

SCIENTIFIC WRITING: METHODS

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Checklist for writing methods

- ✓ Study design
- ✓ Study period
- ✓ Study location
- ✓ Reference population
- ✓ Source population
- ✓ Study participants
- ✓ Inclusion and exclusion criteria
- ✓ Sample size determination

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Leading cause of manuscript rejection

- Write a complete and accurate methods section
- Indispensable part of a successful paper

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- ✓ Sampling methods
- ✓ Data collection (who, where, when, what, how)
- ✓ Variables under study
- ✓ Validity and reliability of the measurement tools
- ✓ Definition of operational terms
- ✓ Study flow chart
- ✓ Statistical analysis
- ✓ Statistical flow chart
- ✓ Ethical issue

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Short form

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- Prevalence and risk factors of job strain among laboratory technicians in Hospital Universiti Sains Malaysia (**Job strain**)
- Prevalence and risk factors for microalbuminuria in patients with type 2 diabetes mellitus in north-eastern Malaysia (**Diabetes Mellitus**)

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Short form

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- Association between electrocardiographic ischemic abnormalities and ischemic heart disease risk factors in Japanese population (**Ischemic heart**)
- Risk factors for diabetic nephropathy among non insulin dependent patients who attended city hall's staff clinic in Kuala Lumpur (**nephropathy**)

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Principle 1: Length

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- Too short ? Too long ?
- Normally too short is the problem
- If less than two double-spaced pages, need to add more details before submission
- Rejection of the paper is common if methods section is less than two pages

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Evaluation 1: length

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- Job strain ✓
- Diabetes mellitus ✓
- Ischemic heart ✓
- Nephropathy X (relatively short)

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Principle 2: Subheadings

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- Organize according to meaningful subheadings
- Subheadings make it much easier for authors as well as reviewers
- Must have enough text to justify such subheading

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Example of subheadings

10

- Study design
- Eligible subjects
- Randomization and blinding
- Intervention
- Compliance
- Assessment of end points
- Statistical analysis

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Evaluation 2: Subheadings

11

- | | |
|---------------------|---|
| • Job strain | ✓ |
| • Diabetes mellitus | ✓ |
| • Ischemic heart | X |
| • Nephropathy | X |

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Principle 3: Study design

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- Appropriateness
- Failure to give a detailed explanation of study design
– a problem most often responsible for outright rejection of a paper

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Study design

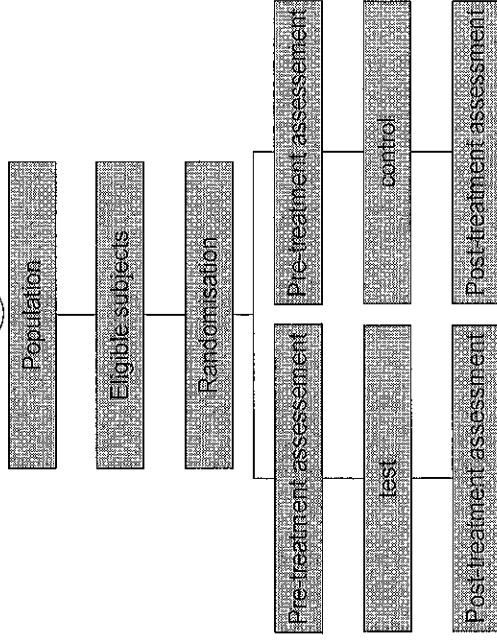
13

- Avoid oversimplifying the study as “retrospective” or “prospective”
- Instead use more specific terms such as “case-control”, “prospective cohort”, “cross-sectional”, “historical cohort”

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RCT (Parallel)

