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Critical Appraisal: Study Design Issues

Hierachy of evidence:

1. SRV = Systematic review of RCTs
2. RCT = Randomized clinical trials
3. PRO = Prospective studies
4. RET = Retrospective studies
5. XSS = Cross-sectional surveys
6. CSE = Case series
7. CRE = Case reports

Strengths & Weaknesses:

Parameter	XSS	RET	PRO	RCT
Cost	Low	Low	High	High
Setup	Easy	Easy	Complex	Complex
Recall bias	Low	High	Low	Low
Rare diseases	Poor	Good	Poor	Good
Rare exposures		Disadvantage	Advantage	Deliberate
Prolonged diseases		Advantage	Disadvantage	
Latent diseases		Advantage	Disadvantage	
Follow-up period	None	Short	Long	Specified
Attrition rate		Low	High	Moderate
Estimate incidence		Poor	Good	
Estimate prognosis		Fair	Good	
Examine several risks		Good	Poor	
Examine several outcomes		Poor	Good	
Inference to target pop'n	Strong	Fair	Strong	Strong

Selection process:

General population
---> Applicability of research question =
= Target population
---> Apply inclusion and exclusion criteria =
= Eligible population
---> Apply random sampling
=Sample population
---> Randomization
= Experimental group & Control Group

Confounding factors (CF): Any factor associated with both the variable of interest AND the outcome of the study.
Intrinsic source of error.
Covert.

Management of CF at <u>design</u> stage:

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Matching = Selecting control subjects who share the same confounding factors as the experimental group.
* Overmatching = too artificial experimental group.

Restriction = Exclude confounding factors from control and experimental group.
* Over-restriction = sample population far removed from target.

Randomization = All subjects have equal chance of being allocated to either group, hence confounding factors become equally likely in both.

Management of CF at <u>result analysis</u> stage:

Data stratification = Separating all collected data (i.e. Alcoholic / Non-A) by a confounding factor (Smoker / Non-S).

Statistical modelling = Complex statistical manoeuvres to determine the exact nature of the relationship between variables and outcomes, along with impact of CFs.

Bias: Overt systematic error, undermining results and subsequent conclusions.

Can occur at any stage of a study: Design - Data collection - Result analysis

Types (OSPRI): Observer - Selection - Prevalance - Recall - Information

Observer Bias: Subjective influence on recording of observations.

$ Blinding: Subjects unaware as to which group (control/experimental) they belong.
Single = Subjects
Double = Subjects + Clinicians
Triple = Subjects + Clinicians + Analyst

$ Structured interviews: Reduce element of subjectivity.

$ Multiple assessors: Minimize impact of individual assessor bias.
* Ineffective if all are biased. Must have pre-training.

Selection Bias: Factor associated with variable affects probability of being selected for participation in study, leads to unrepresentative sample population.

$ Simple random sampling: Random selection from population.

$ Systematic sampling: First random, then every *n*th patient.

$ Stratified random sampling: Population divided into strata, then random sampling applied to each strata.

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$ Multistage random sampling: Random sampling applied at 2+ stages in the selection process (i.e. centre + subject).

$ Cluster sampling: Initial random sampling of centres only, then all subjects within these taken.

Prevalence Bias: Specialized subjects chosen (rare disorder etc.) which tend to have more chronic or severe forms, less applicable to rest of target population.
i.e. Obese patients from a specialist obesity clinic population - likely to be more obese or have associated morbidity.

Recall Bias: Over-recollection of perceived past exposures in a disease population when compared to a healthy population.
Increased contact with health services = increased disease awareness.
Response priming = result of previous similar questioning.
Problem especially with retrospective studies.
$ Use of objective instruments in information gathering (i.e. records)
$ Control group with another disease to reduce impact of recall bias

Information Bias: Systematic misclassification of data, arising from:
* Poor theoretical understanding of disorder or associated factors
* Carelessness or errors in recording data
* Use of instruments with poor validity, variable measured inaccurately
* Responder-related bias

Reliability: Constitency of test results on repeat measurements.

Inter-rater = Extent of agreement between two raters measuring simultaneously.
Test-retest = Extent of agreement of initial results with repeat measurements taken later.
Alternate forms = Extent of agreement between two similar tests measuring a variable simulataneously.

Validity:

Face = Measures what test purports to measure.

External = Generalizability of results to wider population.

Internal = Extent to which design & methodology allow test results to reflect true picture.

Content = Extent to which variables are related to that which the test instrument measures.

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Predictive = Extent to which test predicts what it logically should.

Concurrent = Extent to which test distinguishes what it should.

Cross = Stability of test when applied to different subgroups of a population.

Convergent = Extent of correlation with other, similar tests.

Discriminant = Extent of dissimilarity with other, dissimilar tests.