How to Write Study Methods


SCRATCH
MAYBE I'LL START WITH THE ACKNOW-LEDGEMENTS...
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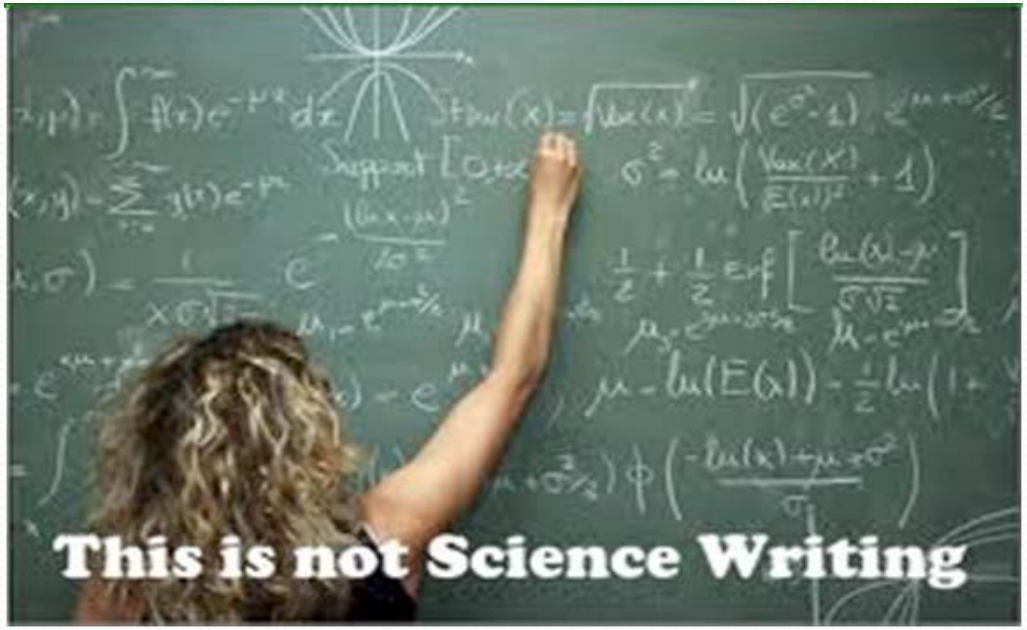
Methods

- Study design
- Study setting
- Population under study
- Sample Size
- Sampling Technique
- Data collection method
- Pilot study
- Data analysis plan
- Ethical considerations

What the Methods Section is Not!

- Results
- Discussion
- Summary
- Conclusions
- Future Work
- Introduction



- **It is a DESCRIPTION of HOW you did your work**
- **Include NO results and NO discussion!**

Design

- **Present key elements of study design early in the paper.**

To understand
the basics of the study

- Cross-sectional
- Case-Control
- Cohort
- Experimental
- Or mixture

+

exactly how and when

Design: Example

Design

- "We will use a case-control study design, with a sample that will include women with breast cancer, with a 1:1 age matched with controls without breast cancer. We age-matched women newly diagnosed with breast cancer (cases) and women with benign breast changes (controls) at two referral services for diagnosis and treatment of cancer in Goiânia, (Goiás State capital)".

