36th South African NATIONAL BLOOD Transfusion Congress
23 - 26 August 2021 - Durban
SHAPING A SUSTAINABLE FUTURE

The South African Society for Blood Transfusion

SASBT Abstract Writing Series

The Methods Section

Karin van den Berg

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UCSF University of California San Francisco

vitalant

UCSF GLOBAL HEALTH SCIENCES
Improving health and reducing disease worldwide

The Methods Section

- Can be the easiest and most straightforward to write
- Can be written in you are stuck with other sections, when you have writer's block

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The Methods Section

- It is where you share the recipe for your study

- Describes how you did the study with enough detail for the reader to judge the study's strengths and weaknesses
- Others must:
  - Understand what you did
  - Replicate what you did – more or less
  - Don't give to much detail

The Methods Section

- Four main points you need to explain:
  - Study Design & Setting (what kind of study you did)
  - Participant and how you selected them (sampling)
  - What measurements you did
    - Lab tests
    - Questionnaires
    - Observations
  - Analysis

The Methods Section

- Do not present results in Methods section
  - For biomedical abstracts and paper, the description of your participants / samples is usually included in the Results Section, not in Methods

- But, must linked to Results section
  - If you add something to the Results, then add it to Methods
  - If you decide not to add a specific outcome to Results, then delete it from Methods

So, Where To Start??

- Ideally, make notes of everything you did
  - What is the research question
  - What variables did you use
  - Where there ones you wanted to use but did not
  - Where there ones you included initially but then excluded?
- Then read (good) papers and abstracts on your topic

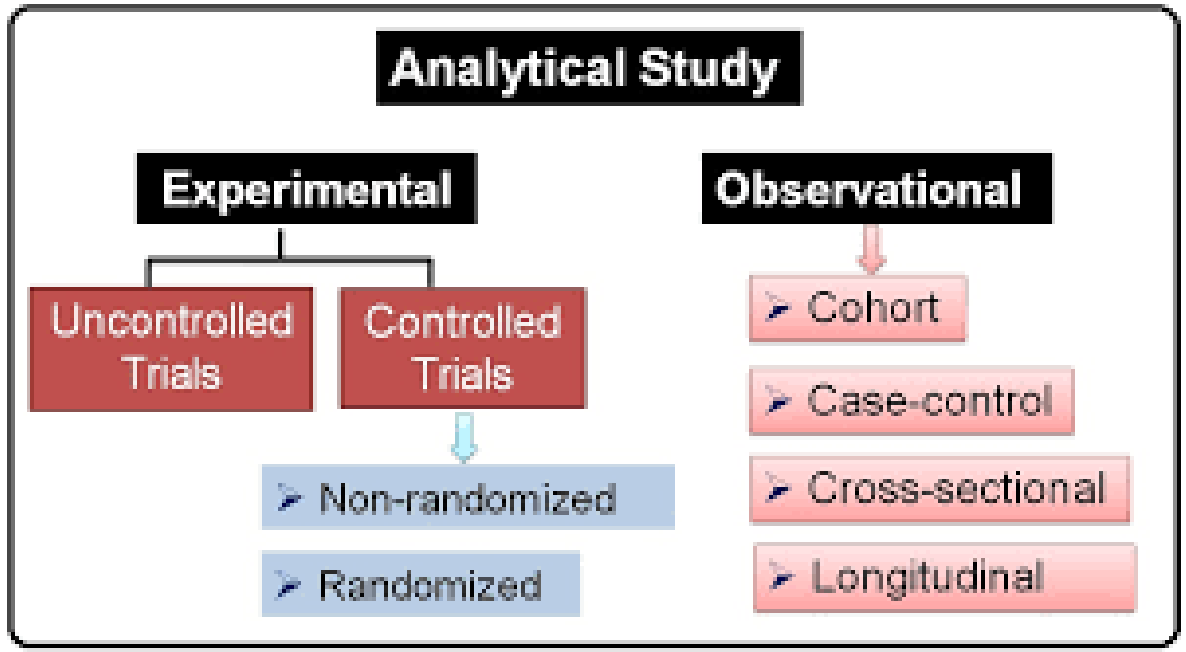
Copy With Pride!!

