

Research Methodology

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The lectures will answer the following questions

- ► Why we do research?
- ▶ How to plan a scientific research?
- ▶ What is the best design for my research?
- ▶ How to select subjects for research?
- ▶ How to plan for data collection?
- ► How to manage & analyse data?
- ► How to report the findings?





Research Methodology Workshop

for Oral Health Division, JKNP 22-24th April 2014

Programme

- ► Day 1 Reason, rationale & conceptual framework; Study design & Sampling plan
- ▶ Day 2 Data collection & data dictionary; Statistical analysis & dummy table
- ▶ Day 3 Writing proposal & report



Part 1 – Reasons & Rationale

Part 1 – Reasons & Rationale

Why we do research?

- ▶ To answer curiosity
- ▶ To solve problem
- ▶ To find alternative
- ▶ To fulfil academic requirements
- ▶ To get promotion



When the topic is important?

- ▶ When it fulfils the need
- ▶ Humankind need
- ► Country need
- ▶ Service need
- ▶ But never a personal need



Type of research

- ► Descriptive e.g. prevalence study
- ► Discovery e.g. new biomarker, new pathway (mostly lab study)
- ▶ Proof causality (hypothesis testing) e.g. cause/causes of a disease or abnormality, reason for certain behaviour, clinical trial (a drug is better than others) etc

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The steps

- 1. Organise research idea
- 2. Understand the problem → do literature review, construct conceptual framework
- 3. Formulate objective
- 4. Know your target population
- 5. Choose best study design
- 6. Choose best sampling method
- 7. Calculate sample size
- Determine variables to collect → prepare data dictionary

- 9. Validate research instrument
- 10. Plan data collection, plan for quality control
- 11. Plan statistical analysis, prepare dummy table
- 12. Estimate & secure budget
- 13. Get approval
- 14. Collect data, monitor quality
- 15. Analyse data
- 16. Report finding





Literature review

- ► Search strategically
 - ► Identify important keywords
 - ► Identify authorities in the subject matter
 - ▶ Observe the dates
- ► Manage bibliographic well use software (e.g. EndNote, Mendeley, Papers)

