeneity, Patient Characteristics*

### **NON-PARAMETRIC STATISTICS/TESTS**

*(Calculations, Study Design)*

- Used in the analysis of correlations between qualitative variables within a population or differences in the distribution of qualitative variables between populations
- Occasionally, quantitative data may be converted or grouped into a qualitative format.

*See also: Descriptive Statistics, Inferential Statistics, Parametric Tests*

### **NULL HYPOTHESIS**

*(Study Design)*

- There is no relationship between or among study variables

### **NUMBER NEEDED TO HARM (NNH)**

*(Calculations, Therapy)*

- The number of patients who must be exposed to an intervention before an adverse event occurred
- The number of clients, who, if they received an intervention, would result in one additional person being harmed (i.e., having a bad outcome) compared to the patients in the control arm of a study
- $NNH = 1 / ARR$

*See also: Absolute Risk Reduction (ARR), Number Needed to Treat (NNT)*

**NUMBER NEEDED TO TREAT (NNT)**

*(Calculations, Therapy)*

- The number of patients who would need to receive the experimental therapy to prevent one bad outcome or cause one additional good outcome; The number of patients who must be exposed to an intervention before the clinical outcome of interest occurred
- $NNT = 1 / ARR$
- If 1000 patients need to be treated to prevent a single bad outcome, the treatment might be less impressive; especially if an alternative therapy provides treatment for only 15 patients to prevent the same bad outcome (assuming relatively equal adverse effects).
- Also useful if the rate of adverse events is known, risk, benefit, and cost can be balanced (e.g., the NNT for a drug to prevent cancer is 300, but the rate of fatal pulmonary embolism is 2%, we know that for every cancer we prevent, we cause 6 fatal pulmonary emboli)

*See also: Absolute Risk Reduction (ARR), Number Needed to Harm (NNH)*

**O**

**OBJECTIVE DATA**

*(Calculations, Study Design)*

- Information that is measurable and quantifiable using a test or evaluation tool (e.g., laboratory finding, imaging study, rating scale)

*See also: Baseline Data, Data, Demographic Data, Quality-of-Life Data, Raw Data, Subjective Data, Survival Data*

**OBSERVATION CONTINUUM**

*(Qualitative)*

- A range of social roles encompassed by participant-observation and ranging from complete observer to complete participant at the extremes

*See also: Participant-Observation*

**OBSERVER DRIFT**

*(Qualitative, Study Design)*

- A decrease in inter-rater reliability

*See also: Inter-Rater Reliability*

**OCCURRENCE RATE**

*(Calculations, Study Design)*

- The rate at which an event occurs

*Syn: Event Rate*

**ODDS**

*(Calculations, Study Design)*

- The chance of an event of an event occurring
- A proportion in which the numerator contains the number of times an event occurs and the denominator includes the number of times the event does not occur

*See also: Odds Ratio*

**ODDS RATIO**

*(Calculations, Study Design)*

- A ratio of the odds of a case patient (i.e., someone in the intervention group) being exposed ( $a/b$ ) divided by the odds of a control patient being exposed ( $c/d$ )

$a$  = exposed (case) patients who are disease positive (*in a 2x2 table, the upper left corner*)

$b$  = exposed (case) patients who are disease negative (*in a 2x2 table, the upper right corner*)

$c$  = unexposed (control) patients who are disease positive (*in a 2x2 table, the lower left corner*)

$d$  = unexposed (control) patients who are disease negative (*in a 2x2 table, the lower right corner*)

*Continued on next page...*

## EBDM GLOSSARY

- A ratio of the odds of having the target disorder in the experimental group relative to the odds in favor of having the target disorder in the control group (cohort studies, systematic reviews)
- A measure of the degree of association or a treatment's effectiveness
- OR > 1.0 represents an increased odds of cases being exposed
- OR < 1.0 represents a decreased odds of cases being exposed
- OR = 1.0 represents no difference between groups

*Syn: Cross-Product Ratio*

*See also: Effectiveness, Odds, Relative Odds*

### OPEN DESIGN

*(Study Design, Therapy)*

- A clinical trial design in which both the investigators and research subjects know the treatment groups to which subjects are assigned

*See also: Blinding, Clinical Trial, Masking*

### OPEN-LABEL TRIAL

*(Study Design, Therapy)*

- A clinical trial in which doctors and participants know which drug or vaccine is being administered
- A trial in which all patients are receiving the investigational new drug after the completion of a controlled trial that had positive results
- FDA allows patients who are likely to benefit to receive the new drug while the company awaits FDA approval to commercially market the drug

*See also: Clinical Trial*

### OPINION LEADERS

*(EBP)*

- Individuals who are typically highly knowledgeable and well respected in a system; as such, they are often able to influence change

### OPPORTUNITY COST

*(Economic Analysis)*

- Addresses resource allocation (if resources are used in a particular way, they cannot be used for something else) whether monetary, staff time, room use, etc.

### ORDINAL DATA

*(Study Design)*

- Variables that have ordered categories with intervals that cannot be quantified (e.g., mild, moderate, or severe anxiety)

*See also: Interval Data, Ratio Data*

### ORPHAN DRUGS

*(Study Design, Therapy)*

- An FDA category that refers to medications used to treat diseases and conditions that occur rarely
- There is little financial incentive for the pharmaceutical industry to develop medications for these diseases or conditions.
- Gives a manufacturer specific financial incentive to develop and provide such medications

### OUTCOME

*(Study Design)*

- The ultimate result of a medical test or treatment given to patient
- Examples of general, patient-oriented outcomes are overall survival rates, disease-free survival rates, treatment-related morbidity, and mortality
- Indirect outcome measures do not tell us directly about how well a patient is—although some indirect measures may be correlated with health improvements (e.g., tumor response rates, laboratory tests, and imaging studies)

*Syn: Treatment Outcome*

*See also: End Point, Interval Data, Ordinal Data, Ratio Data*

## EBDM GLOSSARY

### OUTCOMES MANAGEMENT

(EBP)

- The use of process and outcomes data to coordinate and influence actions and processes of care that contribute to patient achievement of targeted behaviors or desired effects

### OUTCOMES MEASUREMENT

(EBP, Study Design)

- A generic term used to describe the collection and reporting of information about an observed effect in relation to some care delivery process or health promotion action

### OUTCOMES RESEARCH

(EBP, Study Design)

- The use of rigorous scientific methods to measure the effect of some intervention on some outcome(s)

## P

### PARADIGM

(EBP, Qualitative, Study Design)

- A world view or set of beliefs, assumptions, and values that guides all types of research by identifying where the researcher stands on issues related to the nature of reality (*ontology*), relationship of the researcher to the researched (*epistemology*), role of values (*axiology*), use of language (*rhetoric*), and process (*methodology*)

*See also: Axial Coding*

### PARAMETRIC STATISTICS/TESTS

(Calculations, Study Design)

- Used in the analysis of correlations between quantitative variables within a population or differences in the distribution of quantitative variables between populations

*See also: Descriptive Statistics, Inferential Statistics, Parametric Tests*

### PARTICIPANT-OBSERVATION

(Qualitative)

- Observation and participation in everyday activities in study informants' natural settings

*See also: Observation Continuum*

### PARTICIPATORY ACTION RESEARCH (PAR)

(Qualitative)