Study Design

- Ok, so back to the 4 sections of the Methods:
  - Study Design & Setting (what kind of study you did)
  - Participant and how you selected them (sampling)
  - What measurements you did
  - Analysis
- Pivotal / Most important sentence of Methods
- Can occasionally be the last sentence of your Introduction
  - If it is, don't repeat it here

Types of Study Design

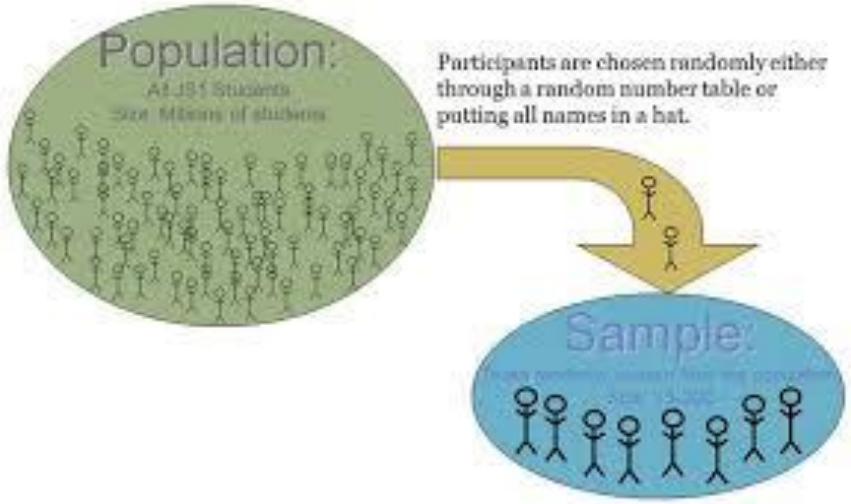
- Basic study designs:
  - Cross-sectional survey- include surveillance unless sentinel surveillance over time (e.g., nationally representative 2-stage cluster surveillance study)
  - Case-control study
  - Cohort study: longitudinal vs. retrospecti
  - Randomized controlled trial
  - Before-after study
- Combinations (describe both)
- Special cases
  - Secondary data analysis
  - Meta-analysis



Study Setting

- Geography
  - ❖ What areas were included in your study
  - ❖ Branch / zone / whole of SANBS / whole of South Africa
  - ❖ What ar the unique characteristics of the area included in the study
- Facility or Agency
  - ❖ Was the study done at SANBS / Hospital / General Public, etc
- Time frame
  - ❖ What period of time does your study cover