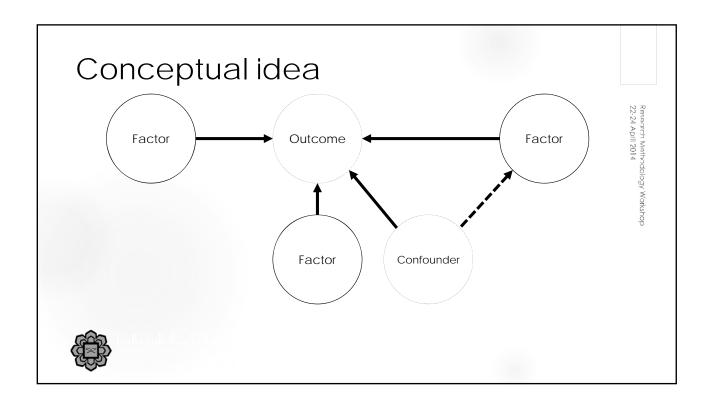


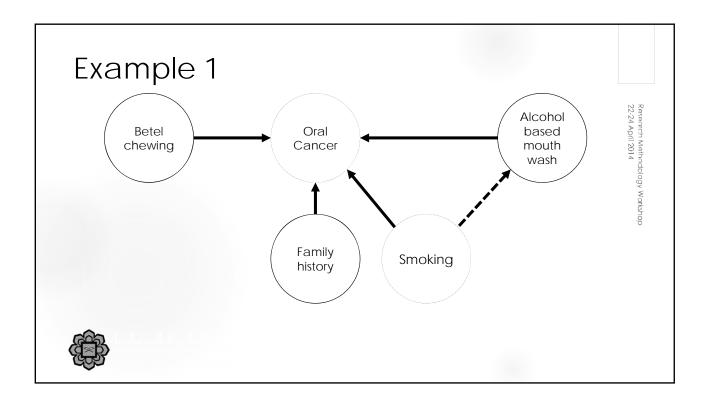
Part 2 – Conceptual Framework

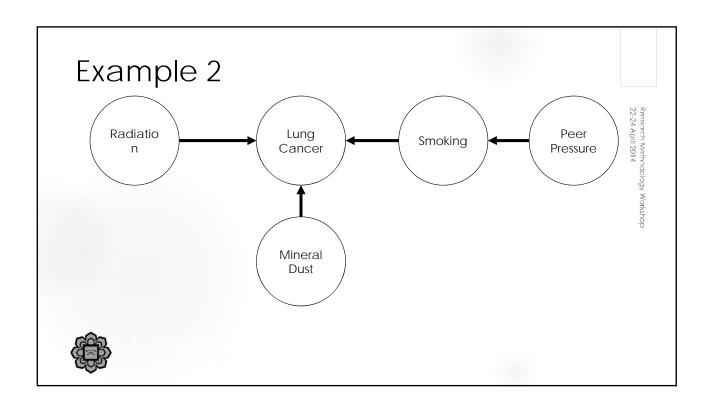
Build the concept

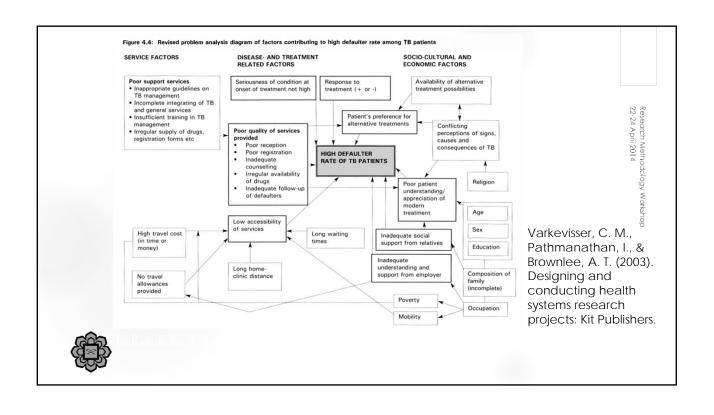
- 1. Main outcomes
- 2. Explanatory (exposures, factors) variables
- 3. Confounding variables

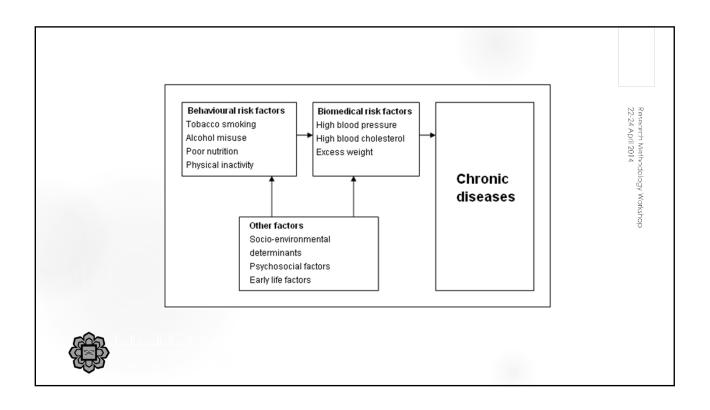


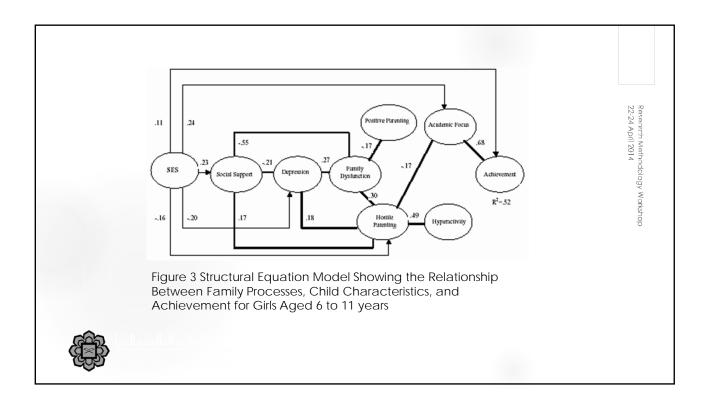


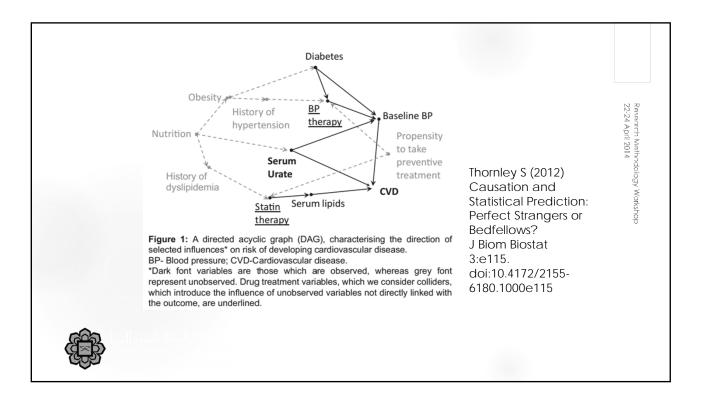












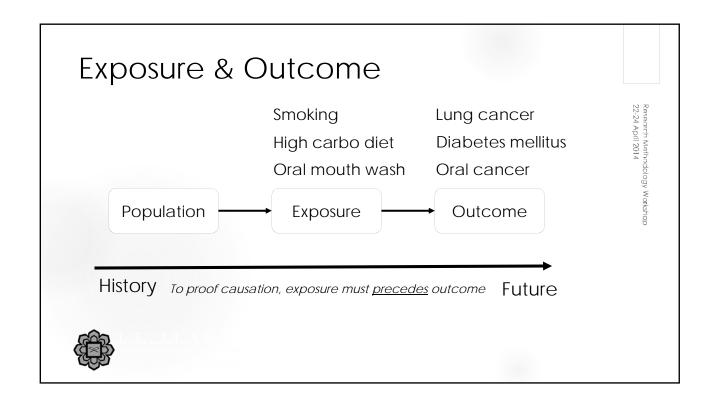
Group Work #1 (2 hours)