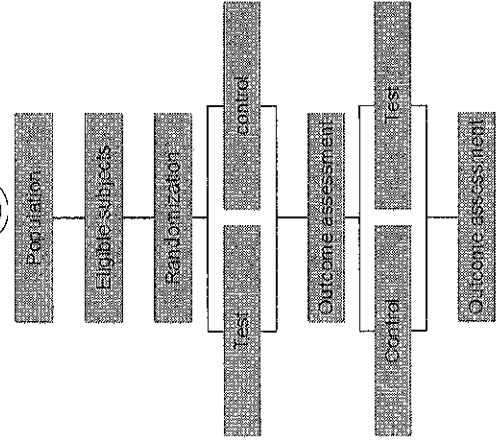
14



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Cross-over

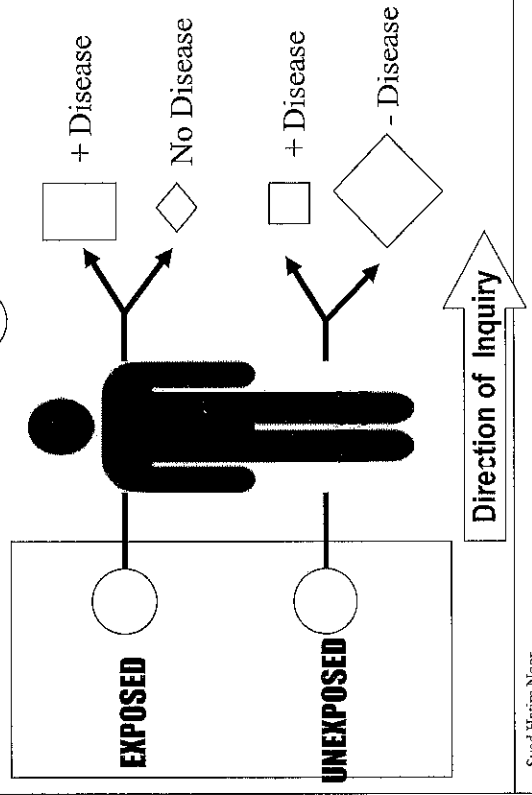
15



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Design of a Prospective Cohort Study

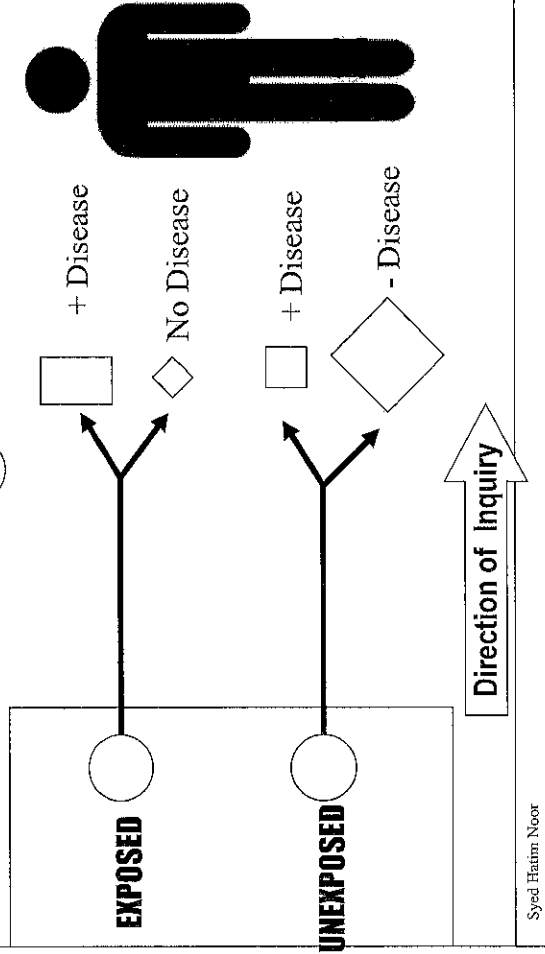
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Design of a Retrospective Cohort Study (RRR)

