Summary and Synthesis: How to Present a Research Proposal

Maninder Singh Setia, Saumya Panda

Abstract
This concluding module attempts to synthesize the key learning points discussed during the course of the previous ten sets of modules on methodology and biostatistics. The objective of this module is to discuss how to present a model research proposal, based on whatever was discussed in the preceding modules. The lynchpin of a research proposal is the protocol, and the key component of a protocol is the study design. However, one must not neglect the other areas, be it the project summary through which one catches the eyes of the reviewer of the proposal, or the background and the literature review, or the aims and objectives of the study. Two critical areas in the “methods” section that cannot be emphasized more are the sampling strategy and a formal estimation of sample size. Without a legitimate sample size, none of the conclusions based on the statistical analysis would be valid. Finally, the ethical parameters of the study should be well understood by the researchers, and that should get reflected in the proposal.

KEY WORDS: Biostatistics, research proposal, research protocol, study design

As we reach the end of an exhaustive module encompassing research methods and biostatistics, we need to summarize and synthesize the key learning points, to demonstrate how one may utilize the different sections of the module to undertake research projects of different kinds. After all, the practical purpose behind publishing such a module is to facilitate the preparation of high-quality research proposals and protocols. This concluding part will make an attempt to provide a window to the different sections of the module, underlining the various aspects of design and analysis needed to formulate protocols applicable to different kinds of clinical research in dermatology.

Components of a Research Proposal
The goal of a research proposal is to present and justify the need to study a research problem and to present the practical ways in which the proposed study should be conducted. A research proposal is generally meant to be presented by an investigator to request an agency or a body to support research work in the form of grants. The vast majority of research proposals, in India, however, are not submitted to agency or body for grants, simply because of the paucity of such agencies, bodies, and research grants. Most are academic research proposals, self-financed, and submitted to scientific and ethics committee of an institution. The parts of a proposal include the title page, abstract/project summary, table of contents, introduction, background and review of literature, and the research protocol.

The title page should contain the personal data pertaining to the investigators, and title of the project, which should be concise and comprehensive at the same time. The table of contents, strictly speaking, is not necessary for short proposals. The introduction includes a statement of the problem, purpose, and significance of the research. The protocol is the document that specifies the research plan. It is the single most important quality control tool for all aspects of a clinical research. It is the instrument where the researcher explains how data will be collected, including the calculation for estimating sample size, and what outcome variables to measure.

A complete clinical research protocol includes the following:
• Study design
• Precise definition of the disease or problem
• Completely defined prespecified primary and secondary outcome measures, including how and when these will be assessed
• Clear description of variables
• Well-defined inclusion and exclusion criteria
• Efficacy and safety parameters

This is an open access article distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as the author is credited and the new creations are licensed under the identical terms.

For reprints contact: reprints@medknow.com

How to cite this article: Setia MS, Panda S. Summary and synthesis: How to present a research proposal. Indian J Dermatol 2017;62:443-50.

Received: August, 2017. Accepted: August, 2017.
setia and panda: how to present a research proposal.

one of the main limitations of found that the prevalence reported prevalence though previous studies have assessed the association between anemia and psoriasis, they have not used any objective criteria (such as the patients based on clinical assessment of pallor). our study was the lack of objective criteria for assessing anemia in patients presenting with psoriasis. we classified our study was the lack of objective criteria for assessing anemia in patients presenting with psoriasis. we classified the patients based on clinical assessment of pallor.

the broader impacts (the contribution the research will make to the society) should answer why your research is important for the advancement of the field. the broader impacts (the contribution the research will make to the society) should answer why your research is important for the advancement of the field. the broader impacts (the contribution the research will make to the society) should answer why your research is important for the advancement of the field. the broader impacts (the contribution the research will make to the society) should answer why your research is important for the advancement of the field.

though some studies found the prevalence to be higher in males, others reported that females had a higher prevalence. a study by xxxx et al. found that the prevalence of psoriasis was 20%. it was a hospital-based study conducted in north india. the prevalence was 35% in males and 12% in females. another study by yyyy et al. found that the prevalence of psoriasis was 14%. the study was conducted in a private clinic in north india. the prevalence was 8% in males and 18% in females. a third study by zzzzz et al. found that the prevalence of psoriasis was 5%. this study was a community-based study. the prevalence was 7% in males and 3% in females. in this type of review, the researcher has described all the studies. however, it is useful to understand the findings of these three studies and summarize them in researcher's own words.