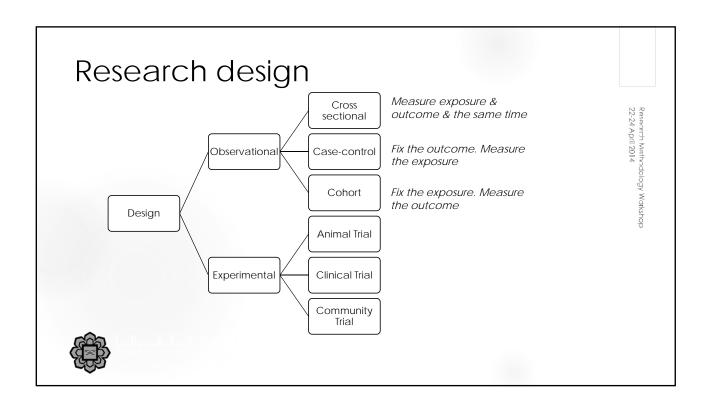
- 1. Suggest the title of your research
- 2. State 3 reasons why your study is important
- Identify the outcome, explanatory factors & the confounders (if applicable)
- 4. Build the conceptual framework
- 5. State the specific objectives of the study

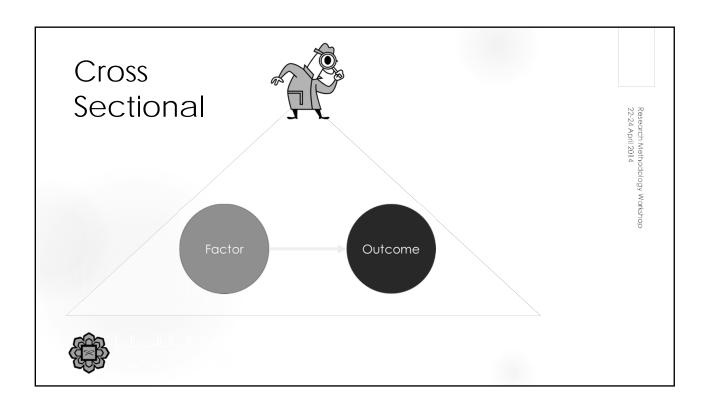


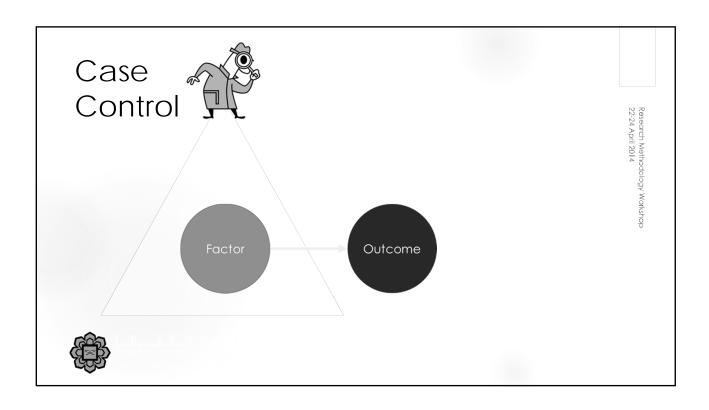
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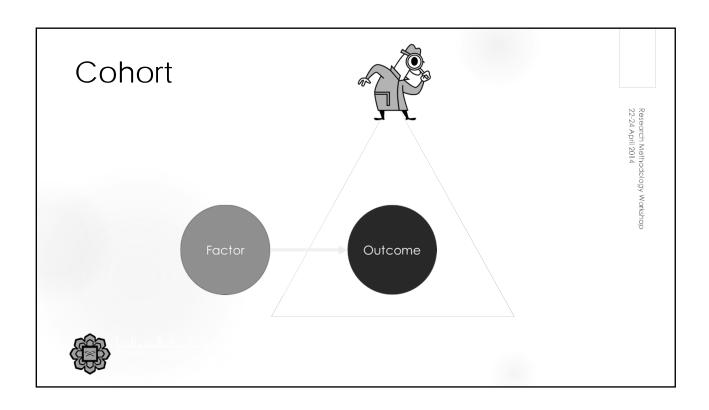