- A form of action research that is participatory in nature
- Researchers and participants collaborate in problem definition, choice of methods, data analysis, and use of findings
- Democratic in principle and reformatory in impulse, its objective is the empowerment of persons through the process of constructing and using their own knowledge as a form of consciousness raising with the potential for promoting social action

### PATIENT CHARACTERISTICS

(Study Design)

- The *medical* qualities or traits of a patient (e.g., disease, stage of disease, blood pressure, weight, hormone receptor status, and prior treatments)
- The *demographic* qualities or traits of a patient (e.g., age, sex, and race)

*See also: Observation Continuum*

### PATIENT EXPECTED EVENT RATE (PEER)

(Calculations)

- Refers to the rate of events expected in a patient who received no treatment or conventional treatment

### PATIENT PREFERENCES

(EBP, Study Design)

- Values the patient holds, concerns the patient has regarding the clinical decision/treatment/situation or Choices the patient has/prefers regarding the clinical decision/treatment/situation

## EBDM GLOSSARY

### PEER REVIEW

*(EBP, Study Design)*

- Project critiqued by a team of reviewers who has expertise in the subject
- Review of a clinical trial by experts (chosen by the study sponsor) for scientific merit, participant safety, and ethical considerations

### PERSPECTIVE

*(Economic Analysis)*

- Viewpoint of the economic evaluation (health service, patient, society, etc.)
- Broader viewpoints are more relevant to resource allocation questions, but also may help identify all relevant outcomes and costs.

*See also: Economic Evaluation*

### PHARMACOKINETICS

*(Therapy)*

- The processes (in a living organism) of absorption, distribution, metabolism, and excretion of a drug or vaccine

### PHENOMENOLOGIC

*(Qualitative)*

- Pertaining to the study of essences (i.e., meaning structures) intuited or grasped through descriptions of lived experience

*See also: Lived Experience*

### PHENOMENOLOGIC REDUCTION

*(EBP, Qualitative)*

- An intellectual process involving reflection, imagination, and intuition

### PHENOMENOLOGY

*(Qualitative, Study Design)*

- A qualitative study design that focuses on the meaning of the “lived experience”. The intention is to examine and describe phenomena as they appear in the lived experience of the individual. Thus human experience is inductively derived and described with the purpose of discovering the essence of meaning. It is an approach pertaining to the study of essences (i.e. meaning structures) intuited or grasped through descriptions of lived experience.

### PHILOSOPHICAL INQUIRY

*(Qualitative, Study Design)*

- A qualitative study design that describes the meaning of nursing phenomena through analysis, reasoning, and logical argument or presentation.

### PHYSICIAN INFLUENCE

*(EBP)*

- A doctor’s power to sway a patient decision based on the patient’s trust in the doctor and the doctor’s reputation and position

### PICO (TT)

*(EBP)*

- A process in which clinical questions are phrased in a manner that yields the most relevant information
- A useful acronym that describes the elements of a well-formed clinical question about therapy:
  - **POPULATION** – a description (helpful, but not overly specific) of the group to which your patient belongs; may include age, gender, race, ethnicity, and/or stage of disease
  - **INTERVENTION** – a description of the test or treatment being considered
  - **COMPARISON** – the alternative, comparison intervention or status
  - **OUTCOME** – generally something that matters to the clinician and the patient
  - **TYPE OF QUESTION** – *Domain* – Diagnosis, Etiology, Harm, Prevention, Prognosis, Therapy
  - **TYPE OF STUDY** – The best study design or methodology to answer the clinical question

## EBDM GLOSSARY

### **PILOT STUDY**

*(Study Design)*

- A small-scale version of a study intended to refine the experimental protocol
- Helps to identify problems and issues that never occurred during the planning stages of a project
- Data generated may be useful in demonstrating proficiency in a field of inquiry and may help to secure funding for larger projects.
- Typically do not require sample size determinations or power analyses – an arbitrary number of subjects is chosen as the target cohort

### **PLACEBO**

*(Therapy)*

- An inactive pill, liquid, powder, or sham medical device that has no treatment value given under the guise of treatment to separate the effects of the actual agent or treatment being evaluated from psychological or other effects
- In clinical trials, experimental treatments are often compared with placebos to assess the treatment's effectiveness.

### **PLACEBO CONTROLLED STUDY**

*(Therapy)*

- A method of investigation of drugs in which an inactive substance (the placebo) is given to one group of participants, while the drug being tested is given to another group. The results obtained in the two groups are then compared to see if the investigational treatment is more effective in treating the condition.

### **PLACEBO EFFECT**

*(Therapy)*

- A health effect from administration of a placebo
- A physical or emotional change, occurring after a substance is taken or administered, that is not the result of any special property of the substance. The change may be beneficial, reflecting the expectations of the participant and, often, the expectations of the person giving the substance.
- This may occur because of patient belief that a treatment is working and because of the attention given by healthcare providers to the patient in the clinical trial.

### **POINT ESTIMATE**

*(Calculations, Study Design)*

- When a parameter is being estimated, the estimate can be either a single number or it can be a range of scores. When the estimate is a single number, the estimate is called a 'point estimate.' When the estimate is a range of scores, the estimate is called an 'interval estimate' or 'confidence interval.'
  - Use of data to calculate a single value/statistic to serve as a best guess for an unknown population parameter
- See also: Confidence Interval, Effect Size, Mean, Standard Deviation, Statistical Significance*

### **POSITIVE PREDICTIVE VALUE (PPV)**

*(Calculations, Diagnosis)*

- Probability of disease among patients with a positive test (those who test positive and truly have the disease)
  - Depends on the prevalence of disease – decreases as the disease becomes more rare in the population
- See also: Negative Predictive Value, Predictive Value, Prevalence, True Positive*

### **POST-QUALIFICATION**

*(MEDLINE)*

- Used with existing broad subject heading search statements to focus the search and reduce the number of postings while increasing their relevance
- To restrict a subject heading to focus, preface the set number with an asterisk (\*) (e.g., if set 1 is Tuberculosis and you wish to find only papers where this is a central focus, create a new search statement by entering "\*1").
- To focus a search by the use of subheadings after the set has been created, enter the set number followed by a forward slash and the two-letter subheading designators desired (e.g., if set 1 is Tuberculosis, and you wish to restrict your search to "prevention and control" and "transmission", enter "1/pc,tm").

*See also: Restrict to Focus*

## EBDM GLOSSARY

### POST-TEST ODDS

(Diagnosis)

- The odds that the patient has the target disorder after the test is carried out  
(Pre-Test Odds) \* (Likelihood Ratio)

*See also: Likelihood Ratio, Post-Test Probability, Pre-Test Odds, Pre-Test Probability, Probability*

### POST-TEST PROBABILITY

(Diagnosis)

- Following diagnostic testing, the number of people who truly have the disease of those who tested positive.  
(Post-Test Odds) / (1 + Post-Test Odds)

*Syn: Positive Predictive Value*

*See also: Likelihood Ratio, Post-Test Odds, Pre-Test Odds, Pre-Test Probability, Probability, True Positive*

### POWER

(Study Design)

- The ability of a study design to detect existing relationships between or among variables

### POWER ANALYSIS

(Calculations, Study Design)

- Procedure used for determining the sample size needed for a study

### PRECISION

(Calculations, Study Design)

- The range in which the best estimates of a true value approximate the true value

*See also: Confidence Interval*

### PRECLINICAL

(Study Design)

- Refers to the testing of experimental drugs, devices, or procedures in the test tube or in animals to find out if the new treatment shows enough promise to be studied in humans
- Occurs before trials in humans may be carried out

### PREDICTIVE VALUE

(Diagnosis)

- In screening and diagnostic tests, the probability that a person with a positive test is a true positive (i.e., does have the disease), or that a person with a negative test truly does not have the disease
- The predictive value of a screening test is determined by the *sensitivity* and *specificity* of the test, and by the *prevalence* of the condition for which the test is used.