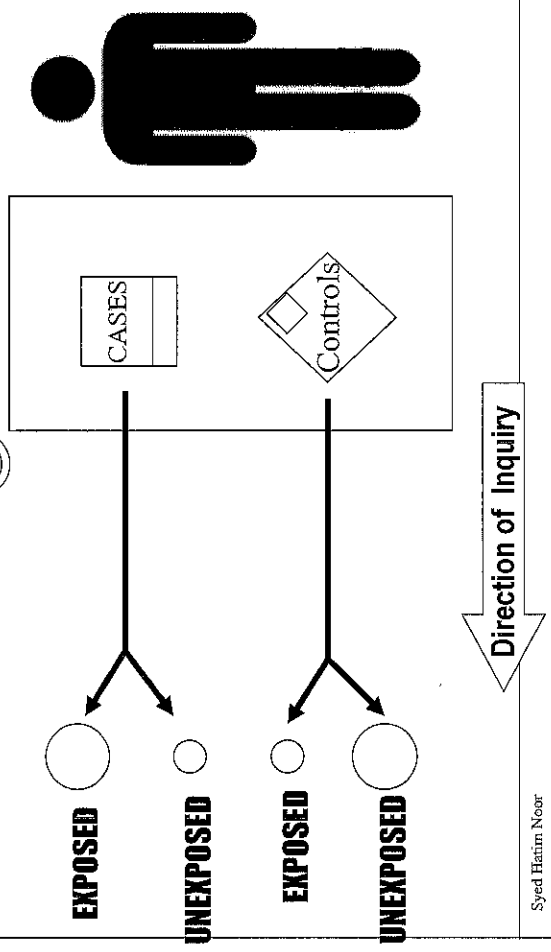
17



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Design of a Case-Control Study

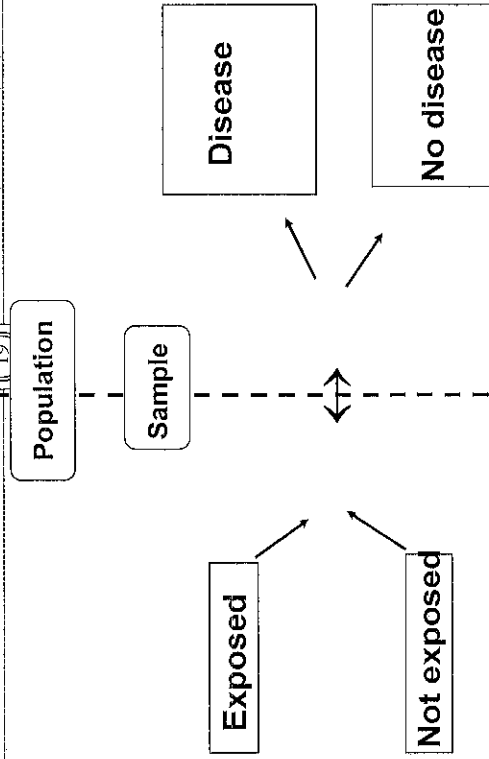
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Observation

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Evaluation 3: Study design

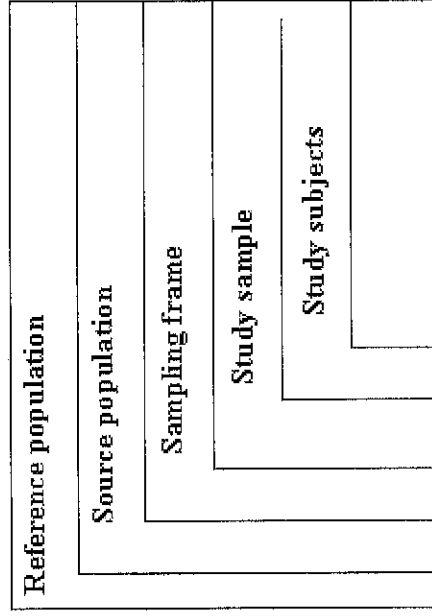
20

• Job strain	✓
• Diabetes mellitus	X (only in abstract)
• Ischemic heart	✓
• Nephropathy	✓

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Population and sample

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Reference population

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- 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

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Source population

23

- 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

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Principle 4: Inclusion and exclusion criteria

24

- Detailed Criteria for inclusion and exclusion
- Number of patients who met criteria
- Number of patients who were excluded

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Evaluation 4: Inclusion and exclusion criteria