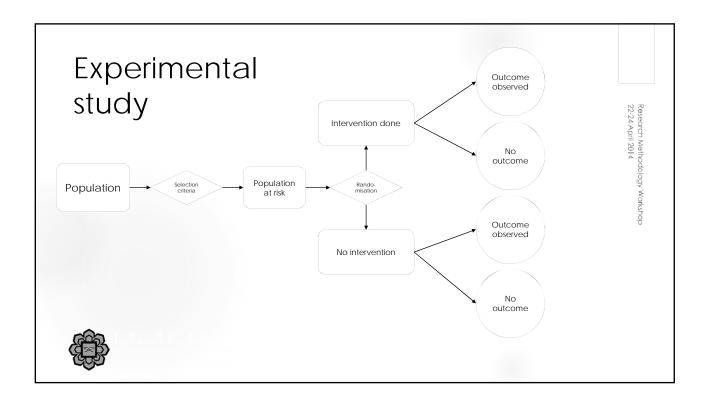


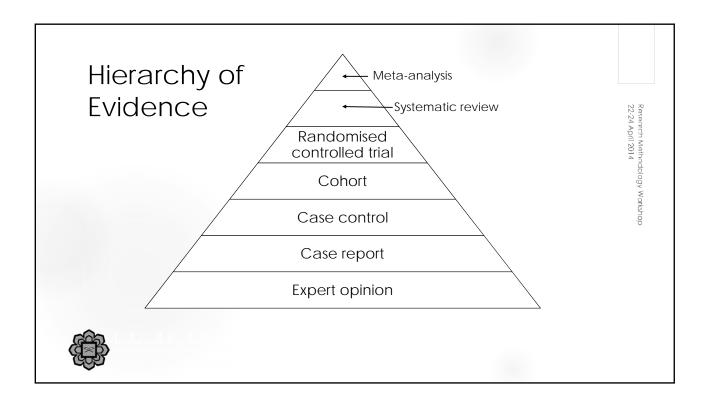












Cross sectional study

- ▶ Population based represent population
- ► Measure exposure & outcomes at the same point in time No temporal association
- ▶ Impossible to infer causality
- ▶ Prevalence study measure magnitude or burden of disease
- Descriptive
- ► Repeated cross-sectional study ~ pseudo-longitudinal e.g. British Association for the Study of Community Dentistry (BASCD) guidance on sampling for surveys of child dental health. A BASCD coordinated dental epidemiology programme quality standard (Pine et al. 1997)



Cross sectional study

Advantages

- Measure prevalence of a population
- Measure multiple exposures & outcomes
- ▶ Relatively inexpensive
- ▶ Relative shorter time

Disadvantages

- No temporal association no inference to causality
- Prevalence-incidence bias (Nyman bias) e.g. if smokers die due to AMI faster, a crosssectional study will reveal less smoker among AMI patients
- Health workers effect e.g. when survey done from house to house, only health respondent are available in their home/office



Cross sectional study - Example

- ► NHMS ~ Household study, all Malaysian (N=47,610 for 2006)
- ► NOHSA ~ Adult (>15) (N=14,444 for 2010)
- ► NMCS ~ GP vs. PHC (N~12,000)
- ► NHANES (US) http://www.cdc.gov/nchs/nhanes.htm

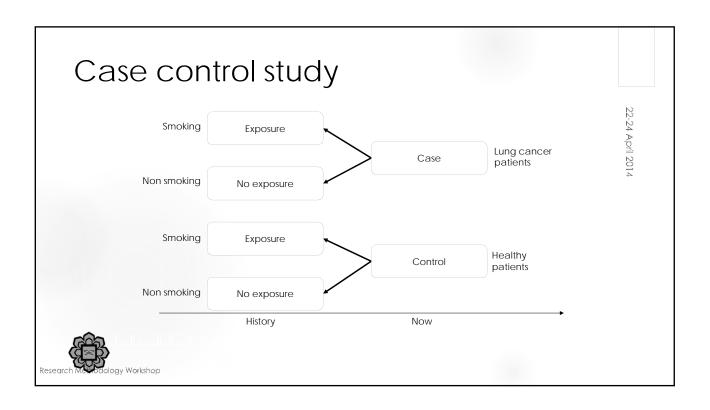


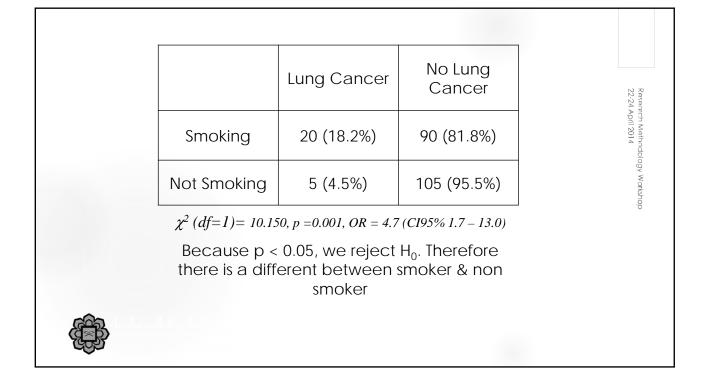
Case control study

- ► Fix the outcomes, measure the exposures
- **▶** Longitudinal
- ▶ Retrospective
- ► Case = outcome of interest
- ► Control = comparing outcome