*See also: False Negative, False Positive, Negative Predictive Value, Positive Predictive Value, Prevalence, Sensitivity, Specificity, True Negative, True Positive*

### PRE-TEST ODDS

(Diagnosis)

- The odds that the patient has the target disorder before the test is carried out  
(Pre-Test Probability) / (1 – Pre-Test Probability)

*See also: Likelihood Ratio, Post-Test Probability, Post-Test Odds, Pre-Test Probability, Probability*

### PRE-TEST PROBABILITY

(Diagnosis)

- Probability or chance of a patient having the disease before the diagnostic test is carried out
- Same as *Prevalence* of that disease in a population similar to the patient
- Based on routine data, practice data, or clinical judgment

*Syn: Prevalence*

*See also: Likelihood Ratio, Post-Test Probability, Probability*

## EBDM GLOSSARY

### PREVALENCE

(*Etiology*)

- Proportion of persons in the at-risk population who have the outcome or disorder in a given “snapshot in time”
- Probability of disease in the entire population at any point in time – total number of cases of a specific disease or condition in a given population at a given time

*See also: Incidence*

### PREVENTION TRIALS

(*Study Design*)

- Trials to find better ways to prevent disease in people who have never had the disease or to prevent a disease from returning
- May include medicines, vitamins, vaccines, minerals, or lifestyle changes

### PRINCIPAL INVESTIGATOR (PI)

(*Study Design*)

- The lead person who is responsible and accountable for the scientific integrity of a study as well as the oversight of all elements in the conduct of that study
- An individual that leads a team of investigators at a trial site

*See also: Clinical Research Coordinator, Investigator, Sponsor-Investigator*

### PROBABILITY

(*Diagnosis*)

- The chance of the event occurring.
- Comparing Pre- and Post- Test Probabilities, certainty of diagnosis may be assessed. If the Post-Test Probability increases or decreases from the Pre-Test Probability, certainty is more or less of the diagnosis, respectively.

*See also: Pre-Test Probability, Post-Test Probability*

### PROGNOSIS

(*Prognosis*)

- The likelihood of a certain outcome
- A forecast of the probable result of a medical condition or disease in a patient
- The possible outcomes of a disease or condition and the likelihood or frequency that each one will occur
- Prognostic results are the number of events that occur over time, expressed in:
  - ABSOLUTE TERMS** (e.g., 5 year survival rate)
  - RELATIVE TERMS** (e.g., risk from prognostic factor)
  - SURVIVAL CURVES** (cumulative events over time)

### PROGNOSTIC FACTOR

(*Prognosis*)

- A patient characteristic that can predict that patient’s eventual outcome
- Demographic, disease-specific, or co-morbid characteristics can be associated strongly enough with a condition's outcomes to predict accurately the eventual development of those outcomes.
- Prognostic or risk factors do not necessarily imply a cause and effect relationship. Prognostic factors may not cause the outcome, but may be associated strongly enough to predict their development.
  - DEMOGRAPHIC** (e.g. age or gender)
  - DISEASE-SPECIFIC** (e.g. tumor stage)
  - CO-MORBID** (other conditions accompanying the disease of interest)

*Syn: Risk Factor*

*See also: Co-Morbidity, Risk Factor*

### PROSPECTIVE STUDY

(*Study Design*)

- One or more groups (*cohorts*) of individuals who have not yet had the outcome event in question are monitored for the number of such events which occur over time

*See also: Cohort, Monitoring, Retrospective Study*

## EBDM GLOSSARY

### PROTOCOL

*(Study Design, Therapy)*

- A study plan on which all clinical trials are based, carefully designed to safeguard the health of the participants as well as answer specific research questions
- Describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study (*design, purpose, length, patient selection, methods, treatment, follow-up, clinical end points, and outcomes to be measured*)
- While in a clinical trial, participants following a protocol are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment

*See also: Clinical Trial, Eligibility Criteria, Exclusion Criteria, Inclusion Criteria, Monitoring*

### PROVIDER

*(Study Design)*

- In healthcare, an individual or group (e.g., physician, hospital) that provides healthcare services

### PUBLICATION BIAS

- Studies with only positive results are published, versus studies with neutral or negative results
- If only published studies are included in a systematic review, it may overestimate the effect of the treatment or intervention.

### PURPOSEFUL SAMPLE

*(Study Design)*

- A sample intentionally selected in accordance with the needs of the study

*Syn: Theoretical Sample*

### P VALUE

*(Study Design)*

- The statistical test of the assumption that there is no difference between an experimental intervention and a control
- Indicates the probability of an event given the assumption that there is no true difference
- By convention a p value less than or equal to 0.05 is considered a statistically significant result.

## Q

### Q STATISTIC

*(Calculations, Meta-Analysis)*

- A test of homogeneity
- Uses a chi-square distribution

*See also: Heterogeneity, Homogeneity, Fixed Effects Models, Meta-Analysis, Random Effects Models*

### QUALITATIVE DATA ANALYSIS

*(Calculations, Qualitative)*

- A variety of techniques that are used to move back and forth between data and ideas throughout the course of the research

### QUALITATIVE DATA MANAGEMENT

*(Qualitative)*

- The act of designing systems to organize, catalogue, code, store, and retrieve data. System design influences, in turn, how the researcher approaches the task of analysis.

### QUALITATIVE DESCRIPTION

*(Qualitative)*

- Description that interprets facts of low-inference or consensus among researchers

### QUALITATIVE EVALUATION

*(Qualitative)*

- A general term covering a variety of approaches to evaluating programs, projects, policies, etc. using qualitative research techniques

## EBDM GLOSSARY

### QUALITATIVE METHODS

(Qualitative, Study Design)

- Methods and techniques of observing, documenting, analyzing and interpreting attributes, patterns, characteristics, and meanings of specific, contextual or gestaltic features of phenomena under study. The research methods are inductive, holistic, emic (insider view), subjective, and process-oriented to understand, interpret, describe and develop theory pertaining to a phenomenon or a setting.

### QUALITATIVE STUDIES

(Qualitative, Study Design)

- Research that involves the collection of data in non-numeric form such as personal interviews, usually with the intention of describing a phenomenon

### QUALITY-ADJUSTED LIFE-YEAR (QALY)

(Calculations, Qualitative)

- A measure which tries to combine a quantitative measure (time gained – months, years, etc.) with a qualitative measure of the quality of that time

### QUALITY OF LIFE

(EBP, Qualitative)

- A standard of living
- In healthcare, it applies to the patient's expressed satisfaction with his or her quality of life as affected by health status.

