CRITICAL APPRAISAL

Professor Dr. Syed Hatim Noor
Unit of Biostatistics and Research Methodology
School of Medical Sciences
Universiti Sains Malaysia
Kubang Kerian, Kelantan

What is critical appraisal?

- Is a systematic process that allows to assess the value of published research upon which one needs to base decisions
- Value includes validity and relevance
- It involves judging the quality of research that has undertaken and assessing the relevance of its results to your own situation

- Evidence-based medicine – finding as well as appraising
- Bridging the gap between findings of research and practice

→It is important to be able to identify quickly the key features of a study when you read a published article

Terms used in CAW

- A ready reference for using the critical appraisal worksheet

Research question

- The essential question the study is designed to answer
- Most studies are concerned with answering one of four types of following questions

Research question

- What is the magnitude of a health problem or health factor?
- What is the efficacy of an intervention?
- What is the casual relation between one factor (or factors) and the disease or outcome of interest?
- What is the natural history of a disease?

Hypothesis

- This is a testable statement that describes the nature of the proposed relationship between two /more variables of interest
- Example:
- There is an association between smoking and coronary heart disease

Study factor

- Exposure/variable of interest to be related to the health problem, disease or outcome of interest
- Known as the independent variable
- e.g. Study of salt intake and its relationship to blood pressure, the study factor is salt intake
- Must be quantifiable, but it may be assessed by a variety of means both direct & indirect, objective & subjective

Outcome factor

- This is the event or occurrence that is supposed to have happened as a result of the influence of the study factor
- The outcome factor is blood pressure, as it is being influenced by the study factor, salt intake
- Also known as the dependent variable
- Measured by a variety of methods both direct and indirect, objective & subjective

Reference population

- Population to whom the researcher wished to refer the results of the study
- Also known as the target population
- Example : A researcher would like to study the prevalence of hearing problem among Malaysian secondary school children
- Reference population: All secondary school children in Malaysia

Source population

- A broad group of people from whom the subjects will be obtained
- A subset of the reference population
- Example: Secondary school children in Kelantan state

Sampling frame

- The List of potential subjects from which a sample will be drawn
- Represents source population
- A sample is collected from all or part of the frame
- Example: class lists of secondary schools in Kota Bharu district

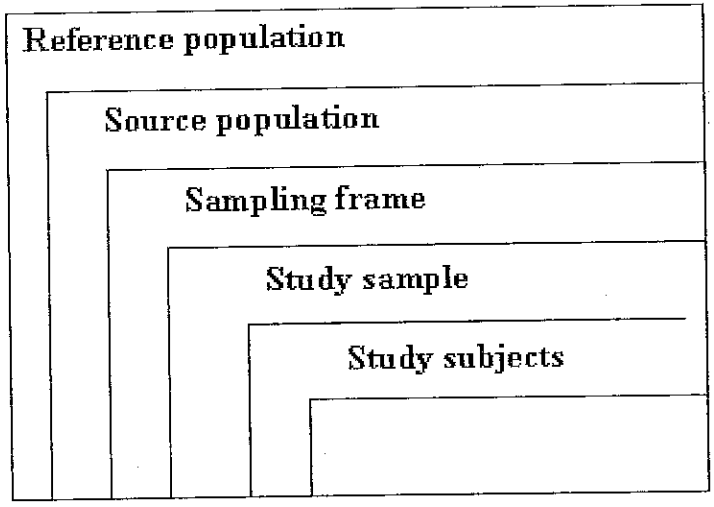
Study sample

- Subjects who are selected to take part in the study
- The subset selected by random or non-random means from the sampling frame
- Example: a random selection of 25% of each class in each of 8 schools which have been randomly selected from 24 secondary schools in Kota Bharu district

Study subjects

- The actual participants in the study who provided data
- Not all of the people in study sample are available or willing to participate
- Example: secondary school students who had parental approval to take part in the study