a possible option can be “the reported prevalence of psoriasis in the indian population varied from 5% to 20%. in general, it was higher in hospital-based studies and lower in community-based studies. there was no consistent pattern in the prevalence of psoriasis in males and females. though some studies found the prevalence to be higher in males, others reported that females had a higher prevalence.”

the researcher should discuss the limitations of the studies. these could be the limitations that the authors have presented in the manuscript or the ones that the researcher has identified. usually, the current research proposal should try to address the limitations of a previous study. an example could be “one of the main limitations of our study was the lack of objective criteria for assessing anemia in patients presenting with psoriasis. we classified the patients based on clinical assessment of pallor.”

the present proposal can mention “though previous studies have assessed the association between anemia and psoriasis, they have not used any objective criteria (such...
as hemoglobin or serum ferritin levels). Furthermore, pallor was evaluated by three clinicians; the authors have not described the agreement between these clinicians.”

In the above example, the authors have stated the limitation of their research in the manuscript. However, in the review of literature, the researcher has added another limitation. It is important to convince the reviewers that the researcher has read and understood the literature. It is also important that some or most of these lacunae should be addressed in the present proposal as far as possible.

**Justify the present proposal by review**

The researcher should adequately justify the present proposal based on the review of literature. The justification should not only be for the research question, but also the methods, study design, variables of interest, study instruments or measurements, and statistical methods of choice. Sometimes, the justification can be purely statistical. For example, all the previous studies have used cross-sectional data or cross-sectional analysis of longitudinal data in their manuscripts. The present proposal will use methods used for longitudinal data analysis. The researcher should justify the benefit of these methods over the previous statistical methods.

In short, the review should not be a “laundry list” of all the articles. The review should be able to convince the reader that the present research is required and it builds on the existing literature (either as a novel research question, new measurement of the outcome, a better study design, or advanced and appropriate statistical methods).

Kindly try to avoid this justification: “It has not been done in our center.”

**Aims and Objectives**

The “aim” of the study is an overarching goal of the study. The objectives are measurable and help the researcher achieve the overall aim.

For example, the overall aim of our study is to assess the long-term health of patients of psoriasis.

The specific objectives are:
1. To record the changes in Psoriasis Area and Severity Index (PASI) score in patients with psoriasis over a period of 5 years
2. To study the side effects of medications in these patients over a period of 5 years.

It is important to clearly state the objectives, since the research proposal should be designed to achieve these objectives.

For example, the methods should describe the following:
- How will the researcher answer the first objective?
- Where will the researcher recruit the study participants (study site and population)?
- Which patients of psoriasis will be recruited (inclusion and exclusion criteria)?
- What will be the design of the study (cohort, etc.)?
- What are all the variables to be measured to achieve the study outcomes (exposure and outcome variables)?
- How will the researcher measure these variables (clinical evaluation, history, serological examination, etc.)?
- How will the researcher record these data (clinical forms, etc.)?
- How will the researcher analyze the data that have been collected?
- Are there any limitations of these methods? If so, what has the researcher done to minimize the limitations?

**Methods**

All the ten modules on research methodology have to be read and grasped to plan and design any kind of research applicable to one’s chosen field. However, some key areas have been outlined below with examples to appreciate the same in an easier manner.

**Study area**

The study setting must be specified. This should include both the geographical location and the population from which the study sample would be recruited.

**Example**

“The study took place at the antiretroviral therapy clinic of Queen Elizabeth Central Hospital in Blantyre, Malawi, from January 2006 to April 2007. Blantyre is the major commercial city of Malawi, with a population of 1,000,000 and an estimated HIV prevalence of 27% in adults in 2004” (Ndekha et al., 2009).

This is a perfect example of description of a study setting which underscores the importance of planning it in detail *a priori*.