*See also: Health Related Quality of Life*

### QUALITY OF LIFE DATA

(Calculations, Qualitative)

- Objective and subjective information that is gathered about patients by researchers or from patient perceptions
- The information concerns the effect that an individual's health status has on how well the patient performs activities of daily living and how the patient feels about his or her ability to fulfill social, familial, and personal roles.

*See also: Baseline Data, Data, Demographic Data, Objective Data, Raw Data, Subjective Data, Survival Data*

### QUALITY OF LIFE TRIALS

(Prognosis, Qualitative, Study Design)

- Trials that explore ways to improve comfort and quality of life for individuals with a chronic illness

*Syn: Supportive Care Trials*

*See also: Quality of Life*

### QUANTITATIVE METHODS

(Qualitative, Quantitative, Study Design)

- Methods that focus on the empirical and objective analysis of discrete and preselected variables that have been derived a priori as theoretical statements in order to determine causal and measurable relationships among the variables under study. The research methods are positivistic, deductive, particularistic and objective primarily designed to test hypotheses or establish relationships.

### QUANTITATIVE RESEARCH

(Calculations, Study Design)

- The investigation of phenomena using manipulation of numeric data with statistical analysis
- Can be descriptive, predictive, or causal
- Comparison within or between groups

### QUANTITATIVE STUDIES

(Study Design)

- Research that collects data in numeric form and emphasizes precise measurement of variables
- Often conducted in the form of rigorously controlled studies

*See also: Case-Control Study, Clinical Trial, Cohort Study, Controlled Clinical Trial, Prospective Study, Randomized Controlled Trial, Retrospective Study*

### QUASI-EXPERIMENTS

*(Study Design)*

- A type of experimental design that tests the effects of an intervention or treatment but lacks one or more characteristics of a true experiment (e.g., random assignment; a control or comparison group)

## R

### RANDOM ERROR

*(Study Design)*

- Measurement error that occurs without a pattern, without purpose or intent
- An unintended distortion because an investigator holds preconceived notions of which he/she is unaware

*See also: Bias, Unconscious Bias*

### RANDOM EFFECTS MODELS

*(Meta-Analysis, Systematic Review)*

- Considers both between-study and within-study variability with the assumption that studies are a random sample from the universe of all possible studies
- With a random effects model, the researcher answers the question, “Will the treatment produce benefit ‘on average’?”
- Fixed and random effects models can give very different answers. Differences occur when studies are not homogenous. Random effects models are therefore more "conservative" and generate a wider confidence interval. They are less likely to show a significant treatment effect than a fixed effects model.
- When heterogeneity is found, one possibility is to do a random effects analysis on all of the studies. However, it may be better to identify an important subgroup difference; then do a fixed effects analysis of each and report all of the results. In general, if the studies are homogenous, the researchers should use a fixed effects model.
- The DerSimonian–Laird statistic is based on a random effects model.

*See also: Heterogeneity, Homogeneity, Fixed Effects Models*

### RANDOM SAMPLING

*(Study Design, Therapy)*

- Selecting subjects to participate in a study by using a random strategy (e.g., tossing a coin)
- In this method of selecting subjects, every subject has an equal chance of being selected.

*See also: Randomized Controlled Trial*

### RANDOMIZATION

*(Therapy)*

- Use of a strategy based on chance to randomly assign subjects to the experimental or control groups
- Process of allocating individuals to the alternative treatments in a clinical trial to avoid bias, producing similar groups, except for the treatment of interest
- Any of the many methods used to assign subjects to an experimental group or control group so that assignment is not influenced in any way by those making the assignments or by the researchers conducting the trial
- Randomization minimizes the differences among groups by equally distributing people with particular characteristics among all the trial arms.
- The researchers do not know which treatment is better. From what is known at the time, any one of the treatments chosen could be of benefit to the participant

*Syn: Random Assignment, Random Allocation*

*See also: Arm, Randomized Block Design, Randomized Controlled Trial*

### RANDOMIZED BLOCK DESIGN

*(Therapy)*

- A type of control strategy used in an experimental design that places subjects in equally distributed study groups based on certain characteristics (e.g., age) so that each study group will be similar prior to introduction of the intervention or treatment

*See also: Randomization*

### **RANDOMIZED CONTROLLED TRIAL (RCT)** (Therapy)

- The strongest type of experimental design (i.e., one that delivers an intervention or treatment) in which subjects are randomly assigned to experimental and control groups to support cause and effect relationships
- Clinical trials that involve (1) at least one test treatment and one control treatment, (2) concurrent enrollment and follow up of the test- and control-treated groups, and (3) in which the treatments to be administered are selected by a random process, such as the use of a random-numbers table.
  - Treatments, interventions, or enrollment into different study groups are assigned by random allocation rather than by conscious decisions of clinicians or patients.
  - If the sample size is large enough, this study design avoids problems of bias and confounding variables by assuring that both known and unknown determinants of outcome are evenly distributed between treatment and control groups.

*Syn: Randomized Controlled Clinical Trial*

*See also: Arm, Clinical Trial, Controlled Clinical Trial, Placebo, Randomization*

### **RANDOMIZED CROSS-OVER CLINICAL TRIAL** (Therapy)

- A prospective, analytical, experimental study using primary data generated in the clinical environment.
- Individuals with a chronic condition are randomly allocated to one of two treatment groups, and, after a sufficient treatment period and often a washout period, are switched to the other treatment for the same period.
- An important variant is the "N of One" clinical trial in which alternative treatments for a chronically affected individual are administered in a random sequence and the individual is observed in a double blind fashion to determine which treatment is the best.
- This design is susceptible to bias if carry over effects from the first treatment occur.

*See also: Arm, Clinical Trial, Controlled Clinical Trial, Placebo, Randomization, Randomized Controlled Trial*

### **RATIO DATA** (Calculations)

- The highest level of data
- Data that has quantified intervals on an infinite scale in which there are equal distances between points and a meaningful zero point (e.g., ounces of water; height)

*Syn: Continuous Data*

*See also: Interval Data*

### **RAW DATA** (Calculations, Study Design)

- Observations, measurements, and activities recorded before performing statistical analysis or drawing conclusions

*See also: Baseline Data, Data, Demographic Data, Objective Data, Quality-of-Life Data, Subjective Data, Survival Data*

### **RECALL BIAS** (Study Design)

- Systematic error due to the differences in accuracy or completeness of recall to memory of past events or experiences.

*See also: Bias*

### **RECURRENT PATTERNING** (Qualitative)

- A criterion for evaluation of a qualitative study that focuses on the analysis of different cognitive and identifiable themes and patterns of living or of behavior. The theme or pattern of behavior formulated is congruent to the peoples being studied. Themes should be verified by the people, but the total gestalt or coherence of ideas rests with the researcher who has rigorously studied how different ideas or components fit together in a meaningful way when linked together. This criterion asks the question: is there consistency in repeated patterns, themes and acts over time?
- Repeated experiences of participants, indicating patterns that are repeated over time

## EBDM GLOSSARY

### RECRUITMENT

(*Study Design*)

- Processes used to attract and enroll trial participants according to inclusion and exclusion criteria  
*See also: Eligibility Criteria, Exclusion Criteria, Inclusion Criteria*

### REFERENCE POPULATION

(*Study Design*)

- Those individuals in the past, present, and future to whom the study results can be generalized

### REFERRAL FILTER BIAS

(*Prognosis*)

- The sequence of referrals that may lead patients from primary to tertiary centers raises the proportion of more severe or unusual cases, thus increasing the likelihood of adverse or unfavorable outcomes.