Sampling



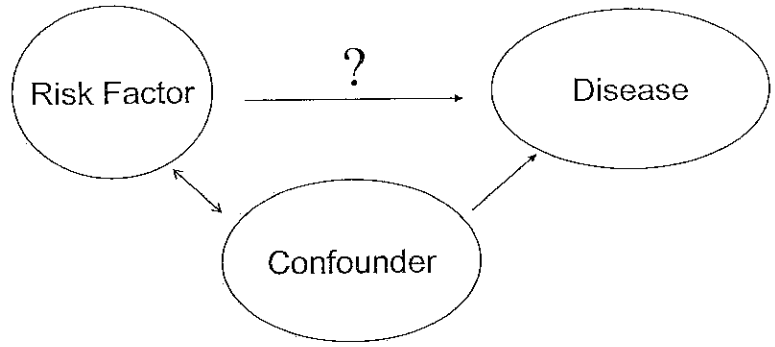
Bias

- Any effect at any stage of investigation tending to produce results that depart from the truth
- Occur as a result of the way samples were selected, the way an intervention was administered or the way data was collected and analyzed

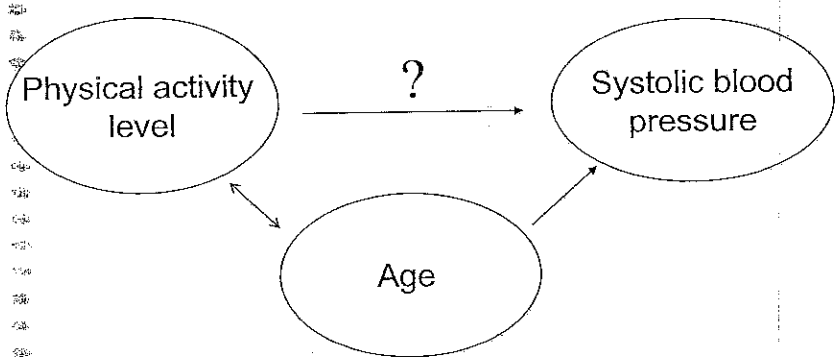
Confounding

- A confounder is a factor that distorts the apparent magnitude of the effect of the study factor on the outcome factor

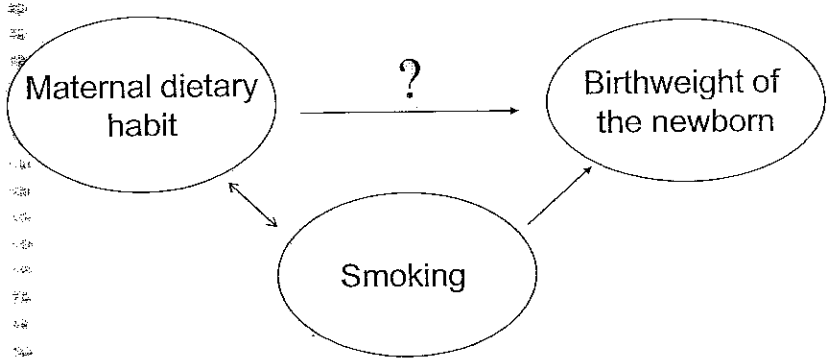
Confounding



Example of confounding



Example of confounding



Confounding

- Influence of maternal nutrition on the birth weight of newborns (hypothesized that women with a poor diet will have low birth weight infants)
- smoking is a confounding factor if women with poor dietary habits are also more likely to smoke (as smoking itself is a risk factor for low birth weight infants)

Study power

- Study will detect a statistically significant difference when a difference really exists

Internal validity

- The group being compared(treated vs non-treated, exposed-no exposed, cases vs controls) have been selected, the measurements undertaken and the analysis conducted in such a way that the results can be considered a good approximation to the truth
- Threats to internal validity come from bias

External validity

- The subjects in the study are selected and described in such a way that the results, given internal validity, can be applied or generalized outside of the study sample to the reference population
- It is often useful to critically examine the inclusion and exclusion criteria for the study

External validity

- Threats to external validity come from the selection and sampling of subjects for a study
- Need to have a clear idea of where the subjects have come from and the group to whom the researchers wish to refer results

Measurement issues

- Measurement validity
- Reilability

Measurement issues (validity)

