

Provide a context or background for the study (that is, the nature of the problem and its significance). State the specific purpose or research objective of, or hypothesis tested by, the study or observation; the research objective is often more sharply focused when stated as a question. The manuscript should clearly state research problem, knowledge gap, research question, research objective, hypothesis and significance of the study. Both the main and secondary objectives should be clear, and any prespecified subgroup analyses should be described. Provide only directly pertinent references, and do not include data or conclusions from the work being reported.

Word count: 300

METHODS

1. Design, setting & duration

Please mention the study design (cross-sectional/case-control/cohort/ trial) with name of the academic/ professional department and name of the academic/ professional institution with city and country. It shows ownership. Add duration of the study with day, month and year.

1. **Ethical approval** from institutional ethical committee & patients' consent.

2. Population & sampling

Research is a problem-solving activity for a specified population; never for a sample. Please specify/ define your population by count, geographic location, socio-demographic and disease factors. Then tell how you calculated the sample size as required by the design of your study with formula/calculation or online calculator/software with reference/link. Then give sampling technique. Then give inclusion and exclusion criteria for one group or separately for each group in case of two or more groups.

1. Equipment, procedure, intervention and follow up

Please narrate here all the steps which you took from enrolment of a subject to its discharge from the study, including history, general & systemic examination, investigations and any intervention (health education, food, exercise, vaccine, drug, device, laser or surgery). Please give details of different equipment, instruments, appliances and tools used, giving the name, model, version, company name and its manufacturing city name in parenthesis.

1. Data collection plan

1. Data collection methods (physical procedures to collect data)

a. Literature survey (secondary data; the data of other researchers collected, mostly qualitative)

b. Questionnaire

c. Interview

d. Observation: clinical examination, laboratory & imaging tests, pre, per and post drug-treatment/ device-procedure/ operation notes/ findings as morbidities, disabilities, mortalities. (b, c and d give us primary & first hand data, the data which we generate ourselves from the sample, mostly quantitative). Tell which one or more methods of data collection are used by you.

2. Questionnaire is framed from literature. The data on research variables is collected by questionnaire. Qualities are transformed into quantities (qualitative variable/data to quantitative variable/data) as in Knowledge, Attitude & Practice (KAP) Surveys. It gives us quantitative data. Its reliability is pretested by a pilot study by selecting sample from a sample and is shown as Cronbach's alpha. It should be based on a 5-point Likert scale, with a range of 1-5 scores (strongly disagree, disagree, neutral, agree & strongly agree, respectively) respectively for each response. It includes respondent demographic. The questionnaire must not be on nominal or ordinal scale.

3. Questionnaire; To-do list

a. Items (questions) are extracted from literature (existing knowledge)

b. Designed as per list of variables, their attributes & their relationship as per theoretical framework

c. Items should be short & to the point

4. Avoid in framing a questionnaire; Not-to-do list

a. Double-Barrel items/questions (Qs)

b. Putting words in mouth of respondent (leading Qs)

c. Memory dependent Qs; should base on cash memory

d. Emotional loaded Qs (positive emotion=happiness, negative are anger, fear, sadness & hatredness)

e. Personal Qs (private, vary from culture to culture)

f. Technical Jargons

g. Too many

h. Too long

i. Negative Qs. I do not like computer. If negative are used, then reverse the scoring at analysis.

2. Name the demographic variables: gender, age in years, age groups, education level, residence, experience, income etc.
3. Name the research variables: pain in flank, category of pain in throat, level of knowledge, level of attitude, level of practice, weight in Kg, height in cm, volume in ml, RBS in mg/dL, T3 level in pcg/ml
7. In case of categorical (nominal or ordinal) variable, tell the attributes (categories/ groups) of the variable a. Age grouping was; group 1 up to 50 years, group 2 more than 50 years in a study "prevalence of HTN in employees of a bank" b. Age in years was categorized as; group 1= 40-49, group 2 = 50-59, group 3 = 60-69, group 4 = 70 and above years for a study "prevalence of DM in adult age shopkeepers" c. The two attributes of residence were urban and rural. The five attributes of education level were: matric = group 1, graduation = group 2, masters = group 3, MPhil = group 4 and PhD = group 5e. Level of knowledge, level of attitude and level of practice (KAP) were determined by a questionnaire based on 5-point Likert Scale. There were so many questions for each of the three KAP variables with a range of 1-5 scores (strongly disagree, disagree, neutral, agree & strongly agree, respectively) for each question.
4. Identify independent, dependent, confounding and matching variables, where required9. Tell the data types (nominal/ordinal/interval/ratio); gender, residence and pain in flank were nominal data. Age groups, education level, and category of pain in throat were ordinal data. Age in years, level of knowledge, level of attitude, level of practice (all three on Likert Scale), pain score (on visual analogue pain scale-VAPS), weight in Kg, height in cm, volume in ml, RBS in mg/dL, T3 level in pcg/ml were interval/ ratio/ numeric/ continuous data.10. Attach Performa and questionnaire. if any.11. Mention which calculator or software was used for data analysis

