

# Study Design

Clinical Epidemiology Concepts and Glossary

### Types of research

- Observational
  - Descriptive
  - Analytic
- Experimental



### **Descriptive Research**

- Case reports
- Case series
- Cross sectional studies
  - simple cross-sectional studies determining, for example, how common (prevalence) is a condition? More complex cross-sectional involving comparisons are dealt with under analytic research.
- Longitudinal studies
  - Subjects must be followed up one or more times to determine their prognosis or outcome

#### **Analytic Research**

- Ecological studies
- Cross-Sectional, two-group studies
- Case control studies (retrospective)
  - Nested case control studies
- Cohort studies (prospective)
  - Historical cohort studies



#### **Intervention Studies**

- Controlled trials
  - Concurrent (parallel) controls
    - Randomized
    - Not randomized
  - Sequential controls
    - Self controlled
    - Crossover
- Studies without controls



# **Systematic Review**

- Systematic reviews can help practitioners keep abreast of the medical literature by summarizing large bodies of evidence and helping to explain differences among studies on the same question.
- A systematic review involves the application of scientific strategies, in ways that limit bias, to the assembly, critical appraisal, and synthesis of all relevant studies that address a specific clinical question.
- A meta-analysis is a type of systematic review that uses statistical methods to combine and summarize the results of several primary studies.



# **Meta Analysis**

- Meta-analysis is not an exact science.
- In putting many studies together, invariably some assumptions have to be made.
- Different methods of calculations are therefore developed using different assumptions. Those who use meta-analysis should therefore be familiar with the theories behind these methods.



# **Steps of Meta Analysis**

- The first step is to create the Effects Table. This effects table is then used for all subsequent procedures.
- The second step is to decide whether it is legitimate to combine the list of studies, so that some estimation of homogeneity is carried out. If the list is heterogeneous, then the reasons is sought, and the list is rearranged so that homogenous sub-lists are selected and used.
- The third step is to combine the studies to produced a summary conclusion. A weighted averaged Effect and its variance is produced.



#### Meta Analysis difference between two Means

Treatment Group		Placebo Group			G4 I	
Number	Mean	SD	Number	Mean	SD	Study
134	5.96	4.24	113	6.82	4.72	S1
175	4.74	4.64	151	5.07	5.38	S2
137	2.04	2.59	140	2.51	3.22	S3
184	2.7	2.32	179	3.2	2.46	S4
174	6.09	4.86	169	5.81	5.14	S5
754	4.72	5.33	736	4.76	5.29	<b>S6</b>
209	10.1	8.1	209	10.9	7.9	S7
1151	2.82	3.05	1122	3.01	3.32	S8



# Meta Analysis OR

	Study Id	Treatment Group		Placeb		
		Death	Survive	Death	Survive	Treatment
	S1	28	176	51	151	Diet
	S2	70	215	38	109	Drug
	S3	37	119	40	79	Drug
	S4	2	86	3	27	Drug
Ī	S5	0	30	3	30	Drug
	S6	61	218	82	194	Drug
	S7	41	165	55	151	Diet



# Meta Analysis OR( Match Design )

(+, +)	(-, +)	(+, -)	(-, -)	Study	Diet
25	18	6	17	S1	A
44	35	15	34	S2	A
53	19	21	22	S3	В
26	25	10	19	S4	A
73	35	49	48	S5	В
58	39	37	66	S6	В
26	47	10	16	S7	A
42	32	18	29	S8	В
56	42	14	25	S9	В
23	25	8	13	S10	A
71	41	21	42	S11	В



#### Meta Analysis HR

LogHR	SELogHR	VarLogHR	Study
-0.135	0.07994	9.88036E-05	S1
-0.257	0.0734	0.00017956	S2
-0.461	0.0492	0.00242064	S3
0.203	0.0401	0.00160801	S4
-0.798	0.1203	0.00041209	S5
-0.324	0.0933	0.00017689	<b>S6</b>
-0.551	0.0577	0.00332929	S7
-0.682	0.1084	0.00007056	S8
-0.334	0.1385	0.00148225	S9
-0.384	0.0472	0.00222784	S10



#### Meta Analysis: Example 2

Study	Treated			Control		
	Mean	SD	n	Mean	SD	n
1	0.30	1.26	162	0.42	1.28	175
2	0.17	0.90	15	0.83	0.98	20
3	0.20	1.10	30	0.45	1.12	32
4	0.17	1.38	27	0.42	1.36	25

Diana B Petitti: P117

Summary mean difference ~(0.00, 0.44)



#### Meta Analysis: Example 2

	Treatment	Control				
European Stroke Prevention Study Group (1987): OR=0.64						
Events	182	264				
Nonevents	1068	986				
United Kingdom Tran	United Kingdom Transient Ischemic Attack Aspirin Trial: OR=0.82					
Events	348	204				
Nonevents	1273	610				
Summary OR=0.72 (0.63, 0.84)						
Diana B. Petitti: P101						