### REGULATIONS

(*Study Design*)

- With respect to clinical research, the federal statutes, codes, and laws that govern the conduct of federally funded clinical trials and privately sponsored clinical trials for new drugs, devices, biologics, and procedures

### RELATIVE RISK (RR)

(*Calculations*)

- Measures the strength of association
- The risk of the outcome in the exposed group ( $R_e$ ) divided by the risk of the outcome in the unexposed group ( $R_u$ ) – a ratio of proportions
- Used in prospective studies such as RCTs and cohort studies
- The ratio of the probability of developing, in a specified period of time, an outcome among those receiving the treatment of interest or exposed to a risk factor, compared with the probability of developing the outcome if the risk factor or intervention is not present.
- $RR = EER/CER$
- $RR > 1.0$  represents an increased risk  
 $RR < 1.0$  represents a decreased risk  
 $RR = 1.0$  represents no difference in risk between groups

*Syn: Risk Ratio*

*See also: Control Event Rate, Experimental Event Rate, Risk Ratio*

### RELATIVE RISK REDUCTION (RRR)

(*Calculations, Therapy*)

- The extent to which a treatment reduces a risk, in comparison with patients not receiving the treatment of interest; the most commonly used measure of risk
- The proportional reduction in rates of bad outcomes between experimental and control participants in a trial
- Expressed as a percent difference; Can be calculated as  $1 - RR$  or  $(EER - CER)/CER$

*See also: Control Event Rate, Experimental Event Rate, Relative Risk*

### RELIABILITY

(*EBP, Study Design*)

- The consistency of an instrument in measuring the underlying construct
- The results of a test or measure are identical or closely similar each time it is conducted.

*Syn: Reproducibility, Repeatability*

### RELIABILITY COEFFICIENTS

(*EBP, Study Design*)

- A measure of an instrument's reliability (often computed with a Cronbach's Alpha)

*See also: Cronbach Alpha*

### RELIABILITY OF STUDY FINDINGS

(*EBP, Study Design*)

- Whether or not the effects of a study have sufficient influence on practice, clinically and statistically
- The results can be counted on to make a difference when clinicians apply them to their practice.

## EBDM GLOSSARY

### **RELIABLE MEASURES**

*(EBP, Study Design)*

- Those that consistently and accurately measure the construct of interest

### **REPRESENTATION**

*(EBP, Study Design)*

- Part of the analytic process that raises the issue of providing a truthful portrayal of what the data represent (e.g., essence of an experience, cultural portrait) that will be meaningful to its intended audience

### **RESEARCH DESIGN MEETING**

*(Study Design)*

- A planning meeting held for the purpose of designing a study and strategizing about potential funding as well as the roles of all investigators

### **RESEARCH SUBJECTS REVIEW BOARD**

*(Study Design)*

- A group of individuals who review a study before it can be conducted to determine the benefits and risks of conducting the research to study participants

*Syn: Institutional Review Board (IRB)*

*See also: Institutional Review Board (IRB)*

### **RESEARCH UTILIZATION**

*(Study Design)*

- The use of some portion of research, typically from a single study, in practice that is similar to the manner in which it was used in the original study

### **RESTRICT TO FOCUS**

*(MEDLINE)*

- A choice offered following selection of a subject heading to be searched; choosing "all documents" at this point will retrieve all references indexed with a particular subject heading
- Choosing "Restrict to focus" will retrieve only references where this concept is a central focus of the article.
- Note that some MeSH headings, such as geographical names or headings relating to experimental design, are almost never designated under "restrict to focus"

### **RESULTS**

*(Calculations, Study Design)*

- An analysis of the data collected during a clinical trial.  
**PRELIMINARY RESULTS:** Results reported before the end of a clinical trial, also refers to results reported from early phase studies

### **RETROSPECTIVE STUDY**

*(Study Design)*

- Study design in which cases where individuals who had an outcome event in question are collected and analyzed after the outcomes have occurred

*See also: Case–Control Study, Prospective Study*

### **REVIEW**

*(Study Design)*

- Any attempt to synthesize results and conclusions of two or more publications on a given topic

*Syn: Overview*

*See also: Systematic Review, Meta–Analysis*

## EBDM GLOSSARY

### RISK

*(Calculations, Study Design)*

- The chance of an event occurring
  - The probability that a person (currently free from a disease) will develop a disease at some point
  - In a clinical trial, the probability of discomfort or harm to participants in a clinical trial
- ACCEPTABLE RISK** – deemed to be reasonable, given the purpose of the trial and its potential benefits for patients in the trial

**UNREASONABLE RISK** – deemed to far outweigh any potential benefit for the patient in the trial

*See also: Prognostic Factor, Risk Factor*

### RISK–BENEFIT RATIO

*(Study Design)*

- The risk to individual participants versus the potential benefits
- The risk/benefit ratio may differ depending on the condition being treated.

### RISK FACTOR

*(Study Design)*

- Patient characteristics or factors associated with an increased probability of developing a condition or disease in the first place
- Neither risk nor prognostic factors necessarily imply a cause and effect relationship.

*See also: Prognostic Factor, Risk*

### RISK RATIO (RR)

*(Study Design)*

- The ratio of risk in the treated group (EER) to the risk in the control group (CER)
- Used in prospective studies such as RCTs and cohort studies
- $RR = EER/CER$

*Syn: Relative Risk*

*See also: Control Event Rate, Experimental Event Rate, Relative Risk, Risk*

## S

### SATURATION

*(Qualitative, Study Design)*

- Repetition of data obtained during the course of a qualitative study. Signifies completion of data collection on a particular culture or phenomenon. This evaluation criterion for a qualitative study asks the question: was the data collected until there was no new information coming forth?
- The point at which categories of data are full and data collection ceases to provide new information
- Taking in all that is known or understood about the phenomenon under study, until no further new discoveries emerge from the data

### SATURATION LEVEL

*(Study Design, Systematic Review)*

- The level at which a searcher no longer finds any new references, but instead, is familiar and knowledgeable with the literature

### SCOPE NOTE

*(MEDLINE)*

- Defines a particular MeSH heading and explains its parameters, provides synonyms covered by the heading, year a MeSH heading was adopted by Medline, previous indexing for the MeSH heading, and cross references to other possibly relevant MeSH headings.

### SCREENING FOR ELIGIBILITY

*(Study Design)*

- Methods (e.g., phone interview, medical tests) used to determine which patients are eligible for a trial

*See also: Eligibility Criteria, Exclusion Criteria, Inclusion Criteria*

## EBDM GLOSSARY

### SCREENING TRIALS

(*Diagnosis*)

- Refers to trials which test the best way to detect certain diseases or health conditions.