Exactly how

Setting

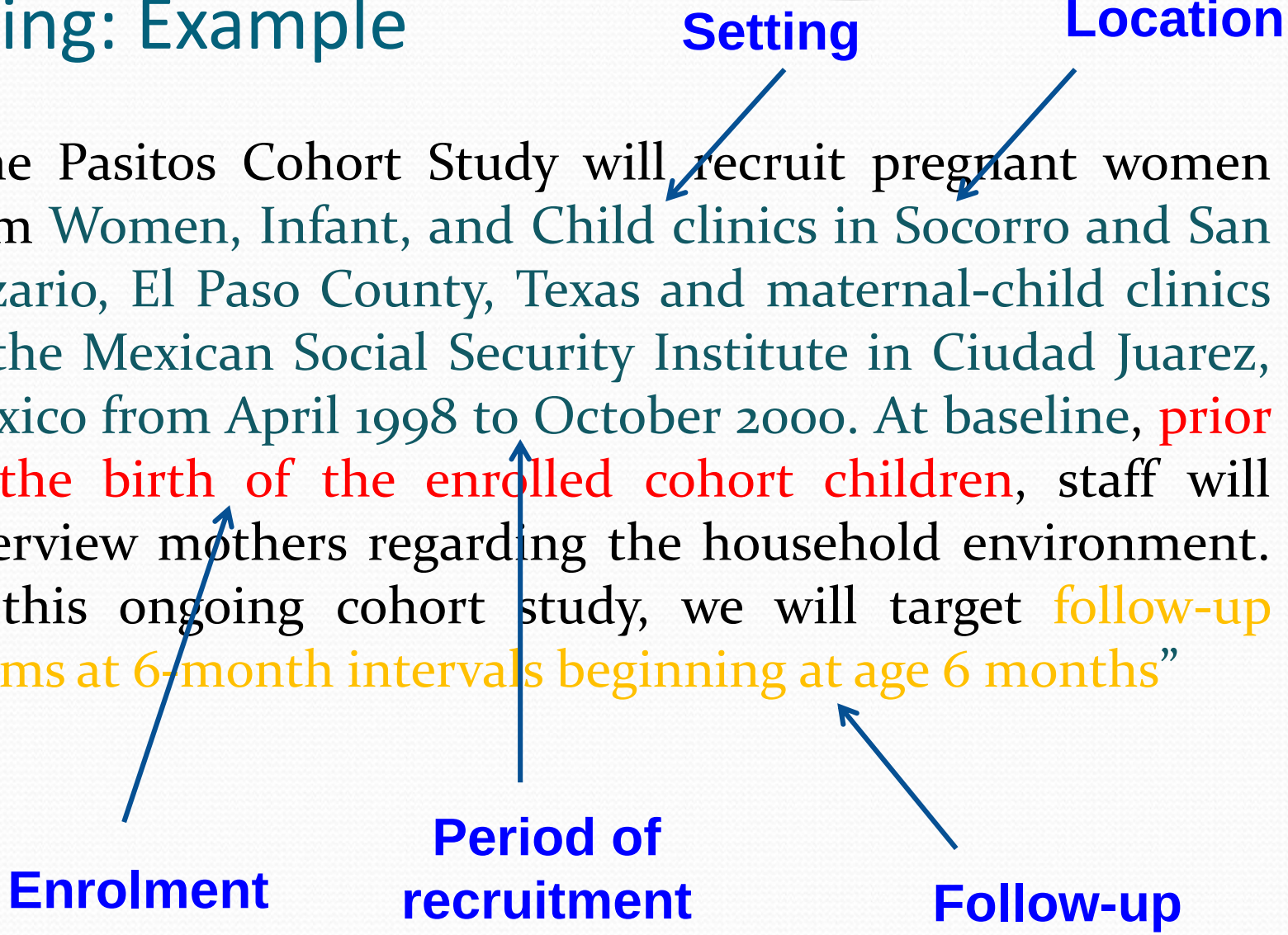
- ***Describe:***

- Setting (recruitment sites or sources)
- Location (countries, towns, hospitals)
- Relevant dates
  - Periods of recruitment
  - Exposure
  - Follow-up
  - Data collection

Generalizability of a study's results

Setting: Example

- "The Pasitos Cohort Study will recruit pregnant women from Women, Infant, and Child clinics in Socorro and San Elizario, El Paso County, Texas and maternal-child clinics of the Mexican Social Security Institute in Ciudad Juarez, Mexico from April 1998 to October 2000. At baseline, prior to the birth of the enrolled cohort children, staff will interview mothers regarding the household environment. In this ongoing cohort study, we will target follow-up exams at 6-month intervals beginning at age 6 months"



Study Population

Detailed descriptions of the study participants

Inclusion, Exclusion

- Eligibility criteria – age, gender, diagnosis, co-morbid conditions, etc
- Sources and methods of selection of participants
- Rationale for the choice of cases and controls
- Sources and methods of case ascertainment and control selection
- Matching criteria and number of exposed and unexposed

How do we pick a study population?