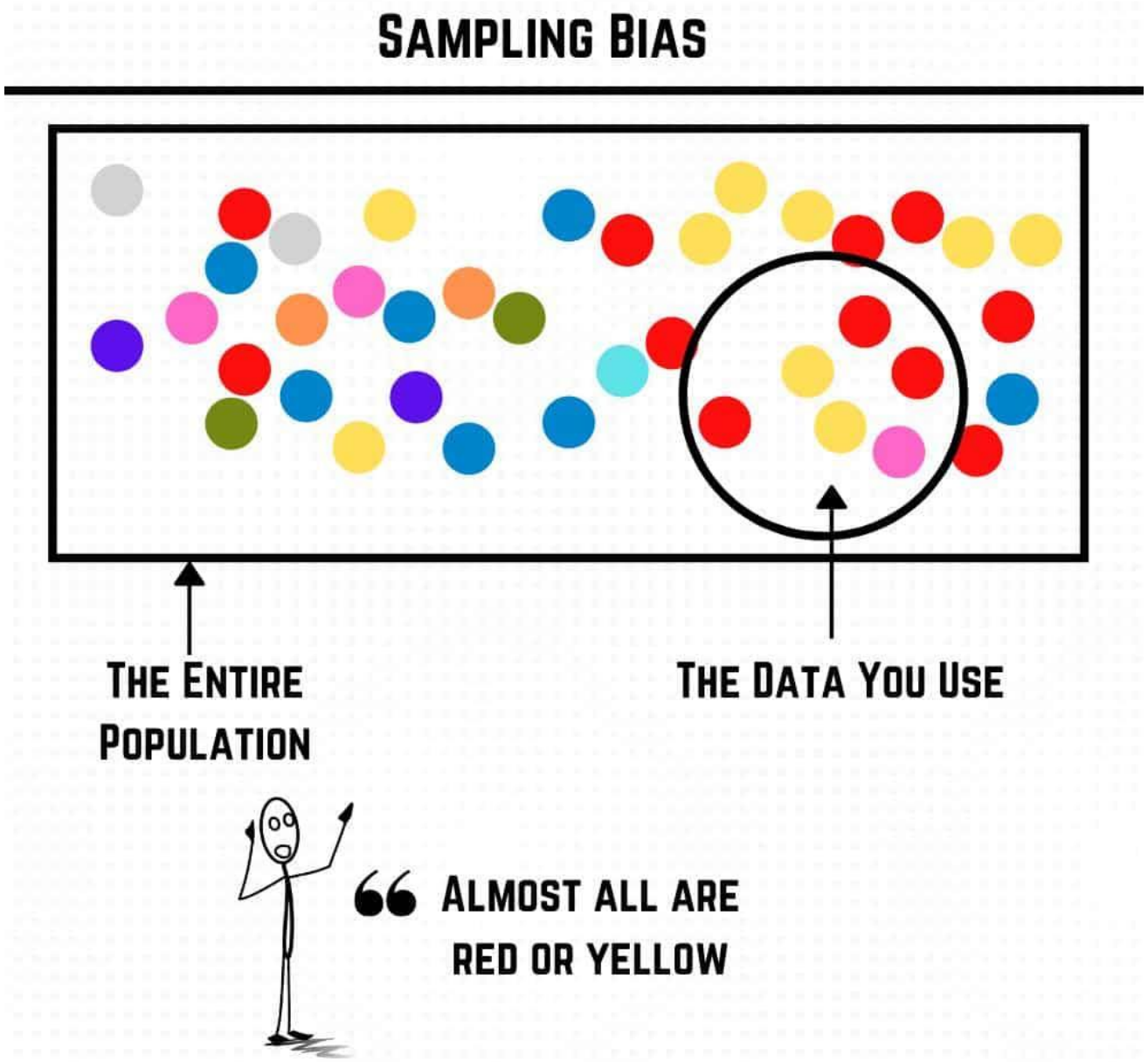
Participants & Sampling



- Ok, on to the next section of the Methods:
  - Study Design & Setting (what kind of study you did)
  - Participant and how you selected them (sampling)
  - What measurements you did
  - Analysis

- Need to tell the reader/audience not only
  - Who you included, but also
  - Who you excluded,
  - Where you found them and
  - How you selected them
  - Time frame of sampling

Sampling


SAMPLING BIAS
THE ENTIRE POPULATION
THE DATA YOU USE
ALMOST ALL ARE RED OR YELLOW

Measurements

- Ok, on to the next section of the Methods:
  - Study Design & Setting (what kind of study you did)
  - Participant and how you selected them (sampling)
  - What measurements you did
  - Analysis
- How did you obtain your data?
  - Laboratory tests
  - Observations
  - Record review – data extracts
  - Questionnaires / Surveys

Measurements – Questionnaires & Surveys

- How was it developed
  - Standardized
  - Developed in one language, translated/back- translated
  - Pilot tested—for comprehension
- Where administered and by whom
  - Self- or interviewer administered
  - Administered in a private setting by trained interviewers in local languages of x,y,z
- How long did it take?
- Other details: entered directly, PDA, ACASI

*I spend some time on this as doing questionnaires and surveys are **EXTREMELY** complex and should only be done with expert support*

Measurements – Variables

- Remember the ideal research question:

In a population of X is Y (predictor variable) associated with Z (outcome variable)

- Already spoke about the participants

- Should mention your main PREDICTOR variable, e.g.:
  - Demographic characteristics
  - Risk factors
  - Specefic types of questions

Information was collected on the following: basic demographics, self reported risk behavior, health seeking behavior; being physically forced to have sex, being otherwise coerced to have sex, but not physically etc.

