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Scientific writing method of Synopsis for Post Graduates students.

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Abstract: Synopsis or a protocol is a written document that describes how a study can be implemented. Synopsis design may prefer based on study types like Descriptive, Experimental, case control, cohort, Analytical, Study of diagnostic accuracy), Literary Study, Animal Experiments, Mixed methods. Any students admitted in post graduates (M.D./M.S.) or post-doctoral course like Ph.D. need to submit a research proposal also called as 'protocol' to the university. Once synopsis is written appropriately as laid guidelines by university, it must be present before ethical Committee of the concern institute. Format of synopsis having various components like title, introduction, objectives, methodology, statistical analysis, case record form and inform consent etc. Research study should be interesting, novel to researchers, mentor and scientific community as well as general populations. There is need to focus many aspects while conducting a good research. Recently universities have started a training program on research methodology. Such program can help in improving knowledge about scientific understanding of research methods.

Keywords: Synopsis, Thesis, Proposal, Ethics, Novel, research methodology

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INTRODUCTION:

After entering into any post graduate study from university, it is necessary to submit a research proposal on concern speciality. A Synopsis may be defined as 'it is a documentation of all the scientific procedures that to be ideally followed when a medical hypothesis is to be evaluated or a clinical study is being conducted on human beings.' A Synopsis or a protocol is nothing but a written document that describes how a study (Social/epidemiological/clinical/experimental/animal) will be implemented. Sometimes it a quite hectic to design or write a synopsis that fit into any research questions. Particularly clinical post-graduation students get very less time to spend to write a proposal despite clinical postings. Different universities have their own guidelines on synopsis writing style., more ever or less it is having similar methodology in most of universities. Precisely, Maharashtra University of Health Science(MUHS) has laid down specific guidelines and format of writing dissertation. However, Synopsis design may prefer based on study types like Descriptive, Experimental, case control, cohort, Analytical, Study of diagnostic accuracy), Literary Study, Animal Experiments, Mixed methods etc.

Objectives:

Objective of this article is to insight the methods of writing styles of Synopsis or Thesis in MD/MS.

Methods:

Review done on various textbooks of Research Methodology, University guidelines and website of health sciences etc.

Need of Synopsis:

Any students admitted in post graduates (M.D./M.S.) or post-doctoral course like Ph.D. neede to submit a research proposal also called as 'protocol' to the university. This document describes when, how and where this study is being conducted and in how much duration. Once synopsis is written appropriately as laid guidelines

by university, it must be present before ethical Committee of the concern institute. After clearance of ethics committee, it can be produced before scientific committee of university. Once university approve it, one may start his/her research work. Synopsis on any subject is a part of research methodology and it also help a scientific attitude towards the research among students as it also forms a base for further publication of completed research. Failure to submit the synopsis within time, student may face the academic loss or the duration of PG course may also be extended by university. During study it is also necessary that all post graduate scholars' students need to submit six monthly progress report to the university. Recently Indian Council of Medical Research (ICMR) also created a portal to register their study on Clinical Trial Registry of India(CTRI). (<http://ctri.nic.in/>) CTRI is a allowed free and online record system for registration of clinical trials being conducted in India.

Concept of Research:

Before starting to write any research proposal one should thought about its feasibility, interesting, novelty in the research, ethically sound and it should have social relevance. This criterion is also known as 'FINERS' criteria for selecting research questions in any stream. Going into details of this criteria demonstrated how the actual research question should have ? If we choosing any research question, then it became priority that how it is adequate in terms of sample size, infrastructure and facility available concern research center. If any research question fails to then there is need to search next research question which fulfils the criteria. Further any study which we are planning to conduct should be interesting and novel to researchers, mentor and scientific community as well as general populations. Similarly, research study should also be approved from ethics committee. Simultaneously any

research in human being should follow ICMR guideline for human trials. Recently Ministry of Health and Family Welfare, Govt of India has published a Gazette notification in March 2019 about New Drugs and Clinical Trials Rules, 2018. According to this notification clinical trial protocol” means a document containing the background, objective, rationale, design, methodology including matters concerning performance, management, conduct, analysis, adverse event, withdrawal, statistical consideration and record keeping pertaining to clinical trial.

Method of Writing Synopsis/Thesis:

Format of synopsis having following components; it is need to take care of inclusion of all below points whenever writing a scientific protocol.

Title: It is the very important and it impress the readers if it is clear and informative in nature that readers must know what you are going to do or what had done in the research. Title of study should be very clear , possibly brief, should reflect study design and objectives. Titles should also have pin point reflection about any study design. It should be not repeated and similar with any previous study.

Introduction: It should includes include rational of study, present scenario with proper citation of research studies. If you are taking any clinical study then introduction should have disease conditions, prevalence, existing treatment, it should contain brief background of the study along with its importance and logical behind conduct of current research or advantage over the current situation. Effort should also made to cite appropriate references in this section.