25

- Job strain ✓
- Diabetes mellitus ✓
- Ischemic heart X
- Nephropathy ✓

Evaluation 5: Sampling frame

27

- Job strain ✓
- Diabetes mellitus ✓
- Ischemic heart ✓
- Nephropathy ✓

Principle 5: Sampling frame

26

- 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

Principle 6: Study sample

28

- 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

Evaluation 6: Study sample

29

- Job strain ✓
- Diabetes mellitus ✓
- Ischemic heart ✓
- Nephropathy ✓

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Principle 7: Study subjects

30

- 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

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Evaluation 7: Study subjects

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- Job strain X
- Diabetes mellitus X
- Ischemic heart X
- Nephropathy X

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Principle 8: Paired or matched samples

32

- Nature of the samples need to be mentioned if necessary
- A matched case-control study
- Pre-intervention and post-intervention – paired sample

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Evaluation 8: Paired or matched samples

33

- | | |
|---------------------|----|
| • Job strain | NA |
| • Diabetes mellitus | NA |
| • Ischemic heart | NA |
| • Nephropathy | ✓ |

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Principle 9: Sampling methods

34

- Process of selecting a study sample from the sampling frame when it is impractical to use the complete source population
- Objective – to select a non-biased sample which can be studied

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Examples of sampling methods

35

- | Probability Sampling | Non-probability Sampling |
|--|---|
| <ul style="list-style-type: none"> • Simple random • Systematic • Cluster • Multistage • Stratified | <ul style="list-style-type: none"> • Quota • Purposive • Universal |

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Evaluation 9: Sampling methods

36

- | | |
|---------------------|---|
| • Job strain | ✓ |
| • Diabetes mellitus | X |
| • Ischemic heart | X |
| • Nephropathy | X |

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Principle 10: Randomization and blinding

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- Explain method of random allocation/ randomization if applicable
- Technique of blinding if applicable

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Evaluation 10: Randomization and blinding

38

- | | |
|---------------------|----|
| • Job strain | NA |
| • Diabetes mellitus | NA |
| • Ischemic heart | NA |
| • Nephropathy | NA |

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Principle 11: Sample size determination

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- A description of the sample size calculation is a crucial but often neglected part of the method section
- Detailed information needs to be included

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Sample size determination

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- Confidence interval
- Level of significance (α)
- Power of the study ($1-\beta$)
- Whichever is applicable - expected detectable difference / prevalence / mean / standard deviation
- Inclusion of estimated drop-outs if necessary

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Data collection

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- When was the data collected? (study period)
- How was the data collected (mode of data collection)?
- Variables included in the questionnaire / data collection form?
- Interview / self-administration? By observation? From Medical records? Etc.

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Data collection

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- Where was the data collected? (operational areas and setting)
- Urban, rural, suburban?
- A teaching hospital / a tertiary care centre?
- Population served by the hospital under study?

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Evaluation 13: Data collection (who collected data)

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- Diabetes mellitus X
- Ischemic heart X
- Nephropathy X

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Evaluation 13: Data collection (when was data collected)

48

- Job strain ✓
- Diabetes mellitus ✓
- Ischemic heart ✓
- Nephropathy ✓

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Evaluation 13: Data collection (where was data collected)

49

- Job strain ✓
- Diabetes mellitus ✓
- Ischemic heart ✓
- Nephropathy ✓

Evaluation 13: Data collection (setting of the operational area)

50

- Job strain X
- Diabetes mellitus X
- Ischemic heart ✓
- Nephropathy X

Evaluation 13: Data collection (How was data collected)

51

- Job strain ✓
- Diabetes mellitus ✓
- Ischemic heart ✓
- Nephropathy ✓

Principle 14: Study factor(s)

52

- Variable(s) of interest that is hypothesized to be related to the health problem, disease or outcome of interest
- Also known as the independent variables / exposure variables / determinants

Evaluation 14: Study factor(s)

53

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- Diabetes mellitus ✓
- Ischemic heart ✓
- Nephropathy ✓

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Principle 15: Outcome factor(s)

54

- The event or occurrence that is supposed to have happened as a result of the study factor
- Also known as the dependent variable

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Evaluation 15: Outcome factor(s)