**Study population, sampling strategy, and sample size**

Study population has to be clearly and precisely defined. For example, a study on atopic dermatitis may be conducted upon patients defined according to the UK Working Party’s modified diagnostic criteria, or the Hanifin and Rajka’s criteria, or some other criteria defined by the investigators. However, it should always be prespecified within the protocol.

Similarly, the eligibility criteria of the participants for the study must be explicit. One truism that is frequently forgotten is that the inclusion and exclusion criteria are mutually exclusive, and one is not the negative image of the other. Eligible cases are included according to a set of inclusion criteria, and this is followed by administration of the exclusion criteria.
Thus, in fact, they can never be the negative image of each other.

**Example**

"Eligible participants were all adults aged 18 or over with HIV who met the eligibility criteria for antiretroviral therapy according to the Malawian national HIV treatment guidelines (WHO clinical stage III or IV or any WHO stage with a CD4 count <250/mm$^3$) and who were starting treatment with a BMI <18.5. Exclusion criteria were pregnancy and lactation or participation in another supplementary feeding program" (Ndekha *et al.*, 2009).

To put in perspective the point we made about inclusion and exclusion criteria, in the above example, “age above 18 years” or “CD4 count >250/mm$^3$” cannot be exclusion criteria, as these have already been excluded.

Sampling strategy has been adequately discussed in the Module 5 of the Methodology series (Setia, 2016). A few points are worth repeating:

1. The sampling strategy should never be misrepresented. Example: If you have not done random sampling, no big deal. There are other legitimate sampling strategies available for your study. But once you have mentioned “random sampling” in your protocol, you cannot resort to purposive sampling.

2. Sometimes, the researcher might want to know the characteristics of a certain problem within a specific population, without caring for generalizability of results. In such a scenario, purposive sampling may be resorted to.

3. Nonprobability sampling methods such as consecutive consenting sampling or any such convenience sampling are perfectly legitimate and easy to do, particularly in case of dissertations where time and resources are limited.

Sample size is one of the most misunderstood, yet fundamentally important, issues among clinicians and has to be addressed once the study objectives have been set and the design has been finalized. Too small a sample means that there would be a failure to detect change following test intervention. A sample larger than necessary may also result in bad quality data. In either case, there would be ethical problems and wastage of resources. The researcher needs just enough samples to draw accurate inferences, which would be adequately powered (Panda, 2015).

Estimation of sample size has been dealt with adequately in the Module 5 biostatistics series (Hazra *et al.*, 2016), including the different mathematical derivations and the available software. Sample size determination is a statistical exercise based on the probability of errors in testing of hypothesis, power of the sample, and effect size. Although, relatively speaking, these are simple concepts to grasp, a large number of different study designs and analytical methods lead to a bewilderingly large number of formulae for determining sample size. Thus, the software are really handy and are becoming increasingly popular.

**Study design**

The study design defines the objectives and end points of the study, the type and manner of data collection, and the strategy of data analysis (Panda 2015). The different types of clinical studies have been depicted in Figure 1. The suitability of various study designs vis-à-vis different types of research questions is summarized in Table 1.

In our previous series of ten modules on methodology, we have discussed all these different kinds of studies and more. Some key issues that require reiteration are given below:

i. The control of a case–control study and that of a randomized controlled trial is more different from each other than chalk is from cheese. The former is an observational study, while the latter is an interventional one. Every study with a control group is not a case–control study. For a study to be classified as a case–control study, the study should be an observational study and the participants should be recruited based on their outcome status (Setia, 2016).

![Figure 1: Types of study (Source: Panda, 2015)](image)

**Table 1: Research questions vis-a-vis study designs**

| Research question | Study design               |
|-------------------|----------------------------|
| Therapy           | Randomized controlled trial|
| Diagnosis         | Cross-sectional study      |
| Screening         | Cross-sectional study      |
| Prognosis         | Cohort                     |
| Etiology          | Cohort or case-control     |
| Side effects      | Case series                |

(Source: Panda, 2015)
yet even now we have publications which confuse between the different kinds of controls (Bhanja et al., 2015).

ii. Due to the fact that the outcome and exposure are assessed at the same time point in a cross-sectional study, it is pretty difficult, if not impossible, to derive causal relationships from such a study. At most, one may establish statistical association between exposures and outcomes by calculating the odds ratio. However, these associations must not be confused with causation.

iii. It is generally said that a cohort design may not be efficient for rare outcomes. However, if the rare outcome is common in some exposures, it may be useful to follow a cohort design. For example, melanoma is a rare condition in India. Hence, if we follow individuals to study the incidence of melanoma, it may not be efficient. However, if we know that, in India, acral lentiginous melanoma is the most commonly reported variant, we should follow a cohort of individuals with acral lentiginous and study the incidence of melanoma in this group (Setia, 2016).