5. Data analysis plan

Research is for a specified population; never for a sample. It is ideal to observe the entire population, but it is not feasible. Statistics as a discipline helps us in collecting data for a sample, analyze it for the sample (descriptive statistics; describe the sample) and then infer it on to the population from which it was drawn (inferential statistics; describe the population based on the

data collected from the sample). Inferential statistics includes estimation of parameter and hypothesis testing. Global literature is full of research articles which are restricted to sample, with no mention of the population. For us, it may be anything, but not research. Our authors have to give analysis plan for all the three components of the statistical analysis. It is widely stated and widely accepted narrative that the cross-sectional studies don't require hypothesis. It is a miss-understanding. Cross-sectional studies do require hypothesis. There may be some one dozen cross-sectional studies, each with many hypotheses published in this journal from 2018 to 2021, regarding burden/ magnitude (prevalence/ distribution) of malaria, leishmaniasis, DS-TB, DR-TB etc. Data analysis is simply a process of converting data (un-organized facts & figures) into information (organized facts & figures). Both qualitative and quantitative data are organized as per requirements of the topic and end users of the findings. When analyzed (organized), qualitative and quantitative facts and figures are mixed together to form a single piece of information or knowledge. There are two types of analysis.

Qualitative analysis

Qualitative data includes text, picture, audio and video. This analysis is based on qualitative argumentation (not included here).

Quantitative analysis

Quantitative data includes nominal, ordinal, interval and ratio data. This analysis is based on statistical computations (included here).

Descriptive analysis

It is the analysis of data collected from the sample. Here each variable is described separately without talking about its difference between the groups or within the groups or its relationships to any other variable in the same population.

Categorical (nominal and ordinal data) is analyzed by count and percentage. Numeric (interval and ratio) is subjected to tests of normality; Skewness, kurtosis, Kolmogorov-Smirnov test & histogram. If it is distributed normally; then it is analyzed by mean, minimum, maximum, range and SD. If it is distributed not normally (skewed); then it is analyzed by median (quartile 2), quartile 1 (Q1), quartile 3 (Q3) and Inter Quartile Range ($IQR=Q3-Q1$).

Inferential analysis: Here the data for the sample is inferred on to population. It includes estimation of parameters and testing of hypotheses.

Estimation of parameters

Here an interval is constructed around a sample statistic to estimate a parameter i.e. mean or proportion for a population at certain level of confidence, usually 95%. It is represented as

confidence interval of mean or proportion, both with lower and upper bounds. The mean RBS of the sample (n=350) was 110 (95% CL, 105.5-114.5) mg/dL. The frequency (%age) of diabetes mellitus in the sample (n=300) was 45 (15%, 95% CL, 12.5-17.5).

Technical information: Identify the methods, apparatus (give the manufacturer's name and address in parentheses), chemicals (give catalogue number, company name and place of manufacture) and procedures in sufficient detail to allow other workers to reproduce the results. Give references to established methods, including statistical methods (see below); provide references and brief descriptions for methods that have been published but are not well known; describe new or substantially modified methods, give reasons for using them, and evaluate their limitations. Identify precisely all drugs and chemicals used, including generic name(s), dose(s), and route(s) of administration. Reports of randomized clinical trials should present information on all major study elements, including the protocol, assignment of interventions (methods of randomization, concealment of allocation to treatment groups), and the method of masking (blinding), based on the CONSORT Statement (<http://www.consort-statement.org>).

Note: Authors submitting review article should include a section describing the methods used for locating, selecting, extracting, and synthesizing data. These methods should also be summarized in the abstract.

RESULTS

Preparing the sample for analysis; number of subjects

- Total number of participants/ respondents/ subjects/ cases/ patients/ controls/ animals/ specimens/ plants/ microorganisms enrolled/ included at inception/ start of the survey/ study/ trial
- Group wise number of participants/ subjects/ cases/ patients/ controls at inception
- Frequency (count) & percentage of responses of the respondents in case of questionnaire based survey.
- Mention if any subject died?
- How many were dropped out & why? Mention different causes with numbers of subject separately i.e. due to which complications of the drugs/ devices/ laser/ surgical procedure etc.
- How many were lost to follow up?
- Mention the missing data at follow ups
- The rest of the subjects are the actual size of the sample/s to be analyzed