Measurements

- Laboratory methods
  - Usually separate subheading
  - Screening and confirmatory tests
  - Where performed and by whom
  - Manufacturer of tests
    - Product name (company name, city, state, or country)
    - HIV1/2 STAT-PAK Rapid test (Inverness Medical, Princeton, NJ)
  - Reference new, experimental tests

- Give specific information on your OUTCOME variable, e.g.:

Acute HIV Infection was defined as antibody negative, PCR positive test results followed by antibody seroconversion…

Data Analysis & Statistical Methods

- Ok, on to the next section of the Methods:
  - Study Design & Setting (what kind of study you did)
  - Participant and how you selected them (sampling)
  - What measurements you did
  - Analysis
- Data entered
  - Where,
  - What program,
  - Exported into what (e.g., SAS version x [Cary, North Carolina]) for analysis
- Statistical tests performed
  - Univariate distribution of factors i.e. Simple frequencies
  - Bivariate (one predictor and one outcome)
  - Stratified analysis
  - Multivariable analysis

Ethical Considerations

- Often at end section on participants, could also be last sentence of Methods
- **MUST** have if reporting on surveys / questionnaires
- Informed consent (if not covered in the section on study population)
- Special considerations:
  - Persons with HIV considered to be a vulnerable population
  - Persons younger than 18
  - Employees where investigator is the employer
  - Persons in prison

Some Examples:

- Study Design & Setting
- Participant and how you selected them
- What measurements you did
- Analysis

- A retrospective review using frequency analysis of laboratory data was performed.
- Batch screening of random donor samples was performed to identify rare types, using extended phenotyping by manual tube indirect antiglobulin and enzyme techniques.
- Results were captured on Meditech, the SANBS operating platform, and extracted to the SANBS Business Intelligence System.
- Screening outcome was assessed by comparing the number of donors screened to the number of rare donors identified.
- Rare units issued by the SARDP from January 2016 to October 2018 are presented, along with an analysis of the number of the active donors.

Some Examples:

- Study Design & Setting
- Participant and how you selected them
- What measurements you did
- Analysis

- We performed a retrospective, descriptive study of the primary activities performed by the VRL between October 2015 and January 2019, focusing on the MATHS case control study.
- Laboratory data was retrieved from the Study Management System and laboratory records.
- Employee perspectives on challenges and benefits were sourced from a semi-structured interview.

Some Examples:

- Study Design & Setting
- Participant and how you selected them
- What measurements you did
- Analysis

- We extracted data on all RBC units issued for the period January to December 2018 from the SANBS Business Intelligence System.
- We analyzed predictors of group O product issues to non-group O patients, including hospital type, issue priority, patient gender, geographical zone and the days' stock on hand using summary statistics in Excel.
- Significance of associations were determined using the chi-square test.

Some Examples:

- Study Design & Setting
- Participant and how you selected them
- What measurements you did
- Analysis

- Blood donations previously confirmed as HIV-positive were further classified as acute (Ab-/RNA+), recent (AB+/RNA+, LAg recent), longstanding (Ab+/RNA+, LAg longstanding) and potential Elite Controller (Ab+/RNA-) HIV cases through HIV antibody (PrISM, Abbott), HIV RNA individual donation nucleic acid testing(NAT) (Procleix, Grifols) and LAg avidity testing.
- Stored plasma of these donations were tested for four ART drugs using qualitative liquid chromatography-tandem mass spectrometry (sensitivity 0. 0.02 µg/mL).
- Chi-square tests were used to assess the association of gender, ethnicity, age, geographic area, donor type, donor clinic type and HIV case type with ARV non-disclosure.

