

APPENDIX 1

CLASSIFICATION OF STUDY DESIGN FOR CLEARINGHOUSE RESEARCH IN DISABILITY SYSTEM

EXPERIMENTAL STUDY	OBSERVATIONAL STUDY	NOT AVAILABLE
1. Randomized Controlled Trial 2. Quasi-Experimental Study (Controlled Trial, Uncontrolled Trial, Pre & Post Study Design) 3. Lab based	1. Cohort (Incidence, Longitudinal Study) Study 2. Case-Control Study/ Retrospective 3. Cross-Sectional (Prevalence Study) Study 4. Case Report /Case Series 5. Systematic review /Meta Analysis 6. Qualitative Study 7. Mixed study (Qualitative + Quantitative) 8. Review	

- 1) **Experimental Studies:** The hallmark of the experimental study is that the allocation or assignment of individuals is under control of investigator and thus can be randomized. The key is that the investigator controls the assignment of the exposure or of the treatment but otherwise symmetry of potential unknown confounders is maintained through randomization. Properly executed experimental studies provide the strongest empirical evidence. The randomization also provides a better foundation for statistical procedures than do observational studies.

- a. **Randomized Controlled Trial (RCT):** An **experiment** in which two or more interventions, possibly including a control intervention or no intervention, are compared by being **randomly** allocated to participants. In most trials one intervention is assigned to each individual but sometimes assignment is to define groups of individuals (for example, in a household) or interventions are assigned within individuals (for example, in different orders or to different parts of the body).

- i. **Cross over trial:** A type of **clinical trial** comparing two or more **interventions** in which the **participants**, upon completion of the course of one treatment, are switched to another. For example, for a comparison of treatments A and B, the participants are randomly allocated to receive them in either the order A, B or the order B, A. Particularly appropriate for study of treatment options for relatively stable health problems. The time during which the first **intervention is** taken is known as the first period, with the second intervention being taken during the second period.
 - b. **Quasi-Experimental Study:** A quasi-experimental study is a type of evaluation which aims to determine whether a program or intervention has the intended effect on a study's participants. Quasi-experimental studies take on many forms, but may best be defined as lacking key components of a true experiment. While a true experiment includes (1) *pre-post test design*, (2) a *treatment group* and a *control group*, and (3) *random assignment* of study participants, quasi-experimental studies **lack one or more** of these design elements.
 - i. **Controlled Trial:** A **clinical trial** that has a **control group**. Such trials are not necessarily randomized
 - ii. **Uncontrolled Trial:** A **clinical trial** that has no **control group**.
 - iii. **Pre & Post Study Design:** Type of experimental study which have pre test, intervention and then followed by post test.
 - c. **Lab based:** A prospective, analytical, experimental study using primary data generated in the laboratory environment.
- 2) **Observational Studies:** The allocation or assignment of factors is not under control of investigator. In an observational study, the combinations are self-selected or are "experiments of nature". For those questions where it would be unethical to assign factors, investigators are limited to observational studies. Observational studies provide weaker empirical evidence than do

experimental studies because of the potential for large confounding biases to be present when there is an unknown association between a factor and an outcome. The symmetry of unknown confounders cannot be maintained. The greatest value of these types of studies (e.g., case series, ecologic, case-control, cohort) is that they provide preliminary evidence that can be used as the basis for hypotheses in stronger experimental studies, such as randomized controlled trials.

- a. **Cohort (Incidence, Longitudinal Study) Study:** A prospective, analytical, observational study, based on data, usually primary, from a follow-up period of a group in which some have had, have or will have the exposure of interest, to determine the association between that exposure and an outcome. Cohort studies are susceptible to bias by differential loss to follow-up, the lack of control over risk assignment and thus confounder symmetry, and the potential for zero time bias when the cohort is assembled. Because of their prospective nature, cohort studies are stronger than case-control studies when well executed but they also are more expensive. Because of their observational nature, cohort studies do not provide empirical evidence that is as strong as that provided by properly executed randomized controlled clinical trials.

- b. **Case-Control Study/ Retrospective:** A retrospective, analytical, observational study often based on secondary data in which the proportion of cases with a potential risk factor are compared to the proportion of controls (individuals without the disease) with the same risk factor. The common association measure for a case-control study is the odds ratio. These studies are commonly used for initial, inexpensive evaluation of risk factors and are particularly useful for rare conditions or for risk factors with long induction periods. Unfortunately, due to the potential for many forms of bias in this study type, case control studies provide relatively weak empirical evidence even when properly executed.

- c. **Cross-Sectional (Prevalence Study) Study:** A descriptive study of the relationship between diseases and other factors at one point in time (usually) in a defined population. Cross sectional studies lack any information on timing of exposure and outcome relationships and include only prevalent cases.

- d. **Case Series:** A descriptive, observational study of a series of cases, typically describing the manifestations, clinical course, and prognosis of a condition. A case series provides weak empirical evidence because of the lack of comparability unless the findings are dramatically different from expectations. Case series are 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. Unfortunately, the case series is the most common study type in the clinical literature.

- e. **Case Report:** Anecdotal evidence. 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.

- f. **Systematic review:** A review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review. Statistical methods (**meta-analysis**) may or may not be used to analyse and summarize the results of the included studies.

- g. **Meta Analysis:** The use of statistical techniques in a **systematic review** to integrate the results of included studies.

- h. **Qualitative:** Qualitative research is a collection of methodological approaches used to study the social world, in which activities are studied in naturalistic settings rather than under experimental conditions, and where the subjective experiences of ordinary people are of greater interest than objective categories and measurements of researchers. Qualitative research uses a variety of methods, including interviews, observations of naturally-occurring activities, detailed description and ethnography, conversation and discourse analysis, analysis of text and semiotic representations, personal accounts, biographies and oral histories

- i. **Mixed study (Qualitative + Quantitative):** A mixed method approach is one in which the researcher collects, analyzes, and integrates both quantitative (quan) and qualitative (qual) data in a single study or in multiple studies in a sustained program of inquiry.

- j. **Review:** A review on specific health care topics – but ones which do not necessarily follow systematic evidence-based criteria.

3) **Not Available**

When there is insufficient information in the article to determine the exact type of the study design.