Clinical researchers should also be accustomed with observational designs beyond case–control, cohort, and cross-sectional studies. Sometimes, the unit of analysis has to be a group or aggregate rather than the individual. Consider the following example:

The government introduced the supplementation of salt with iodine for about 20 years. However, not all states have used the same level of iodine in salt. Certain hilly states have used higher quantities compared with other states. Incidentally, you read a report that high iodine levels are associated with psoriasis. You are intrigued to find if introduction of iodine has altered the picture of psoriasis in the country. You feel compelled to design a study to answer this question.

It is obvious that here the unit of study cannot be individuals, but a large population distributed in a certain geographical area. This is the domain of ecologic studies. An allied category of observational studies is named “natural experiments,” where the exposure is not assigned by the investigator (as in an interventional study), but through “natural processes.” These may be through changes in the existing regulations or public policies or, may be, through introduction of new laws (Setia, 2017).

Another category of research questions that cannot be satisfactorily captured by all the quantitative methods described earlier, like social stigma experienced by patients or their families with, say, vitiligo, leprosy, or sexually transmitted infections, are best dealt with by qualitative research. As can be seen by the examples given above, this is a type of research which is very relevant to medical research, yet to which the regular medical researcher has got a very poor exposure, if any. We shall encourage interested researchers to take a look at the 10th Module of the Methodology series that specifically deals with qualitative research (Setia, 2017).

Clinical studies are experiments that are not conducted in laboratories but in controlled real-life settings on human subjects with some disease. Hence, designing a study involves many pragmatic considerations aside pure methodology. Thus, factors to consider when selecting a study design are objectives of the study, time frame, treatment duration, carryover effects, cost and logistics, patient convenience, statistical considerations, sample size, etc. (Panda, 2015).

Certain truisms regarding study designs should always be remembered: a study design has to be tailored to objectives. The same question may be answered by different designs. The optimum design has to be based on workforce, budgetary allocation, infrastructure, and clinical material that may be commanded by the researchers. Finally, no design is perfect, and there is no design to provide a perfect answer to all research questions relevant to a particular problem (Panda, 2015).

Variables of interest and collection of these variables

Data structure depends on the characteristics of the variables [Figure 2]. A variable refers to a particular character on which a set of data are recorded. Data are thus the values of a variable (Hazra et al., 2016).

Quantitative data always have a proportional scale among values, and can be either discrete (e.g., number of moles) or continuous (e.g., age). Qualitative data can be either nominal (e.g., blood groups) or ordinal (e.g., Fitzpatrick’s phototypes I-VI). Variables can be binary or dichotomous (male/female) or multinomial or polychotomous (homosexual/bisexual/heterosexual) (Panda, 2015).

Changing data scales is possible so that numerical data may become ordinal and ordinal data may become...
nominal. This may be done when the researcher is not confident about the accuracy of the measuring instrument, is unconcerned about the loss of fine detail, or where group numbers are not large enough to adequately represent a variable of interest. It may also make clinical interpretation easier (Hazra et al., 2016).

The variables whose effects are observed on other variables are known as independent variables (e.g., risk factors). The latter kind of variables that change as a result of independent variables are known as dependent variables (i.e., outcome). Confounders are those variables that influence the relation between independent and dependent variables (e.g., the clinical effect of sunscreen used as part of a test intervention regimen in melasma). If the researcher fails to control or eliminate the confounder, it will damage the internal validity of an experiment (Panda, 2015).

Biostatistics begins with descriptive statistics that implies summarizing a collection of data from a sample or population. An excellent overview of descriptive statistics has been given in the Module 1 of the Biostatistics series (Hazra et al., 2016). We would encourage every researcher to embark on designing and collecting data on their own to go through this particular module to have a clear idea on how to proceed further.