- Refers to the expression of the degree to which a measurement measures what it is supposed to measure
- Essential quality for a measurement
- Example: testing content and construct validity of a questionnaire

  Validity testing of a test kit

Measurement issues (reliability)

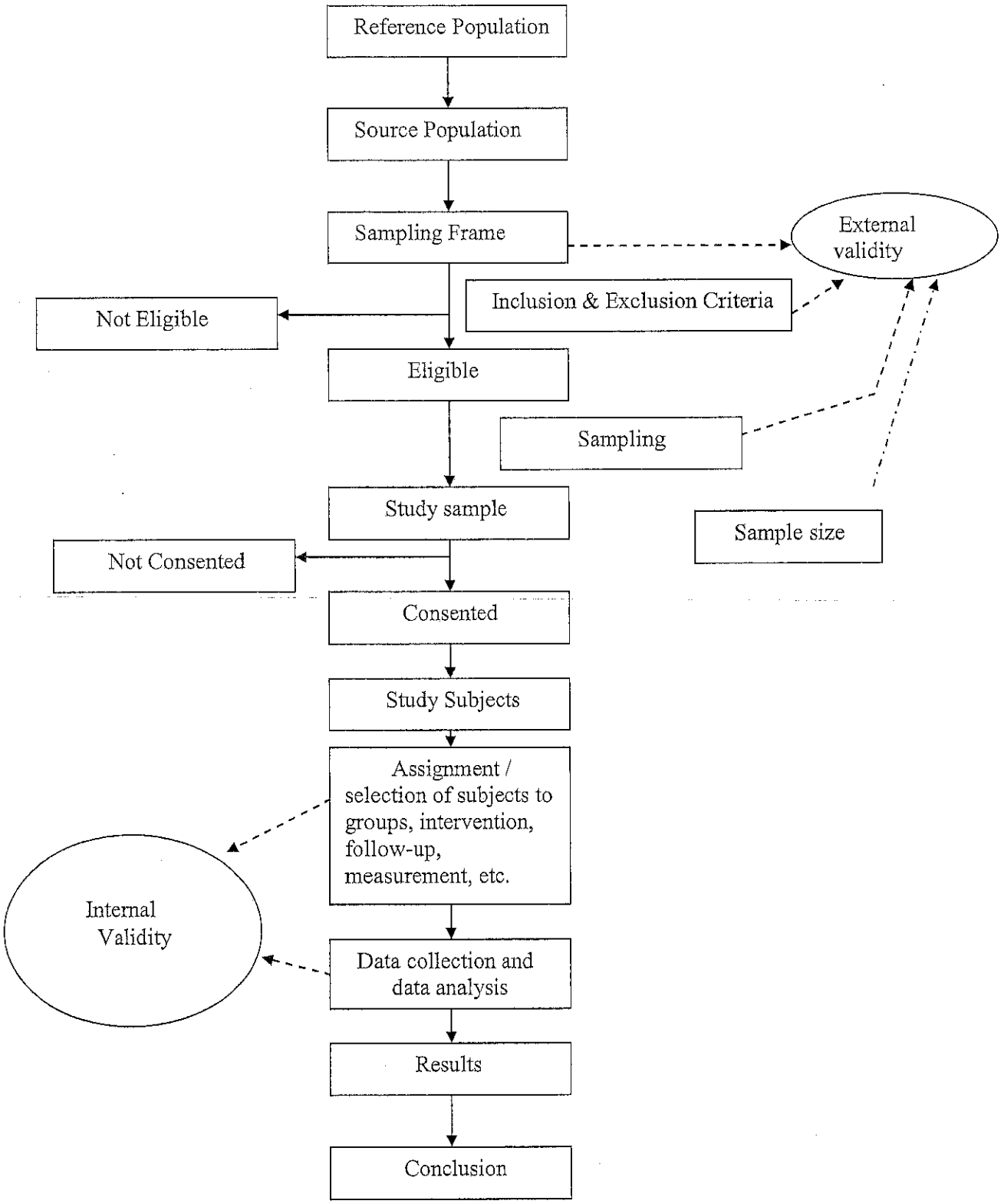
- Refers to the accuracy and precision of a measurement tool
- A measure of the degree of stability exhibited when the measurement is repeated under identical conditions
- Reliability as consistency
- Example: testing reliability of a questionnaire