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Cases

- Well defined
- Source institution vs. population

Control

Matched vs. Unmatched

Matching ~ controls resemble the cases with regard to certain characteristics (age, gender, SES etc)

Individual vs. Group matching

- Source institution vs. population
- ► Ratio to cases ~ up to 4:1



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Case control study

Advantages

- Good for rare conditions or diseases
- Less time needed to conduct the study because the condition or disease has already occurred
- ▶ Measure multiple risk factors
- ► Can establish an association

Disadvantages

- Recall bias
- Not good for evaluating diagnostic tests because it's already clear that the cases have the condition and the controls do not
- It can be difficult to find a suitable control group

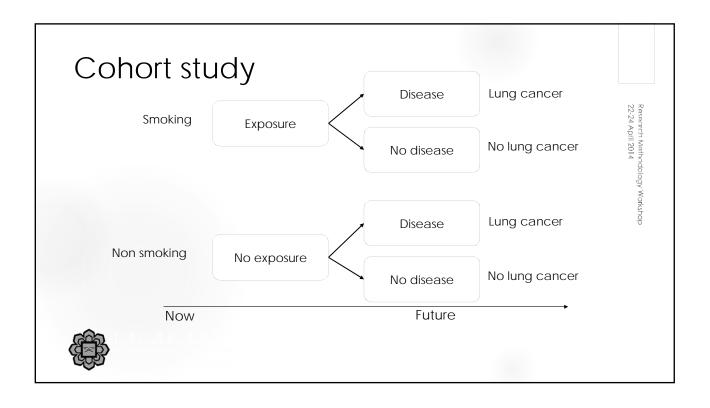


Example Tobacco use a of myocardial infarction in 52 countries in the INTERHEART stu case-control st (Teo 2006) Figure 2: Risk of AMI associated with numbers smoked, by age group pfor interaction - 0-0001. New-never smokers. Form-former smokers. 1-19-currently smoking 1-19 cigarettes per day.

Cohort study

- ▶ Measure outcomes
- ► Compare incidence of a disease (or condition) among exposed and unexposed individuals over time
- ▶ Disease free at the onset (or inception)
- ▶ Repeated measurements ~ follow up
- ▶ Prospective vs. retrospective cohort





Define cohort

- ▶ Both exposed & not exposed groups have equal chance to:
 - ► Develop disease
 - ▶ Be followed-up
- ► Types:
 - ▶ Representative low exposed subjects
 - ► Enriched high exposed subjects
 - ▶ Specific group occupational, institution etc



Measurements

- **►** Exposure
 - ► Carefully defined in advance
 - ▶ Standard measurement for both E+ & E- groups
- **▶** Outcome
 - ▶ Primary vs. Secondary outcome

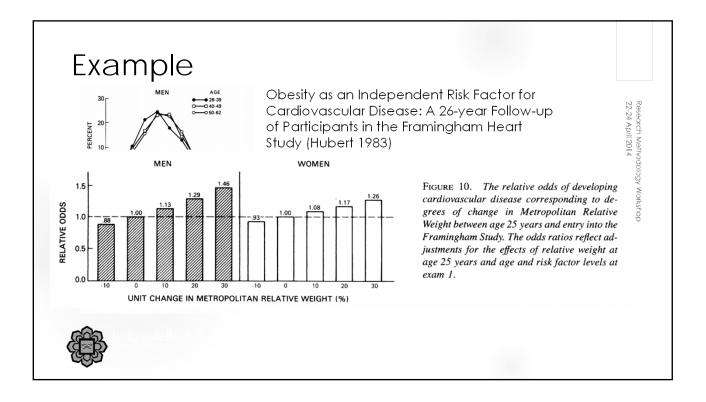


Follow-up

- ► Keep participation at > 90%
- ▶ Equal likelihood to detect disease in all subjects
- ► Active vs. Passive follow-up
- **▶** Blinding



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Cohort study

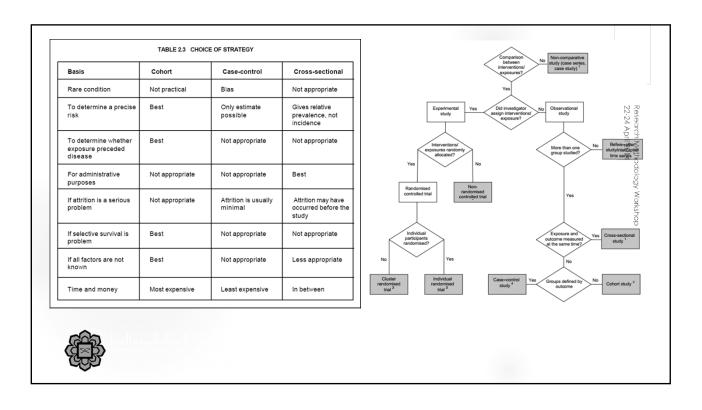
Advantages

- ▶ Infer causality
- Measure multiple outcomes
- ► Study rare exposure
- ► Measure incidence

Disadvantages

- ► Costly
- ► Loss to follow up
- ► Large sample size for rare outcomes
- ► Selection bias





Part 4 – Sample & sampling method



Sampling & sample size

- ► Type of sampling Random vs. Non random
- ► Sample size Based on objective & research design

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Before we sample

Determine study place, duration & subjects

▶ Describe study place – especially if plan to represent a population

- ▶ State time & duration
- ► Who or what are the subjects population, people, animal etc.