**Statistical methods**

As briefly discussed earlier, the “methods” section should also include a detailed description of statistical methods. It is best to describe the methods for each objective.

For example: Which statistical methods will the researcher use to study the changes in PASI score over time?

It is important to first identify the nature of the outcome – will it be linear or categorical?

- It may be noticed that the PASI is a score and can range from 0 to 72. The researcher can measure the actual score and assess the changes in score. Thus, the researcher will use methods for statistical analysis of continuous data (such as means, standard deviations, t-test, or linear regressions)

- However, the researcher may choose to cut off the PASI score at 60 (of course, there has to be justification!) and call it severe psoriasis. Thus, the researcher will have an outcome variable with two outcomes (Yes: >60 PASI, and No: <60 PASI). Thus, in this case, the researcher will use methods for statistical analysis of categorical data (proportions, Chi-square test, or logistic regression models).

The statistical methods have been described in detail in the Biostatistics section of the series. The reader is encouraged to read all the sections to understand these methods. However, the key points to remember are:

- Identify the nature of the outcome for each objective
- Describe the statistical methods separately for each objective
- Identify the methods to handle confounding and describe them in the statistical methods
- If the researcher is using advanced statistical methods or specific tools, please provide reference to these methods
- Provide the name of the statistical software (including the version) that will be used for data analysis in the present study
- Do not provide a laundry list of all the statistical methods. It just shows that the researcher has not understood the relevance of statistics in the study design.

**Multivariate models**

In general, multivariate analyses are used in studies and research proposals. These analyses are useful to adjust for confounding (though these are also useful to test for interaction, we shall discuss confounding in this section). For example, we propose to compare two different types of medications in psoriasis. We have used secondary clinical data for this study. The outcome of interest is PASI score. We have collected data on the type of medication, age, sex, and alcohol use. When we compare the PASI score in these two groups, we will use t-test (if linear comparison) or Chi-square test (if PASI is categorized – as described earlier). However, it is possible that age, sex, and alcohol use may also play a role in the clinical progression of psoriasis (which is measured as PASI score). Thus, the researcher would like to account for differences in these variables in the two groups. This can be done using multivariate analytical methods (such as linear regression for continuous variables and logistic regression for categorical dichotomous variables). This is a type of mathematical model in which we include multiple variables: the main explanatory variable (type of drug in this study) and potential confounders (age, sex, and alcohol use in this study). Thus, the outcome (PASI score) after multivariate analyses will be “adjusted” for age, sex, and alcohol use after multivariate analysis. We would like to encourage the readers to consult a statistician for these methods.

TRIVIA: The singular for “data” is “datum,” just as “stratum” is the singular for “strata.” Thus, “data were analyzed…” “data were collected…,” and “data have been….”

**Clinical Record Forms**

We have discussed designing of questionnaires and clinical record forms (CRFs) in detail in two modules. We shall just highlight the most important aspects in this part. The CRF is an important part of the research protocol. The CRF should include all the variables of interest in the study. Thus, it is important to make a list of all parameters of
interest before working on the CRF. This can be done by a thorough review of literature and discussion with experts. Once the questionnaire/CRF has been designed, the researcher should pilot it and change according to the feedback from the participants and one’s own experience while administering the questionnaire or recording data in the CRF. The CRF should use coded responses (for close-ended questions), this will help in data entry and analysis. If the researcher has developed a scale, the reliability and validity should be tested (methods have been discussed in earlier sections). The CRF can be paper based or computer based (it will depend on the resources).

**Ethics**

It is very important to describe the ethics for the present study. It should not be restricted to “The study will be evaluated by an Institutional Review Committee...” The researcher should demonstrate that s/he has understood the various ethical issues in the present study. The three core principles for ethics are: autonomy (the participants have a right to decide whether to participate in the study or opt out), beneficence/nonmaleficence (the study should not be harmful to participants and the risk–benefit ratio should be adequately understood and described), and justice (all the risks and benefits of the present study should be equally distributed).