### SELECTION BIAS

(*Study Design*)

- Bias that results from choosing patients for participation in a trial without taking into account patient characteristics that can skew the results
- A bias in assignment or a *confounding variable* that arises from study design rather than by chance
- Can occur when the study and control groups are chosen so that they differ from each other by one or more factors that may affect the outcome of the study

*See also: Bias, Confounder/Confounding Variable*

### SEMIOTICS

(*Qualitative, Study Design*)

- The theory and study of signs and symbols applied to the analysis of systems of patterned communication

### SEMI-STRUCTURED INTERVIEWS

(*Qualitative, Study Design*)

- Formal interviews that provide more interviewer control and question format structure but retain a conversational tone and allow informants to answer in their own ways

*See also: Structured, Open-Ended Interviews, Unstructured, Open-Ended Interviews*

### SENSITIVITY

(*Calculations, Diagnosis*)

- The proportion of people with disease who have a positive test result or Probability of a positive test among patients with disease – *True Positives*
- The proportion of truly diseased persons, as measured by the gold standard, who are identified as diseased by the test under study – probability of a diagnostic test finding disease among those who have the disease
- Not effected by Prevalence
- $1 - \text{Sensitivity} = \text{Proportion of False Negatives}$

*See also: False Negative, False Positive, Likelihood Ratio, Prevalence, Specificity, True Negative, True Positive*

### SENSITIVITY ANALYSIS

(*Economic Analysis, Meta-Analysis*)

- In *meta-analyses*, a way of looking at only certain studies, certain groups of patients, or certain interventions.
- In *economic analyses*, the standard method for allowing for uncertainty in economic evaluations.
  - Involves varying the values of key parameters, individually, to see if the results of the evaluation are sensitive to the assumptions made

*See also: Economic Evaluation, Meta-Analysis*

### SIDE EFFECTS

(*Therapy*)

- Any undesired actions or effects of a drug or treatment
- Negative or adverse effects may include headache, nausea, hair loss, skin irritation, or other physical problems.
- Experimental drugs must be evaluated for both immediate and long-term side effects.

*See also: Adverse Reaction, Experimental Drugs*

### SIGN

(*Study Design*)

- Any objective evidence of a disease (as detected by a test or clinical examination by a doctor)

### SNNOUT

(*Calculations, Diagnosis*)

- When a test has a high sensitivity, a negative result rules out the diagnosis
- **Sensitivity rules Negative OUT**

*See also: Sensitivity*

**SOLOMON FOUR GROUP DESIGN**

(Study Design)

- A type of experimental study design that uses a before-after design for the first two experimental groups and an after-only design for the second experimental and control groups so that it can separate the effects of pre-testing the subjects on the outcome measure(s)

**SPECIFICITY**

(Calculations, Diagnosis)

- The proportion of people free of a disease who have a negative test or the probability of a diagnostic test finding NO disease among those who do NOT have the disease – *True Negatives*
- The proportion of truly non-diseased persons, as measured by the gold standard, who are so identified by the diagnostic test under study
- Specificity is not affected by *Prevalence*
- $1 - \text{Specificity} = \text{Proportion of False Positives}$

See also: *False Negative, False Positive, Likelihood Ratio, Prevalence, Sensitivity, True Negative, True Positive*

**SPONSOR–INVESTIGATOR**

(Study Design)

- An individual, company, institution, or organization (sponsor) that is responsible for conducting a clinical trial at a trial site

See also: *Clinical Research Coordinator, Investigator*

**SPIN**

(Calculations, Diagnosis)

- When a test has a high specificity, a positive result rules in the diagnosis
- **S**pecificity rules **P**ositive **I**N

See also: *Specificity*

**STABILITY COEFFICIENT**

(Study Design)

- Definition?

See also: *Test-Retest Reliability*

**STANDARD ERROR (SE)**

(Calculations)

- An estimate due to sampling error of the deviation of the sample from the true population
- Standard Error where the outcome is an event – one group: Formula for *Proportion*
  - $SE - \text{Proportion} = \text{square root of } [(p*(1-p))/N]$
- Standard Error where the outcome is an event – comparison of two group: Formulas for Absolute Relative Risk (*ARR*), Relative Risk (*RR*), Odds Ratio (*OR*); Not calculated for Number Needed to Treat (*NNT*) or Relative Risk Reduction (*RRR*)
  - $SE - ARR = \text{square root of } [(p_1(1-p_1))/n_1 + (p_2(1-p_2))/n_2]$
  - $SE - RR = SE \text{ of } \log_e(RR) = \text{square root of } [(1/r_1) + (1/r_2) - (1/n_1) - (1/n_2)]$
  - $SE - OR = SE \text{ of } \log_e(OR) = \text{square root of } [(1/r_1) + (1/r_2) - (1/(n_1-r_1)) - (1/(n_2-r_1))]$   
 where  $OR = ((r_1(n_2-r_2)) / (r_2(n_1-r_1)))$
- Standard Error where the outcome is a measurement: Formulas for *Mean, Mean Difference*

[SD = Standard Deviation – also  $s_1$  and  $s_2$ ]

  - $SE - \text{Mean} = SD / \text{square root of } N$
  - $SE - \text{Mean Difference} = \text{square root of: } \frac{[(n_1-1)s_1^2 + (n_2-1)s_2^2] * (1/n_1 + 1/n_2)}{(n_1+n_2-2)}$
- Standard Error where the outcome is in a diagnostic study: Formulas for *Sensitivity/Specificity/Predictive Values, Likelihood Ratio (LR)*
  - $SE - \text{Sens/Spec/PPV/NPV} = \text{square root of } [(p*(1-p))/N]$
  - $SE - LR+ = \text{square root of } [1/a + 1/b - 1/(a + c) - 1/(b + d)]$
  - $SE - LR- = \text{square root of } [1/c + 1/d - 1/(a + c) - 1/(b + d)]$

See also: *Confidence Interval*

## EBDM GLOSSARY

### STANDARD TREATMENT

(*Study Design, Therapy*)

- Considered to be effective in the treatment of a specific disease or condition
- A treatment currently in wide use and approved by the FDA

*See also: Experimental Drug*

### STANDARDS OF CARE

(*Study Design, Therapy*)

- Treatment regimen or medical management based on state of the art participant care

### STATISTICAL MODEL VARIABLES

(*Calculations, Study Design*)

- **Dependent Variables**
  - Outcome Variables (e.g., Disease Positive/Disease Negative, Cholesterol Levels)
- **Independent Variables**
  - Study Variables (e.g., gender exposure status)
  - Confounders (associated with risk factor, causally related to outcome)

*See also: Confounders, Dependent Variables, Independent Variables, Measurement Data Types, Outcomes*

### STATISTICAL SIGNIFICANCE

(*Calculations, Study Design*)

- The probability that an event or difference occurred by chance alone
- The results of statistical analysis of data are unlikely to have been caused by chance, at a pre-determined level of probability
- In clinical trials, the level of statistical significance depends on the number of participants studied and the observations made, as well as the magnitude of differences observed.
- An index of how probable it is that an observed difference is the result of chance rather than of the experimental treatment. This is expressed as a “*p*” value. Convention holds that the *p* value should be  $<0.05$  to call an effect statistically significant. A value of  $<0.05$  means that there is a  $<5\%$  probability that the observed results were due to chance. A statistically significant result does not always mean that the finding has clinical importance.

*See also: Clinical Significance, P Value*

### STRATIFICATION

(*Study Design, Therapy*)

- A strategy that divides the study population into two or more subpopulations and then samples separately from each
- A process to control for differences in *confounding variables*, by making separate estimates for groups of individuals who have the same values for the confounding variable

*See also: Confounding Variable*

### STRENGTH OF INFERENCE

(*Study Design*)

- The likelihood that an observed difference between groups within a study represents a real difference rather than mere chance or the influence of confounding factors, based on both *p* values and confidence intervals.
- Weakened by various forms of bias and by small sample sizes.