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Subjects

- ▶ Target population
- ► Study population
- ► Sampling frame
- ► Sampling unit
- ▶ Observation unit



Example - NHMS III 2006

► Target population All Malaysian

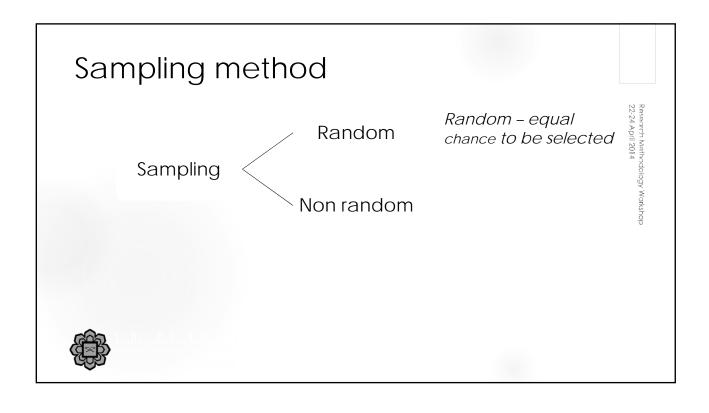
► Study population Household up to strata 6

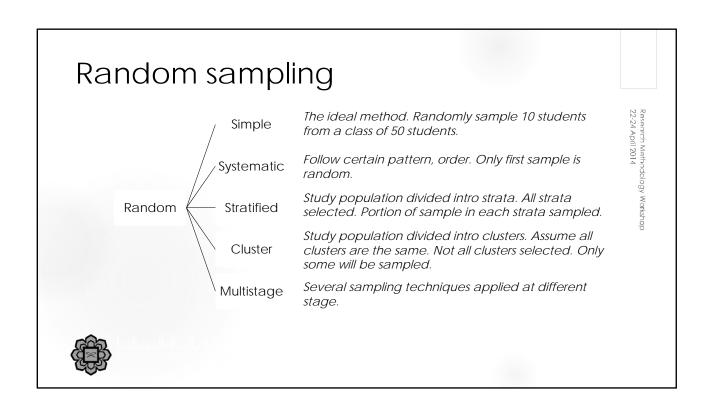
► Sampling frame List of Enumeration Block & Living Quarters

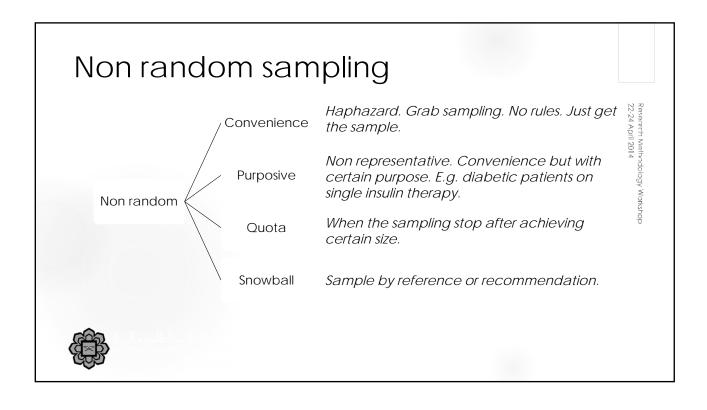
► Sampling unit Enumeration Block & Living Quarters

► Observation unit All household in the selected Living Quarters









Example - NHMS III 2006

Two stage stratified random sampling

► Target population All Malaysian

► Study population Household up to strata 6

▶ Strata State & location (urban or rural)

► Clusters Enumeration Block & Living Quarters

► Sampling frame List of Enumeration Block & Living Quarters

► Sampling unit Enumeration Block & Living Quarters

► Observation unit

All household in the selected Living Quarters

► Sample distribution Proportionate to size



Sample size

- ► How many sample required
- ► An estimate
- ▶ Adequate size to
 - 1. Represent population
 - 2. Test hypothesis
- ▶ Size affects duration & budget of the research
- ▶ Do not sample more than required



Sample size

- ► Sample size depends on
 - 1. Objective of the study
 - 2. Study design (design effect)
 - 3. Sampling method
 - 4. Expected (& precision) effect size
 - 5. Variability of sample
 - 6. Non-response rate
- ▶ Even the expected outcomes/effect size are estimates



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Sample size - formula

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- ▶ No single formula for all
- ▶ Depending on purpose single proportion, compare two proportions, compare 3 proportions etc.
- ► Use of software or calculators e.g. PS Power and Sample Size, PASS etc.
- ► Anticipate non response, drop-out, loss to follow up, death (esp. animal study)