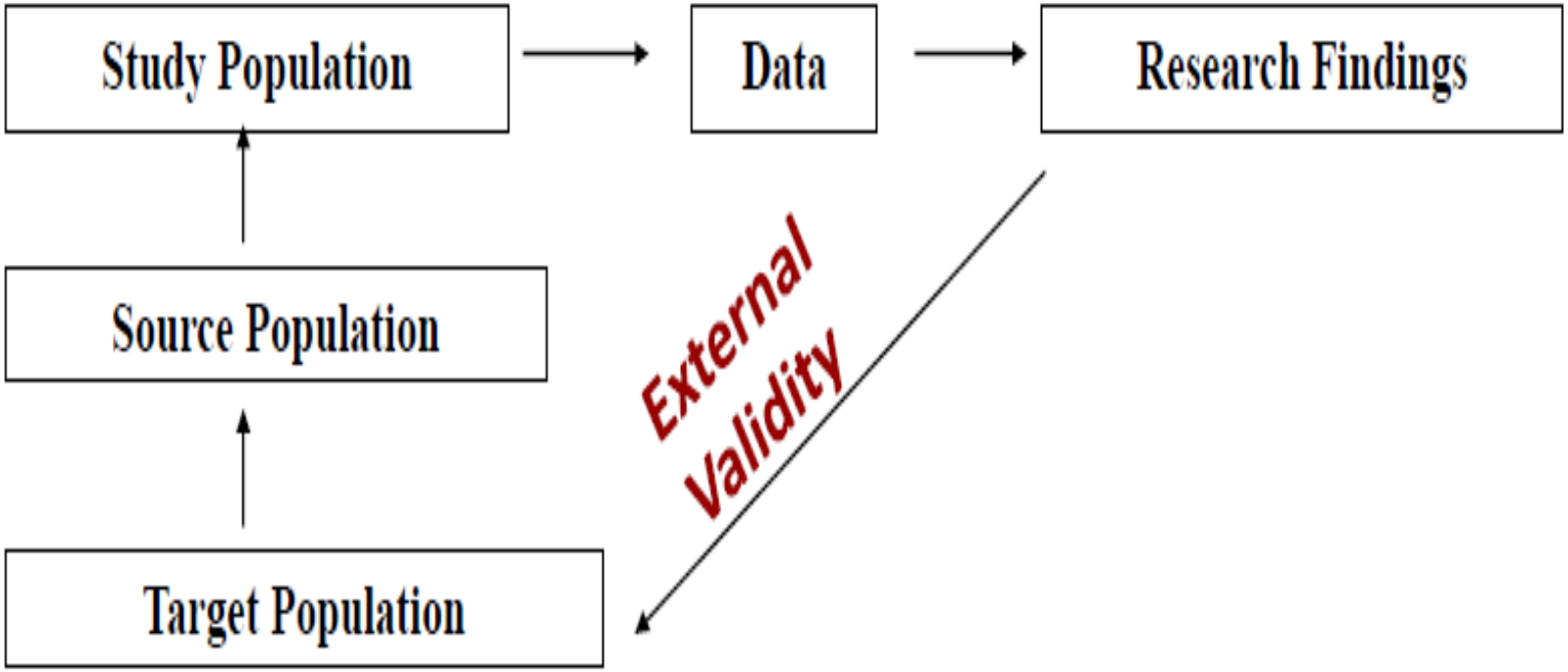
- Convenience and feasibility
- Likely response rate
- Population characteristics
  - Socioeconomic
  - Racial and ethnic
- Generalizability of findings

Study population, source population, Target population

The group studied

The group from whom the study population is drawn

The group to whom inferences will be made


Study Population
Data
Research Findings
Source Population
External Validity
Target Population

Population: Examples

- "Participants in the Iowa Women's Health Study will be selected by a random sample of all women ages 55 to 69 years derived from the state of Iowa automobile driver's license list in 1985, which represents approximately 94% of Iowa women in that age group….