Aim and Objective: Objective may be primary or secondary. Sometime aim of the study may be similar with the title of the study. Objectives of the study should be measurable and answerable to the research questions. Objectives are taken to identify the study outcomes. The objective in a synopsis

should be 4 to 5 in numbers. Generally, they started with word like “to determine, to estimate, to analyze, to evaluate” however the vague term like ‘to study’ should be avoided inwriting the objectives. Objective could be written by following SMART criteria i.e. it should be Smart, Measurable, Achievable, Realistic and time related.

Hypothesis: There are two hypotheses need to mention in most of clinical study i.e. null hypothesis or alternate hypothesis. It should be clearly stated, brief and should be related to primary research question. However, research question is not applicable for the study like Literary or conceptual Study, Qualitative study and Descriptive study. It should reflect the exposure outcome or relation between two variables in the study. Hypothesis must be mention in randomized clinical trials, intervention study, case control study and cohort studies.

Previous work done: It is very important to add previously conducted studies in the synopsis and thesis. For the previous work a vigorous review of literature is needed from various sources like pub med, Cochrane search, Google search, AYUSH research portal, DHARA or some universities website. It can also be searched from different National as well as International Journal from the internet.

Methodology: This is very core part of any study. Methodology gives an idea about how, when, where the research study is being conducted. Methodology itself describes the study types, sampling methods, assessment criteria, method of analysis, duration of the study etc. As above said, it also differs from study to study. It should be having inclusion and exclusion criteria if study is clinical or being conducted on humans. These criteria should be very clear. In this section there should be clear cut mention treatment protocol, duration drug details, group and randomization, blinding techniques etc. It is also necessary to mention the assessment criteria for objectives, investigation

need to perform and its full procedures. For animal study it should be as per the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) guidelines. If the study is on drug standardization or analysis, then entire drug analysis method and required equipment should be mentioned as per Ayurvedic Formulation of India. The textual or Samhita reference of the drugs with its detail's contents should be mentioned in this section. Operational definitions should be provided for the Coining of terms as per study subjects.

Sample size: It is very necessary to mention proper sample size with appropriate formula for calculation of study sample. It is the actual number of participants or subjects which are going under trial. Sample size calculation is depending upon the study designs, disease prevalence, treatment effects and objective of the study. Statistical analysis plan and method of blinding and randomization should be taken into consideration to avoid bias from the study. More the sample size more the precision of study results., however it depends upon many factors e.g. study duration. Sometime duration of study and duration post-graduation may affect to enroll big number of sample size. There is various statistical software available to calculate appropriate sample size.

Study Design: There should be always mention type or name of study design. If possible, it will be good to add to a flow chart of study to clear the process of study.

Data recording/Observations: Data collection is utmost important in any study as it yield results for the study conducted. Data recording tool may be a clinical examination, record or report of any machine or instrumental reading. All the information can be recorded in Case Record Form (CRF) either in writing or by computers on e-CRF. Recently the trend is going on to collect the data electronic method by creating eCRF or questionnaire. It allows us clean data collection

and can be error free, easy and quick for statistical analysis.

Data analysis: Statistical methods for analysis is also depend on variables used in the study, data type and study design. Implementation of proper statistical test are very essential to yield conclusion or test hypothesis. Improper analysis sometimes yield poor results and affects study outcome, to avoid this data cleaning and selection of appropriate statistical test is utmost important.

Annexures:

To collect the data for analysis and for record purpose all essential study documents should be protected till study complete. Sometimes it may be asked during open defense viva or at the time of publications in high impact journals. , Case Record Form (medium for collecting the study data), Questionnaire, Patient Information sheet, Informed consent (Including version in vernacular language), Assessment Proforma, References (Vancouver style), Bibliography, Timeline/Gantt Chart.

Discussion:

Synopsis or Thesis is essential part of post graduate's curriculum, this method promotes research attitude among students. Research methodology is a process of scientific collection of data, analysing it with proper method to yield proper results. Usually during MD/MS students gain the knowledge about research methodology and medical biostatistics, however along with other academic work, it is also responsibility of the post graduate student to do the research in their concern speciality. This create skilled human resources in the field of research and it also yield some good research in the good faith of public health. For pursuing MD/MS and doing research in priorities area many institutes, organization and universities gives financial supports to the qualified aspirants through Junior research fellowship, senior research fellowship. This article only highlighted on the research methods and how to

develop a research protocol. There is need to focus many aspects while conducting a good research. Many universities now have started a training program for students as well as teachers about research methodology. Such program can help in improving knowledge about scientific understanding of research methods.

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Conflicts of interest

Nil.

CONCLUSION:

Appropriate and scientific writing of a synopsis or thesis is need of hour. It creates a confidence in new aspirant about health research or any research. A good writing of synopsis assures its acceptance by the university.

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