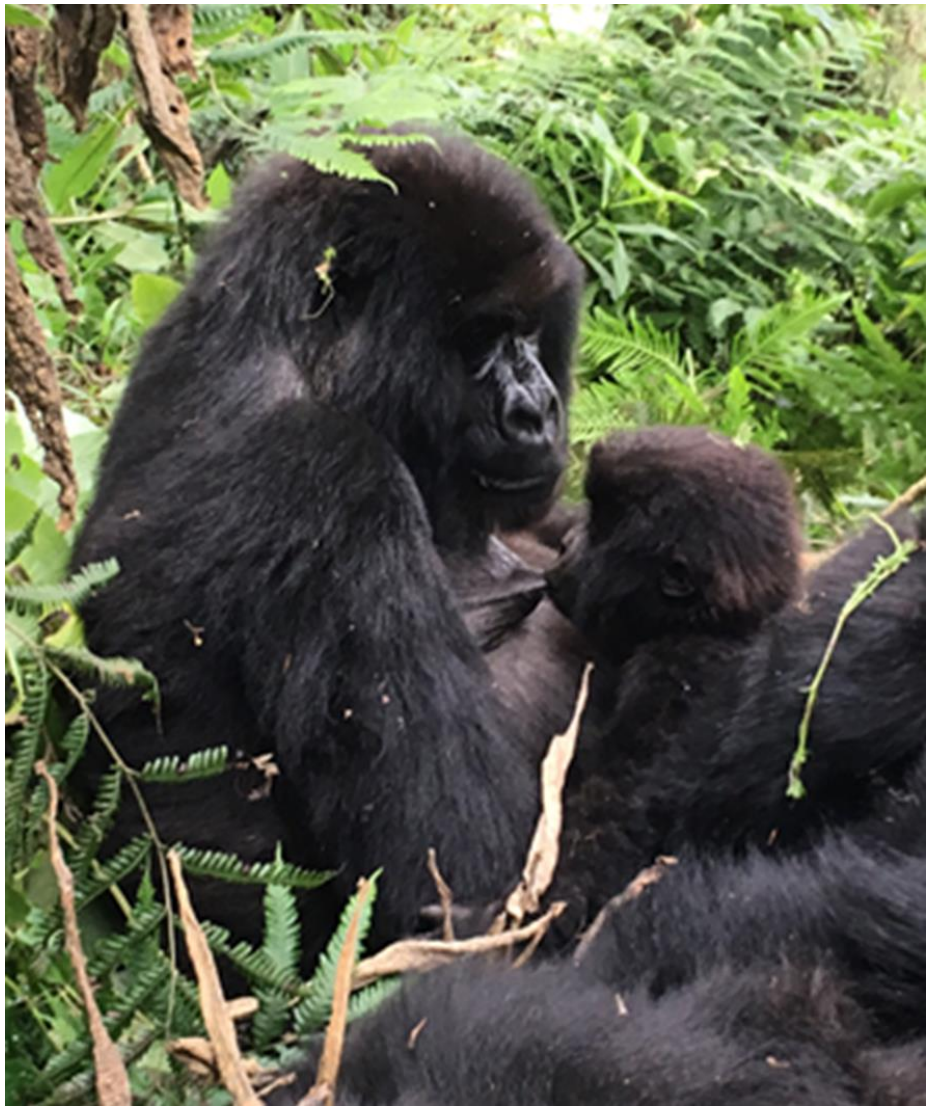
Some Examples:

- Study Design & Setting
- Participant and how you selected them
- What measurements you did
- Analysis

- Plasma samples from HIV seropositive FT donors during calendar years 2012 through 2016 were tested with a limiting antigen avidity (LAg) assay (Sedia Biosciences, Portland OR).
- We used a cutoff of 1.50 normalized optical density units corresponding to an incidence “window” of 129 days.
- Incidence was calculated as cases/1,000 PY of which numerator cases were recent infections as classified by the LAg assay.
- Each uninfected donor contributed the full 129-day person-time to the denominator while recently infected donors contributed half that.
- We used multiple imputation to adjust incidence for missing LAg results for 414 (7%) confirmed HIV-positive donors.
- Donors classified as longstanding HIV were excluded from both the numerator and denominator. 95% confidence intervals were calculated using the Poisson method.

ANY OTHER QUESTIONS??

THANK YOU!



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