Critical appraisal worksheet (CAW)

A general approach to critical appraisal of scientific literature

CRITICAL APPRAISAL WORKSHEET

Can you find this information in the paper?	Is the way this was done a problem?	Does this problem threaten the validity of the study?
1. What is the research question?	Is it concerned with the impact of an intervention, causality, or determining the magnitude of a health problem?	
2. What is the study type?	Is the study type appropriate to the research question?	If not, how useful are the result produced by this type of study?
3. What are the outcome factors and how are they measured?	a) Are all relevant outcomes assessed? b) Is there measurement error?	a) How important are omitted outcome? b) Is measurement error an important source of bias?
4. What are the study factors and how are they measured?	Is there measurement error?	Is measurement error an important source of bias?
5. What important potential confounders are considered?	Are potential confounders controlled for?	Is confounding an important source of bias?
6. What are the sampling frame and sampling method?	Is there selection bias?	Does this threaten the external validity of the study?
7. In an experimental study how were the subjects assigned to group? In a longitudinal study how many reached final follow-up? In a case-control study are the controls appropriate?		Does this threaten the internal validity of the study?
8. Are statistical tests considered?	Were the tests appropriate for the data? Are confidence intervals given? Is the power given if a null result?	
9. Are the results clinically/socially significant?	Was the sample size adequate to detect a clinically/socially significant result?	Is the study useful or is the result inconclusive?
10. What conclusion did the authors reach about the study question?	Do the results apply to the population in which you are interested?	


Reference Population
Source Population
Sampling Frame
External validity
Inclusion & Exclusion Criteria
Not Eligible
Eligible
Sampling
Study sample
Sample size
Not Consented
Consented
Study Subjects
Assignment / selection of subjects to groups, intervention, follow-up, measurement, etc.
Internal Validity
Data collection and data analysis
Results
Conclusion

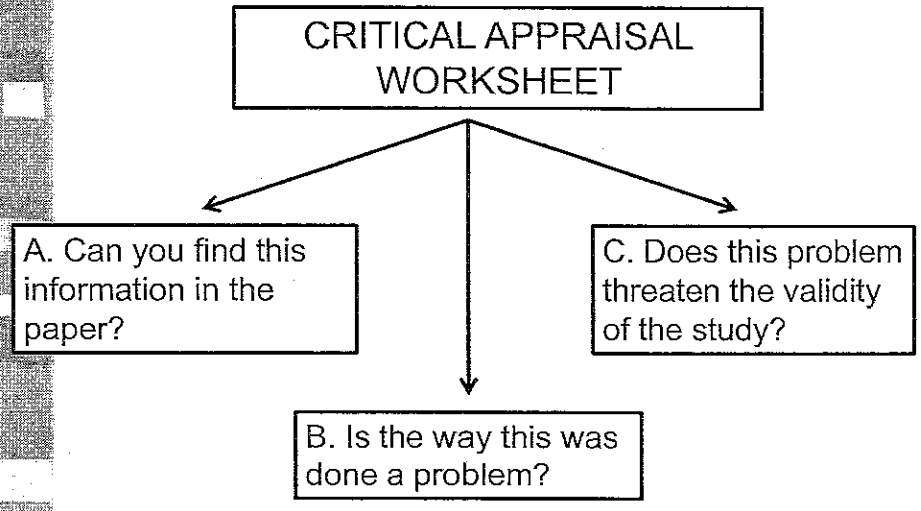
CRITICAL APPRAISAL EXAMPLE

Professor Dr. Syed Hatim Noor
Unit of Biostatistics & Research Methodology
School of Medical Sciences
Universiti Sains Malaysia

Needleman, H.L. Schell, A. Bellinger, D. Leviton, A. and Allred,E.N. The long-term effects of exposure to low doses of lead in childhood. An 11-year follow-up report. N. Engl. J. Med, 1990; 322(2): 83-88.