55

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- Diabetes mellitus ✓
- Ischemic heart ✓
- Nephropathy ✓

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Principle 16: Measurement issues (validity)

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- Reliable and valid
- Reliable but not valid X
- Valid but not reliable X

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Principle 16: Measurement issues (validity)

57

- 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

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Evaluation 16: Measurement issues (validity)

58

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- Diabetes mellitus ✓
- Ischemic heart ✓
- Nephropathy X

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Principle 17: Measurement issues (reliability)

59

- 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

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Evaluation 17: Measurement issues (reliability)

60

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- Diabetes mellitus X
- Ischemic heart X
- Nephropathy X

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Principle 18: Treatment regimen/ intervention

61

- Provide specifics for any drugs that were tested
- Example: dosage of the drug, route of administration, activities of intervention and control groups, etc.

Evaluation 18: Treatment regimen/ intervention

62

- Job strain NA
- Diabetes mellitus NA
- Ischemic heart NA
- Nephropathy NA

Principle 19: Definition of operational terms

63

- Provide operational definitions for all independent and outcome variables
- Examples: smoking status (current smoker, ex-smoker, never smoker), disease severity (by grading), pain score, etc.

Evaluation 19: Definition of operational terms

64

- Job strain ✓
- Diabetes mellitus ✓
- Ischemic heart ✓
- Nephropathy ✓

Principle 20: Statistical Analysis

65

- Need to show the understanding of statistical methods applied
- Clearly report statistical results

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Statistical Analysis (descriptive)

66

- Statistical values used for descriptive statistics
- Mean and standard deviation for continuous variables
- Frequency and percentage for categorical variables
- Median and inter-quartile range for skewed data, etc.

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Statistical Analysis (univariable)

67

- Distribution of the variables : normal and other distributions (usage of parametric and non-parametric tests)
- Univariable analysis
- Mention tests applied in univariable analysis
- Examples: Independent t-test for comparing means, Chi-square test / Fisher's exact test for categorical data, etc.
- Level of significance (α)
- One/ two tailed tests

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Statistical Analysis (multivariable and multivariate)

68

- Need to mention which variables were included in multivariable and multivariate analysis and why
- The multivariable and multivariate method applied – information on outcome variable(s), potential confounders which were adjusted for
- Brief explanation about modeling procedure (examples: stepwise backward multiple logistic regression followed by checking interaction terms, Maximum likelihood estimate with the application of likelihood ratio test, etc.)

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Statistical Analysis (multivariable and multivariate)

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- Goodness-of-fit test for final model needs to be included (example: Hosmer-Lemeshow test in multiple logistic regression, etc.)
- Checking interaction terms if applicable

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Statistical Analysis

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- Measures of risk (strength of association)
- Regression coefficient/odds ratio/relative risk/hazards ratio
- 95% confidence interval
- State if it is -intention-to -treat / interim analysis, etc.
- Treatment of outliers (extreme values) if applicable
- Treatment of missing data if applicable
- Statistical software used for data entry/validation/data analysis (name, version, etc.)

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Evaluation 20: Statistical analysis

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- Job strain ✓
- Diabetes mellitus ✓ (need to stress more in multivariable)
- Ischemic heart ✓ (need to stress more in multivariable)
- Nephropathy ✓ (need to stress more in multivariable)

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Principle 21: Ethical issue

72

- Ethical clearance to be granted from the local or regional research and ethics committee if necessary
- Needs to be mentioned in methods section
- Clear description of procedure which is of great concern to ethical issue needs to be included (examples: withdrawing blood, DNA studies, way of sacrificing animals, etc.)

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Evaluation 21: Ethical issue

73

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- Diabetes mellitus ✓
- Ischemic heart X
- Nephropathy X

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Principle 22: Informed consent

74

- Information about informed consent is necessary to be included
- All procedures must be explained such as - a written informed consent was obtained after explaining the participants with information sheet about the research made available to the participant

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Evaluation 22: Informed consent

75

- Job strain X
- Diabetes mellitus ✓
- Ischemic heart X
- Nephropathy X

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