*See also: Confidence Intervals, P Values*

### STRUCTURED, OPEN-ENDED INTERVIEWS

(*Qualitative, Study Design*)

- Formal interviews with little flexibility in the way that questions are asked but with question formats that allow informants to respond on their own terms (e.g., “What does.... mean to you?” “How do you feel/think about...?”)

*See also: Unstructured, Open-Ended Interviews, Semi-Structured Interviews*

## EBDM GLOSSARY

### STUDY ENDPOINT (Study Design)

- A primary or secondary outcome used to judge the effectiveness of a treatment.

### STUDY TYPE (Study Design)

- Primary investigative techniques used in an observational protocol
- Types are Purpose, Duration, Selection, and Timing.

### SUBHEADINGS (MEDLINE)

- Generic terms to narrow and focus a MeSH subject heading search
- On OVID systems, the scope of each subheading is presented on the right hand panel of the search screen where subheadings are selected.
- One or several headings may be selected at a time, and "all subheadings" may be selected.

### SUBJECT (Study Design)

- An individual who participates in research
- A vulnerable subject is an individual whose willingness to voluntarily participate in a clinical trial may be unduly influenced by their expectation of benefit or fear of retaliation if they don't participate.

### SUBJECTIVE DATA (Calculations, Study Design)

- Patients' feelings and perceptions about their health status and functioning (e.g., patient satisfaction)
- See also: Baseline Data, Demographic Data, Objective Data, Quality-of-Life Data, Raw Data, Survival Data*

### SURVEYS (Study Design)

- Assumes that the answer to the research question lies in present practice or opinion; the goal is to examine a sample of individuals in order to make statements about the population from which the sample was drawn
- **Non-experimental** – the only variable that the investigator has control over is the percentage of subjects that complete the survey; a kind of **observational** study because no intervention is involved.
- When one group is compared with another, the survey is **comparative**. If a variable is known to influence one group differently than another group, the survey is **evaluative**. If it is repeated over time, the survey is **longitudinal**.
- The analysis of survey data relies on samples being random samples from the population.
- Survey questionnaires may contain open-ended questions to explore subjective perception or, more commonly, they contain closed-ended questions, the answers to which are much easier to integrate into a database. Questions should be written so as not to lead the subject into a particular answer; should be unambiguous, but not judgmental; and preferably should be quantifiable.

*Syn: Questionnaires, Random Sampling*

### SURVIVAL CURVE (Prognosis)

- A graph of the number of events occurring over time or the chance of being free of these events over time.
  - The events must be discrete and the time at which they occur must be precisely known. In most clinical situations, the chance of an outcome changes with time.
  - In most survival curves the earlier follow-up periods usually include results from more patients than the later periods and are therefore more precise.

### SURVIVAL DATA (Calculations, Study Design)

- Measurements of who remains alive at certain time points after treatment, usually expressed from the date of diagnosis or from a starting point of a treatment

*See also: Baseline Data, Demographic Data, Objective Data, Quality-of-Life Data, Raw Data, Subjective Data*

## EBDM GLOSSARY

### SYMBOLIC INQUIRY

*(Qualitative, Study Design)*

- A qualitative study design that explores how people define reality and how their beliefs are related to their actions. It is based on the assumption that humans learn about and define their world through interaction with others.

### SYMBOLIC INTERACTION

*(Qualitative, Study Design)*

- Theoretical perspective on how social reality is created by human interaction through ongoing, taken-for-granted processes of symbolic communication

### SYMPTOM

*(Study Design)*

- Any evidence of disease perceived by the patient
- May not necessarily be detected by a test or clinical examination by a doctor

### SYSTEMATIC REVIEW

*(Study Design)*

- A summary of evidence, typically conducted by an expert or expert panel on a particular topic, that uses a rigorous process (to minimize bias) for identifying, appraising, and synthesizing studies to answer a specific clinical question and draw conclusions about the data gathered.
- A review which comprehensively and systematically identifies and synthesizes literature on a given topic (sometimes called an overview), according to predetermined criteria. The unit of analysis is the primary study and the same scientific principles and rigor apply as for any study. If a review does not state clearly whether and how all relevant studies were identified and synthesized, it is not a systematic review.
- A systematic review can be performed on any type of scientific evidence, both quantitative and qualitative.
- Systematic reviews may incorporate meta-analyses. Meta-analysis is not necessary in systematic review. However, a meta-analysis that is not a systematic review is likely to be highly biased and should be used with extreme caution or not used at all.
- Key characteristics of a systematic review include:
  - Clearly stated title and objectives for the review
  - Comprehensive strategy to search for studies that address the objectives of the review (relevant studies) to include unpublished as well as published studies\
  - Explicit and justified criteria for the inclusion or exclusion of any study
  - Comprehensive list of all studies identified
  - Clear presentation of the characteristics of each study included and an analysis of methodological quality
  - Comprehensive list of all studies excluded and justification for exclusion
  - Clear analysis of the results of the eligible studies using statistical synthesis of data (meta-analysis) if appropriate and possible
  - Sensitivity analyses of the synthesized data if appropriate and possible
  - Structured report of the review clearly stating the aims, describing the methods and materials and reporting the results

*Syn: Overview*

*See also: Meta-Analysis, Review*

## T

### TECHNIQUES

*(Calculations, Study Design)*

- Tools or procedures used to generate or analyze data (e.g., interviewing, observation, standardized tests and measures, constant comparison, document analysis, content analysis, statistical analysis).
- Method-neutral
- May be used, as appropriate, in any research design – either qualitative or quantitative.

## EBDM GLOSSARY

### TEST–RETEST RELIABILITY

(*Study Design*)

- A test of an instrument's stability over time assessed by repeated measurements over time
- See also: Stability Coefficient*

### TEXTWORD

(*MEDLINE*)

- A word that is not a part of the database's controlled vocabulary/thesaurus
- Textwords (exact words) are searched only in titles and abstracts
- Useful for searching if no MeSH heading exists for a specific concept.
- Requires the use of synonyms and by-passes the mapping feature that allows "restrict to focus" and subheading selection.
- Generally, prefer thesaurus searching (i.e., using the subject or MeSH headings).

*Syn: Keyword*

*See also: MEDLINE, MeSH (MeSH Heading), Restrict to Focus*

### THEMATIC ANALYSIS

(*Qualitative, Study Design*)

- Systematic description of recurring ideas or topics (themes) that represent different, yet related, aspects of a phenomenon

### THEMES

(*Qualitative, Study Design*)

- Used to describe a structural meaning unit of data that is essential in presenting qualitative findings.

### THEORETICAL FRAMEWORK

(*Study Design*)

- The basis upon which a study is guided; its purpose is to provide a context for selecting the study's variables, including how they relate to one another as well as to guide the development of an intervention in experimental studies

### THEORETICAL SAMPLING

(*Study Design*)

- Decision making, while concurrently collecting and analyzing data, about what further data and data sources are needed to develop the emerging theory.