- "We will aim to select 5 controls for every case from among individuals in the study population who had no diagnosis of autism or other pervasive developmental disorders (PDD) recorded in their general practice record and who are alive and registered with a participating practice on the date of the PDD diagnosis in the case.

Sample size

How to calculate the sample size?

Use the following formula if you know the prevalence or you can get the prevalence of the condition from the literature:

$$N= (Z_{1-\alpha}) (P(1-P)/D^2)$$

N= The sample size
Z= Confidence intervals=1- α (1.96)
P= Prevalence of the condition
D= Precision (0.05)

Sample size

- “A survey of postnatal depression in the Middle East had documented a prevalence of 19.8%. Calculate the sample size for the prevalence of post natal depression in a population in Saudi Arabia with 0.5% precision and 80% power.

$$N = (Z_{1-\alpha})\,(P(1-P)/D^2)$$

N= The sample size

Z= Confidence intervals=1- α (1.96)

P= Prevalence of the condition

D= Precision (0.05)

Thus for a condition of prevalence of 20% the sample size will be

$$N = 1.96x\ (0.20\ (1-0.2)/0.5^2) = 246$$

What if you there are no previous studies?

- Conduct a pilot study to have an idea in about the prevalence in your population

- Assume that the prevalence is 50% which will give the largest possible sample size

Sampling methods

- Probability Sampling – each member has the same chance (equal and independent)
  - Simple random sampling
  - Systematic sampling
  - Stratified random sampling
  - Cluster sampling
  - Multi-stage sampling

Sampling methods

- Non-probability Sampling – each member does not have the same chance
  - Convenience sampling
  - Snowball Sampling
  - Purposive Sampling
  - Quota Sampling

Sampling methods

Example

- A simple random sampling design will be used.
- The mobile phone network of the STC will be chosen as a sampling frame. Computer generated random number list will be generated. STC mobile phone numbers will be the sampling element.

- **Data collection methods:**
  - Form [questionnaire/ case report form]
  - Measurements [e.g. biometric / anthropometric]
  - Laboratory investigations [types, referenced techniques / kits for each]

Data Collection

- For each variable of interest, give sources of data and details of methods of measurement. Describe comparability of assessment methods if there is more than one group.
  - Report the way of measurement, esp. for different groups
  - Report the findings of any studies of the validity or reliability of assessments or measurements
  - The materials and methods should describe the study in sufficient detail so that a skilled investigator in the field could replicate the study

Wahabi *et al. BMC Public Health* 2013, **13**:341
http://www.biomedcentral.com/1471-2458/13/341

BMC Public Health

RESEARCH ARTICLE Open Access

Effects of secondhand smoke on the birth weight of term infants and the demographic profile of Saudi exposed women

Hayfaa A Wahabi[1*], Rasmieh A Alzeidan[1], Amel A Fayed[3,4], Ahmed Mandil[2], Ghadeer Al-Shaikh[5] and Samia A Esmaeil[1]

Data on SHS exposure will be collected by self-administered questionnaire, data on the maternal demographic characteristics and obstetric performance will be collected from maternal medical records and data for the neonatal anthropometric measurements which are measured by the attending midwife will be collected from the delivery records. The study will be carried out for 12 months

Gestational diabetes mellitus: maternal and perinatal outcomes in King Khalid University Hospital, Saudi Arabia

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Received 22 January 2013
Accepted 20 April 2013

Journal of the Egyptian Public Health Association 2013, 88:104–108

Background

The prevalence of gestational diabetes mellitus (GDM) has increased worldwide, with a subsequent increase in the associated adverse pregnancy outcomes.