The researcher should try to address these issues in the section of “Ethics.” Currently, the National Institutes of Health has proposed the following seven principles of “Ethics in Clinical Research:” social and clinical value, scientific validity, fair subject selection, favorable risk–benefit ratio, independent review, informed consent, and respect for potential and enrolled subjects. The Indian Council of Medical Research has also published guidelines to conduct biomedical research in India. We strongly encourage the readers to be familiar with these guidelines. Furthermore, the researchers should keep themselves updated with changes in these regulations. If it is a clinical trial, the researcher should also be familiar with Schedule Y and Consent form requirements for these types of clinical trials.

**Concluding Remarks**

This module has been designed as a comprehensive guide for a dermatologist to enable him/her to embark on the exciting journey of designing studies of almost any kind that can be thought to be of relevance to clinical dermatology. There has been a conscious attempt to customize the discussion on design and analysis keeping not only dermatology, but also Indian conditions in mind. However, the module can be of help to any medical doctor embarking on the path to medical research. As contributors, it is our ardent hope that this module might act as a catalyst of good-quality research in the field of dermatology and beyond in India and elsewhere.

**Financial support and sponsorship**

Nil.

**Conflicts of interest**

There are no conflicts of interest.

**Bibliography**

1. Ady, L. A., Designing & Conducting Health Surveys. Second ed. 1996, San Francisco, USA: Jossey-Bass.
2. Alejandro R, Jadad, & Enkin, M. W. (2007). Randomized Controlled Trials. Questions, Answers, and Musings (Second ed.): Blackwell Publishing.
3. Bagatin E, Miot HA. How to design and write a clinical research protocol in cosmetic dermatology. An Bras Dermatol 2013;88:69-75.
4. Bhanja DC, Ghoshal L, Das S, Das S, Roy AK. Azathioprine in autologous serum skin test positive chronic urticaria: A case-control study in a tertiary care hospital of eastern India. Indian Dermatol Online J 2015 May-Jun; 6(3):185-8.
5. Central Drugs Standard Control Organization. (2014). Draft Guidelines on Audio-Visual Recording of Informed Consent Process in Clinical Trial. Retrieved 14 June, 2016, from http://www.cdsco.nic.in/writereaddata/Guidance_for_AV%20Recording_09.January. 14.pdf.
6. Central Drugs Standard Control Organization. Good Clinical Practice Guidelines. Retrieved 14, June, 2016, from http://www. cdsco.nic.in/html/GCP1.html
7. Central Drugs Standard Control Organization. Schedule Y. Retrieved 16 June, 2016, from http://cdsco.nic.in/html/D&C_Rules_Schedule_Y.pdf.
8. Charles H. Hennekens, & Julie E. Buring.(1987). Epidemiology in Medicine (First ed.). Philadelphia, USA: Lippincott Williams & Wilkins.
9. Clinical Center-National Institutes of Health.(2017). Patient Recruitment; Ethics in Clinical Research. Retrieved 11 August, 2017, from https://clinicalcenter.nih.gov/recruit/ethics.html.
10. Hazra A, Gogtay N. Biostatistics series module 1: Basics of biostatistics. Indian J Dermatol 2016;61:10-20.
11. Hazra A, Gogtay N. Biostatistics series module 2: Overview of hypothesis testing. Indian J Dermatol 2016;61:137-45.
12. Hazra A, Gogtay N. Biostatistics series module 3: Comparing groups: Numerical variables. Indian J Dermatol 2016;61:251-60.
13. Hazra A, Gogtay N. Biostatistics series module 4: Comparing groups-categorical variables. Indian J Dermatol 2016;61:385-92.
14. Hazra A, Gogtay N. Biostatistics series module 5: Determining sample size. Indian J Dermatol 2016;61:496-504.
15. Hazra A, Gogtay N. Biostatistics series module 6: Correlation and linear regression. Indian J Dermatol 2016;61:593-601.
16. Hazra A, Gogtay N. Biostatistics series module 7: The statistics of diagnostic tests. Indian J Dermatol 2017;62:182-4.