Example - Single proportion

- $ightharpoonup N = rac{z^2 p(1-p)}{d^2}$, where
- ► N is the sample size,
- ► z = z value for intended confidence interval,
- ▶ p is the estimated proportion (in decimal) &
- ▶ d is the precision of p (deviation from p) (in decimal)



Example - Single proportion

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- ► Calculate sample size if you wish to do a study estimating the prevalence of DM as 20% with 5% variation at 95%CI (z for 95%CI is 1.96) anticipating 20% non response
- ► Answer: 246, ~ 250 then add 20% ~ 300 samples required



Group Work #2

- 1. What is the best study design? Give one reason
- Describe the sample planned for your study target, study, sampling frame, sampling unit & observation unit
- 3. Calculate the sample size required



Part 5 – Data collection

Plan for data collection

- ► Identify all variables of interest produce detail data dictionary declare all definitions & the measure types
- Must check validity & reliability of research toolsincluding questionnaires
- ▶ Training ensure similar ways of collecting data
- ► Key word here STANDARD



Research instruments

- ► Must be both valid and reliable
- ▶ Valid content, face, criterion, construct etc
- ► Reliable repeatability
- ► Must declare all tools used
- ► Including the questionnaire

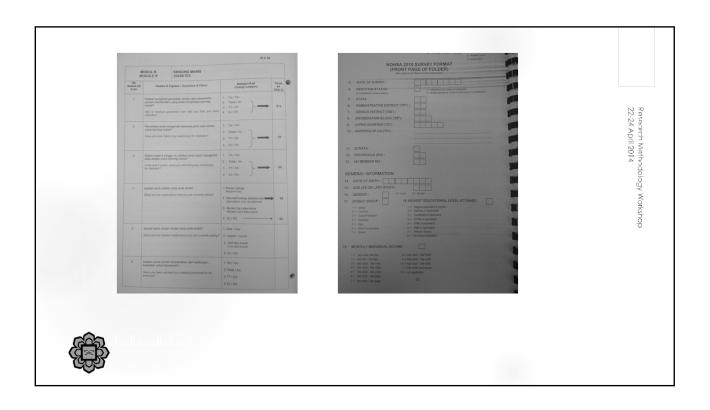


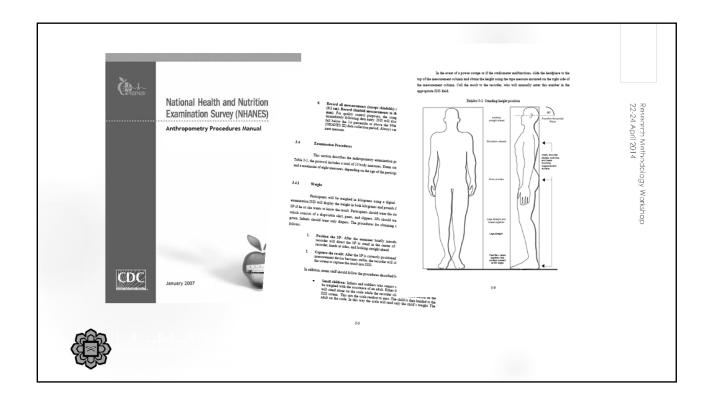
Questionnaire or Record Form

- ► Face-to-face vs. self-filled (online or paper-based) vs. postal vs. telephone
- ▶ Specific questions (fulfill the objectives)
- ▶ Open vs. closed ended
- ► Structured usually closed-ended e.g. dichotomous, Likert scale, multiple choice.
- ▶ Response code e.g. 1=Male, 2=Female



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Data dictionary

- ▶ List of variables
- ► Definitions & working definitions e.g. When you say a subject is diabetes? Hypertensive?
- ► Cut-of-point e.g. How many age category
- ➤ Outcome vs. factors
- ▶ Type of measures dependent or independent
- ► Coding e.g. 1=Male, 2=Female



Data dictionary - Example

AMALTIC AND REPORTING OUTDILINES:
The Third Retional Bulber and studied Execution Examination Survey,
MANUS III (1988-8)

October, 1996

National Center for Health Statistics Centers for Disease Control and Prevention Hyattsville, Maryland SECTION T AND PROPERTY OF THE PROPERTY OF THE

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Suggested details to include

| 1 | Name | The name normally required in computer such as in database and statistical analysis. Name can be in one short word e.g. agecat for Age Category | | | |
|---|--------------------------|--|--|--|--|
| 2 | Label | The name that can appear in table, graph or report | | | |
| 3 | Definition | The definition used in the research. It is advisable to include references used | | | |
| 4 | Instrument used | When relevant, we can describe the instrument used which include the brand and the method of calibration if relevant | | | |
| 5 | Level of measurement | Should specify either it is nominal, ordinal or continuous | | | |
| 6 | Category option and code | If the variable is categorical, the options should be specified e.g. Gender; Male=1, Female=2 | | | |
| 7 | Unit of measurement | If the variable is numerical, we should specify its unit e.g. mmol/L, mg/dL | | | |
| 8 | Precision of measurement | How precise the variable is measured e.g. Age is measured to the nearest 1 year old. Income is measured to the nearest RM100 | | | |
| 9 | Data linkage | If this variable is related to other variable, we can specify here e.g. Missing value (Question on pregnancy) if respondent is Male (Question on Gender) | | | |

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Data dictionary is very important!!