### THEORETICAL SENSITIVITY

(*Qualitative, Study Design*)

- A conceptual process to accompany techniques for generating grounded theory

*See also: Grounded Theory*

### THEORETIC INTEREST

(*Qualitative*)

- A desire to know or understand it better

### THICK DESCRIPTION

(*Qualitative*)

- Description that does more than describe human experiences by beginning to interpret what they mean, involving detailed reports of what people say and do, incorporating the textures and feelings of the physical and social worlds in which people move, with reference to that context (i.e., an interpretation of what their words and actions mean)

### TOXICITY

(*Therapy*)

- An adverse effect produced by a drug that is detrimental to the participant's health.
- The level of toxicity associated with a drug will vary depending on the condition which the drug is used to treat.
- Poisonous to a living organism or person
- Ability to cause grave harm or death.

*See also: Adverse Reaction, Side Effects*

## EBDM GLOSSARY

### TRANSFERABILITY

(EBP, Qualitative, Study Design)

- A criterion to evaluate qualitative research that examines the probability that the research findings have meaning to others in similar situations. This criterion asks the question: are the findings transferable?
- Demonstrated by information that is sufficient for a research consumer to determine whether findings are meaningful to other people in similar situations (analytic or theoretical vs. statistical generalizability)
- Determines if the findings from the study would have similar meanings within similar environments, contexts, or circumstances

*Syn: External Validity, Generalizability, Theoretical Generalizability*

*See also: External Validity, Fittingness*

### TREATMENT EFFECT

(Therapy)

- When the experimental treatment reduces the probability of a bad outcome

*See also: Absolute Risk Reduction*

### TREATMENT IND

(Therapy)

- FDA makes promising new drugs available to desperately ill participants as early in the drug development process as possible.
- Treatment INDs are made available to participants before general marketing begins, typically during Phase III studies.
- To be considered for a treatment IND a participant cannot be eligible to be in the definitive clinical trial.

*See also: Investigational New Drug*

### TREATMENT TRIALS

(Study Design, Therapy)

- Trials which test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy

*See also: Controlled Clinical Trials, Randomized Controlled Trials*

### TREE

(MEDLINE)

- Classified listing of subject headings, showing broader and narrower concepts.
- Can be searched selectively using the "Tools" function on OVID.

### TRUE EXPERIMENT

(Study Design, Therapy)

- A strongest type of experimental design for testing cause and effect relationships
- True experiments possess three characteristics: (1) a treatment or intervention; (2) a control or comparison group; and (3) random assignment

*See also: Randomization, Randomized Controlled Trial*

### TRUE NEGATIVE

(Diagnosis)

- A condition where the test correctly indicates that the person does not have the outcome of interest.

*See also: False Negative, False Positive, True Positive*

### TRUE POSITIVE

(Diagnosis)

- A condition where the test correctly indicates that the person has the outcome of interest.

*See also: False Negative, False Positive, True Negative*

### TRUNCATION

(MEDLINE)

- Searching for all variations based on a word stem.
- The truncation symbol on OVID is \$. (e.g., predict\$=predict, predicts, prediction, predicting, etc.)

## EBDM GLOSSARY

### **TYPE 1 ERROR** *(Study Design)*

- Mistakenly rejecting the null hypothesis when it is actually true
- See also: Type 2 Error*

### **TYPE 2 ERROR** *(Study Design)*

- Mistakenly accepting (not rejecting) the null hypothesis when it is false
- See also: Type 1 Error*

## U

### **UNCONTROLLED TRIAL** *(Study Design)*

- A trial that has no control groups – no comparisons between treatments or treatments and placebo are made
- Syn: Case Series*  
*See also: Case Series*

### **UNSTRUCTURED, OPEN-ENDED INTERVIEWS** *(Qualitative, Study Design)*

- Informal conversations that allow informants the fullest range of possibilities to describe their experiences, thoughts, and feelings
- See also: Structured, Open-Ended Interviews*

### **UTILITY** *(Decision Analysis)*

- The preference or desirability of a particular outcome.
- See also: Decision Analysis, Decision Tree*

## V

### **VALIDITY** *(Study Design)*

- The extent to which a variable or intervention measures what it is supposed to measure or accomplishes what it is supposed to accomplish (i.e., the extent to which the results of a study can be believed)
- See also: External Validity, Internal Validity*

### **VALIDITY OF STUDY FINDINGS** *(Study Design)*

- Whether or not the results of the study were obtained via sound scientific methods
- See also: External Validity, Internal Validity, Validity*

### **VALID MEASURES** *(Study Design)*

- Those that measure the construct that they are intended to measure (e.g., an anxiety measure truly measures anxiety, not depression)
- See also: External Validity, Internal Validity, Validity*

### **VARIABLE** *(Study Design)*

- Any attribute or characteristic that can change or that may have more than one value over time (e.g., height, weight, religion, age, medical characteristics)
- See also: Patient Characteristics*

### **VOLUNTARY** *(Study Design)*

- Free of coercion, duress, or undue inducement
- In a clinical trial, refers to a participant's decision to enroll

## EBDM GLOSSARY

### **VOLUNTEER SAMPLE**

*(Study Design)*

- A sample obtained by solicitation or advertising for participants who meet study criteria

## W

### **WASHOUT PERIOD**

*(Study Design)*

- Time in the course of a clinical trial when participants receive no treatment for the indication under study

### **WEIGHTED MEAN DIFFERENCE (WMD)**

*(Calculations, Study Design)*

- In a meta-analysis, a different statistical technique used to deal with different types of outcome. Outcomes can either be discrete or continuous.
  - The most common type of discrete outcomes are dichotomous, yes/no outcomes e.g. death/survival, occurrence of disease/no occurrence of disease. There is no in-between with dichotomous outcomes, they either happen or they don't. These outcomes can be compared using an Odds Ratio.
  - Other outcomes are measured on a continuous scale, e.g. blood loss, length of hospital stay, height, etc. Continuous outcomes cannot be compared using Odds Ratio as a statistical method. WMD is used.
  - Interpretation of the results is exactly the same as with odds-ratio results, e.g. a result lying to the left of the line of no effect (i.e. a WMD of less than 0) means that the outcome under investigation is less likely to occur in the treatment group than in the control group.
  - Confidence intervals are calculated around WMD too and again should be interpreted in the same way as with odds-ratio.

*See also: Confidence Intervals, Mean, Odds Ratio*

### **WITHDRAW**

*(Study Design)*

- In a trial, to end a patient's participation before he or she reaches the designated end point
- See also: End Point*

## X

## Y

### **YIELD**

*(Study Design)*

- The number of hits obtained by a literature search; this can be per database and/or total yield
- There can be several levels of yield, e.g., first yield and final yield, that is, only those studies that were kept for review

*See also: Hits*

## Z

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<http://nursing.asu.edu/caep/resources/glossary.htm>

Bandolier

<http://www.medicine.ox.ac.uk/bandolier/glossary.html>

CDC Community Guide

[http://www.thecommunityguide.org/library/ajpm355\\_d.pdf](http://www.thecommunityguide.org/library/ajpm355_d.pdf)

Centre for Clinical Effectiveness – MONASH University

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Centre for Evidence Based Medicine

<http://www.cebm.utoronto.ca/glossary/>

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<http://www.cche.net/usersguides/main.asp>

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<http://www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME>

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ECRI – Emergency Care Research Institute

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