17. Hazra A, Gogtay N. Biostatistics series module 8: Assessing risk. Indian J Dermatol 2017;62:123-9.
18. Hazra A, Gogtay N. Biostatistics series module 9: Survival analysis. Indian J Dermatol 2017;62:251-7.
19. Hazra A, Gogtay N. Biostatistics series module 10: Brief overview of multivariate methods. Indian J Dermatol 2017;62:358-66.
20. Indian Council for Medical Research. (2006). Ethical Guidelines for Biomedical Research on Human Participants. New Delhi, India.
21. Jewell N. (2004). Statistics for Epidemiology. Boca Raton, US: Chapman and Hall/CRC.
22. Kenneth J. Rothman, Sander Greenland, & Timothy L. Lash. (2008). Modern Epidemiology (Third ed.). Philadelphia, USA: Lippincott Williams & Wilkins.
23. Kleinbaum D, Kupper L, & Morgenstern H. (1982). Epidemiologic research. New York, US: John Wiley & Sons, Inc.
24. Lawrence M. Friedman, Curt D. Furberg, and DeMets, D. L. (1998). Fundamentals of Clinical Trials (Third ed.). New York, USA: Springer.
25. Miquel Porta (Ed.); Sander Greenland, Miguel Hernán, Isabel dos Santos Silva, John M. Last (Assoc. Ed.); Andrea Burón (Asst. Ed.) (2014); A Dictionary of Epidemiology; New York, USA: Oxford University Press.
26. National Institutes of Health. (2016). Guiding Principles for Ethical Research; Pursuing Potential Research Participants Protections. Retrieved 11 August, 2017, from https://www.nih.gov/health-information/nih-clinical-research-trials-you/guiding-principles-ethical-research.
27. Ndekha MJ, van Oosterhout JJ, Zijlstra EE, Manary M, Saloojee H, Manary MJ. Supplementary feeding with either ready-to-use fortified spread or corn-soy blend in wasted adults starting antiretroviral therapy in Malawi: randomised, investigator blinded, controlled trial. BMJ 2009;338:1867-75.
28. Panda S. Designing a research protocol in clinical dermatology: Common errors and how to avoid them. Indian J Dermatol Venereol Leprol 2015;81:115-23.
29. Setia, M. S. (2016). Methodology Series Module 1: Cohort Studies. Indian J Dermatol, 61(1), 21-25.
30. Setia, M. S. (2016). Methodology series module 2: Case-control studies. Indian J Dermatol, 61(2), 146-151.
31. Setia, M. S. (2016). Methodology series module 3: Cross-sectional studies. Indian J Dermatol, 61(3), 261-264.
32. Setia, M. S. (2016). Methodology series module 4: Clinical trials. Indian J Dermatol, 61(4), 393-402.
33. Setia, M. S. (2016). Methodology series module 5: Sampling strategies. Indian J Dermatol, 61(5), 505-509.
34. Setia, M. S. (2016). Methodology series module 6: Systematic reviews and meta-analysis. Indian J Dermatol, 61(6), 602-607.
35. Setia, M. S.(2017). Methodology series module 7: Ecologic studies and natural experiments. Indian J Dermatol, 62(1), 25-28.
36. Setia, M. S. (2017). Methodology series module 8: Designing questionnaires and clinical record forms. Indian J Dermatol, 62(2), 130-134.
37. Setia, M. S. (2017). Methodology series module 9: Designing questionnaires and clinical record forms-part II. Indian J Dermatol, 62(3), 258-261.
38. Setia, M. S. (2017). Methodology series module 10: Qualitative health research. Indian J Dermatol, 62(4), 367-370.
39. Shott, S. (1990). Statistics for Health Professionals. USA: Saunders.
40. Stephen B. Hulley, Steven R. Cummings, Warren S. Browner, Deborah Grady, Norman Heast, & Thomas B. Newman. (2001). Designing Clinical Research (Second ed.). Philadelphia, USA: Lippincott Williams & Wilkins.
41. Streiner DL and Norman GR., Health Measurement Scales—a practical guide to their development and use. 2003, Oxford, UK: Oxford University Press.
42. SzkloM, and Javier Nieto F. (2004). Epidemiology: Beyond the basics. Sudbury, MA: Jones and Bartlett Publishers, Inc.
43. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979). The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Retrieved 10 July, 2017, from https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html. https://clinicalcenter.nih.gov/recruit/ethics.html.