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Part 6 - Statistical analysis plan



Statistical analysis plan

- ▶ Based on objective, especially the specific objectives orderly manner
- ► Descriptive vs. analytical analysis
- ▶ The product is dummy table
- ▶ State all statistical tests planned to be used
- ► State significant level
- ► State software used
- ▶ Engage a statistician from the beginning!



Dummy table - example

To compare blood glucose level between gender

Variables involved

| Variable label | Working definition (linkage data) | Status | Variable name | Level of measurement | Category label (if relevant) | Variable Unit | Precision of measurement | Missing value |
|----------------|--------------------------------------|-------------|------------------|----------------------|---------------------------------|------------------|--------------------------|------------------|
| Blood glucose | As measured | Dependent | glu | Interval | | mmol/L | 0.1 | 999 |
| Gender | As reported | Independent | sex | Nominal | 1 = Male, 2 = Female | | | None |

Statistical analysis

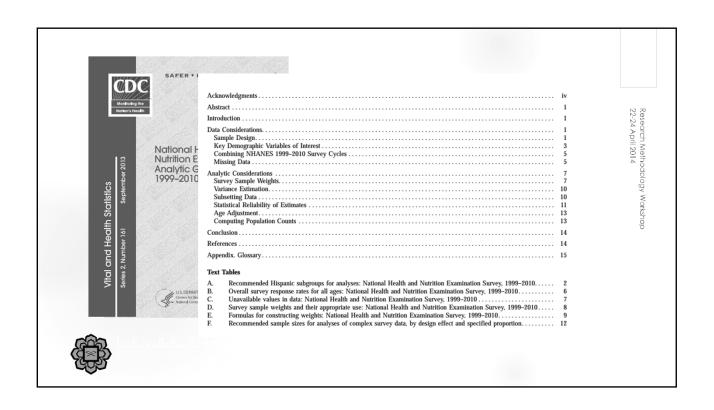
- 1. Check normality of glu2. If glu Normal, run Independent sample t-test; if glu not Normal, run Mann-Whitney U-Test
- Significance level = 0.05

Dummy table

| | Mean (SD) | Statistics | df | P |
|--------|------------|------------|----|-------|
| Male | nn.n (n.n) | n.nnn | nn | 0.nnn |
| Female | nn.n (n.n) | | | |

SD = Standard deviation





Data quality

- Valid value e.g. age > 200 years, weight > 500 kg, pregnant male etc
- ▶ No missing value
- Relevant skip response
 e.g. Not Applicable response for number of pregnancy
 for male respondent
- ► Declare method to ensure good data quality e.g. double data entry



Group Work #3

- ▶ Prepare the data dictionary
- ▶ Describe what you will do with the data
- Prepare dummy table for each specific objective

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Part 7 – Writing report

Before you write

- ▶ Decide the target audience
- ► Scientific publication or report
- ► Choose journal
- ► Study the format & requirement
- ► Separate text, table & graphics



The structure

Publication

- ▶ Title
- Abstract
- ► Keywords
- ▶ Introduction
- ▶ Method
- Results
- Discussion
- ▶ References



Report/thesis*

- ▶ Title
- ▶ Abstract
- ▶ Introduction
- ► Literature review
- ▶ Objective
- ▶ Methodology
- Results
- Discussion
- ► References
- * Institution specific

The suggested sequence

- Based on specific objective, analyse the data & produce planned tables
- 2. Interpret & describe the results in Result section
- 3. Discuss in Discussion section
- 4. Answer the research questions
- 5. Complete the method & introduction
- 6. Finally, write the abstract



Writing result

- ▶ Describe your result (no discussion)
- ► No reference (usually)
- ► Text vs. table vs. graphic (no redundancy)
- ► Text to summarise, Table for detail, Graphic to show trend
- ► May state relevant statistics done (if not mentioned in method)



Writing discussion

- ► Should answer the research questions mentioned in Introduction
- ▶ Discuss the result
- ▶ Do not repeat text as in Result
- ▶ May state limitation (but don't go overboard)
- ▶ Recommend
- ▶ Conclude



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Part 8 – The administration

Other things to plan

- 1. Ethical consideration consent form, advisory committee
- 2. Budget
- 3. Approval



In summary, what are the critical information

- 1. Specific objectives
- 2. Conceptual framework
- 3. Data dictionary
- 4. Dummy table & analytics guidelines