Objectives

The objective of this study was to determine the prevalence of GDM and to compare the maternal and neonatal outcomes of women with GDM with nondiabetic women.

Materials and methods

This is a retrospective cohort study investigating the maternal and the neonatal outcomes of women with GDM who delivered in King Khalid University Hospital as compared with the outcomes of nondiabetic women who delivered during the same period. The data were collected from the 1st of January to the 31st of December 2010 from the labor ward registry. The pregnancy outcomes of the women with GDM were compared with the outcomes of nondiabetic women who delivered during the same

The BMI will be calculated for each subject using the maternal weight and height which will be recorded during the booking visit, according to the following equation; BMI=weight (kg) / height $(m)^2$.

The diagnosis of gestational diabetes will be based on the results of 75g oral glucose tolerance test (OGTT) done between 24-32 weeks gestation and requires that two or more of the venous plasma glucose concentrations exceed the following: fasting, 5.3mmol/l (95 mg/dl), one hour, 10.0mmol/l (180 mg/dl), two hours, 8.6mmol/l (155 mg/dl) and three hours, 7.8mmol/l (140 mg/dl).

- **Plan for statistical techniques and methods to be used**
  - Descriptive
  - Analytical

    as related to study objectives / expected outcomes
  - The statistical methods should be explained with enough details to enable a knowledgeable reader with access to the original data to verify the reported results

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Statistical analysis

Statistical analyses will be performed using SPSS, version 18.0 (SPSS Inc., Chicago, IL, USA). Descriptive statistics will be computed for non-smoking pregnant women exposed and unexposed to SHS. Univariate analyses will be performed to compare the birth weight, infant's length and head circumference between the two groups as well as to evaluate the baseline characteristics between the groups which we considered as confounding factors. Chi-squared will be used to compare dichotomous outcomes and Student's t- test will be used to compare continuous outcomes. Stepwise logistic regression models will be used to adjust for potential confounders including maternal age, parity, BMI, GDM and gestational age (37–42 weeks). *P* value of < 0.05 will be considered statistically significant.

Expectations of Ethical Considerations

Design of a bilingual consent form (for written approval of participants)

Assurance of respect of human rights in research involving human subjects, including:

1. Benefits outweigh risks
2. Confidentiality
3. Anonymity
4. Voluntary participation

Ethical Consideration

Example

- All participants will receive a written consent form. The interviewer will inform all participants about the purpose of the research, why they were chosen, all potential risks and benefits and that they could refuse to participate, or could withdraw from the study at any point in time.
- Participants anonymity will be assured by assigning each student with a code number for the purpose of analysis only.
- No incentives or rewards will be given to the participants, the purpose of the snack and refreshments is to establish a bond with the students and is offered to all students with no obligation to participate.

The Pilot Study

Purpose of the pilot study:

1. Estimate the sample size…..????
2. Examine the logistics
3. Test the questionnaire administration
4. Test reliability and validity of the survey…????

✓Pilot studies should have a well-defined set of aims and objectives to ensure methodological rigor and scientific validity.

✓Participants pilot study should not later be included in the main study

✓The analysis of a pilot study should be mainly descriptive or should focus on confidence interval estimation.

- Results from hypothesis testing should be treated as preliminary and interpreted with caution, as no formal power calculations have been carried out.

- The temptation not to proceed with the main study when significant differences are found should be avoided.

Important …..Before you Start your Proposal….

You Have to Read Many Studies Addressing the Same Research Q

NCBI Resources How To Sign in to NCBI

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National Institutes of Health

PubMed Search

Advanced Help

Filters activated: Free full text available Clear all

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PubMed comprises more than 23 million citations for biomedical literature from MEDLINE, life science journals, and online books. Citations may include links to full-text content from PubMed Central and publisher web sites.

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- Clinical Queries
- Topic-Specific Queries

More Resources

- MeSH Database
- Journals in NCBI Databases
- Clinical Trials
- E-Utilities
- LinkOut

References / Readings

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THANK
YOU


Any
Questions