Critical appraisal worksheet (CAW)

A general approach to critical appraisal of scientific literature



What is the research question?

- Is exposure to low doses of environmental lead, as measured by dentine lead in primary teeth, a risk factor for impaired neurobehavioral function?
- Is it concerned with the impact of an intervention, causality, or determining the magnitude of a health problem?
- It is concerned with investigating an association as part of collecting evidence for causal relationship

What is the study type?

- A longitudinal study

Is the study type appropriate to the research question?

- An appropriate design to answer this question?
- A good design

If not, how useful are the result produced by this type of study?

What are the outcome factors and how are they measured?

- Behavioral evaluation
- Baker and Letz Neurobehavioral Evaluation test, other tests of learning, naming figure drawing and word identification
- Self-reported data on delinquency and school record information on performance, attendance, etc.

a) Are all relevant outcomes assessed?

- Relevant outcomes are assessed
- Authors do not provide information on the validity and reliability of the tests

b) Is there measurement error?

- ??? Measurement error – questionable

a) How important are omitted outcome?

- No idea as they were not mentioned

b) Is measurement error an important source of bias?

- A very important source of bias

What are the study factors and how are they measured?

- Lead exposure
- Measured by chemical analysis of lead levels in at least one shed promary tooth
- Data treated in two ways:
- Numerical
- Categorical (high>20 ppm, medium10-19 ppm, low<10 ppm)

- Other factors
- Venous blood taking discontinued in 48 subjects because of level well below CDC definition of undue lead exposure
- ???Should have been continued?

- Other study factors
- Head injuries and alcohol use – obtained from where?

Is there measurement error?

- No information on validity and reliability of using dentine lead as a measure of lead exposure

Is measurement error an important source of bias?

- Still an important source of bias

What important potential confounders are considered?

- History of head injuries, alcohol use
- Others possible confounder not considered – drug use, meningitis, encephalitis, other toxic exposure to barin

Are potential confounders controlled for?

- Yes
- Design stage – inclusion and exclusion criteria
- Statistical analysis

Is confounding an important source of bias?

- Yes. As it can give misleading relationship between study factors and the outcome factor

What are the sampling frame and sampling method?

- Reference population – children
- Source population – those who enrolled in the first and second grades in the Chelsea and Somerville, Massachusetts school system
- Sampling frame – 70% of children who provided at least one of their shed primary teeth for lead analysis (2335)
- Sampling method – not mentioned

Is there selection bias?

- Yes. Selection bias
- English speaking children only
- Authors admitted that 132 subjects who participated in the follow-up study were not representative of the original group studied

Does this threaten the external validity of the study?

Yes. Most likely.

In an experimental study how were the subjects assigned to group?

In a longitudinal study how many reached final follow-up?

In a case-control study are the controls appropriate?

Other possible sources of biases

- Recall bias – self-reported measures of delinquency
- Confounding bias – other possible confounders- not considered
- Incomplete follow-up – less than 50% of original study population were able to be follow-up

Does this threaten the internal validity of the study?

Yes. Definitely.

Are statistical tests considered?

- Yes.
- Univariate analysis – Chi-square and t-test
- Multivariate analysis –
- For continuous outcome – Multiple linear regression
- For dichotomous outcome – Multiple logistic regression

Were the tests appropriate for the data?

- Overall the statistical analyses – appropriate

Are confidence intervals given?

- Confidence intervals given for odds ratio in the logistic regression

Is the power given if a null test?

- Power of the study – not reported

Are the results clinically or socially significant?

Was the sample size adequate to detect a clinically/socially significant result?

Is the study useful or is the result inconclusive?

What conclusion did the authors reach about the study question?

- Exposure to lead in childhood is associated with deficits in central nervous system functioning that persist into young adulthood

- Difficult to say whether the sample size was sufficient to detect results are clinically / socially significant
- Sample size issues were not considered

Do the result apply to the population in which you are interested?

- Authors provide strong evidence for an association
- However, the poor response rate and large loss to follow –up introduce so much doubt about internal and external validity
- Final conclusion is doubtful