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Anesthesiology

INTRODUCTION TO RESEARCH FOR MEDICAL STUDENTS

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Research in comman parlance refers to a search for knowledge. The aim of a research is to discover answers to questions and to find out the hidden and undiscovered truth through the application of scientific procedures. Different research studies have different purposes. Research methodology is a systematic way to solve a problem. The knowledge of methodology enables a new research worker to do better research ability to evaluate and use research results with reasonable confidence. It also make him able to judge the adequacy of the methods by which they have been obtained and use them intelligently and efficiently. Therefore knowledge of research is must for medical students

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Meaning, Objectives and Types of Research

Research in comman parlance refers to a search for knowledge. Research is defined as a careful investigation or inquiry specially through search for new facts in any branch of knowledge. Redman and Mory define research as a systematized effort to gain new knowledge.

The aim of a research is to discover answers to questions and to find out the hidden and undiscovered truth through the application of scientific procedures. Research can provide important information about analysis of patterns of occurrences, determinants and natural history of disease, outcomes of treatment or interventions, drug safety surveillance and social studies , along with testing the efficacy and safety of new medical interventions, functional abilities, patterns of care and health care costs and use. Since research led to significant discoveries, the development of new therapies, and a remarkable improvement in public health and health care , contributing greatly to the national economy.

Different research studies have different purposes. Exploratory or formulative research studies are to be more familiar with a phenomenon or procedure and to achieve new insights into it. Descriptive research studies are to describe accurately the characteristics of a particular individual, situation or a group. Diagnostic research studies are to determine the frequency of disease or any other factor and their association. Hypothesis-testing research studies are to test a hypothesis of a causal relationship between variables.

Research methodology

Research methodology is a systematic way to solve a problem. It is a science of studying how research is to be carried out. Essentially, the procedures by which researchers go about their work of describing, explaining and predicting phenomena are called research methodology. It is also defined as the study of methods by which knowledge is gained. Its aim is to give the work plan of research. A general set of sequential components of research is the following: 1. Selection of a research topic 2. Definition of a research problem 3. Literature survey and reference collection 4. Assessment of current status of the topic chosen 5. Formulation of hypotheses 6. Research design 7. Actual investigation 8. Data analysis 9. Interpretation of result 11 10. Report . So aim of this article is to provide understanding of basic research methods .

A brief description of the research steps

Research question is the first step towards research. Research question should be specific, relevant to content, measurable, achievable within time limits—and simple to understand. It has a PICOT format varying according to the studies. Research question of an interventional study includes population, intervention, comparison, outcome and time. Observational studies includes population, exposure, outcome and time.

After a research question, a hypothesis should be formulated. Null

hypothesis is defined as hypothesis of no difference. Alternate hypothesis states that there is a difference which can be one tailed or two tailed i.e. One is either more or less effective than the other or interpretation of result in favour of NA can be in either direction better or worse.

Depending on the hypothesis, a study design is chosen. Study can be quantitative or qualitative. Quantitative studies are intended to quantify attitudes, opinions, behaviours and other defined variables using statiscal methods. It is classified as observational and experimental designs. Descriptive study describes a particular condition in terms of time, place and person and analytical study is used to find the association between factor and condition. Descriptive study includes case reportor series, ecological and cross sectional studies. Analytical studies are classified as case control, cohort and cross sectional studies depending on direction of enquiry. Observational studies designs are associated with bias and confounding. Experimental or interventional studies are done to find causal relationship between intervention and outcome.

There are several types of experimental designs including uncontrolled and controlled studies. Uncontrolled studies are done at either individual or cluster design. Controlled studies are either non randomized or randomized. Non randomized studies are done with either historical, external or concurrent control whereas randomized studies are done at individual, cluster level with parallel or cross over designs.

Qualitative research is intended to understand how things occur in natural setting and not in the laboratory. It helps identify cultural and social factors that affect health and provision of health care positively or negatively. The common study designs include ethnography, phenomenology, action research, historical backgrounds, acse studies and grounded therapy.

Depending upon the studies, there are different measurements. In this article, only epidemiological measurements are taken describing the occurance of disease, associations between risk factor and outcome and measures of impact. Population is defined as a group of people with a common characteristics such as age, gender, place of residence, religion, village, community etc.

First step is usually measuring the frequency or occurance of disease or any health related condition in population. Two important measure of occurance are incidence and prevalence. They include a numerator representing number of people affected by disease, denominator representing the size of the population and time period involves the period for which the measures are calculated. They are used for descriptive analysis as only describe a condition in one or more group in a population.

Prevalence is the measure of the frequency of an existing disease. It is defined as proportion of persons in study population that has the disease or health related condition of interest over/at a specified period

or point in time. It assesses the magnitude of disease thereby assess heath care needs and planning of health services and resources.

Incidence refers to new cases of disease over a specified time period occurring among those who are at risk of disease but previously unaffected by disease. Cumulative incidence or risk is defined as proportion of new cases that occur in a population initially free of condition during specified period of time. It is the average risk (probability) of getting a disease over specified period of time. It is used for fixed population.

Incidence evaluates impact of intervention or prevention programme. Incidence rate is defined as occurance of new cases of disease that arise during person – time of observation as shown in Table 1. Person time is the time accured by every individual member of study population. It is mainly done in dynamic population.

Table 1

Point prevalence = no of existing (old and new) cases of disease at a POINT in time

Number in study population

Period prevalence = no of existing (old and new) cases of disease during PERIOD of time

Number in study population

Cumulative incidence = $\underline{\text{no. of new cases of disease in specified}}$ $\underline{\text{time period}}$

Incidence rate = Population at risk at start of same period

Person time of observation in study population

PAR = risk (total population) – risk (unexposed)
Population attributable fraction (PAF) = risk (total population) –
risk (unexposed)
Risk (total population)
= PAR/risk (total population)

Risk difference = risk (exposed) – risk (unexposed) Rate difference = risk (exposed) – risk (unexposed) Risk in exposed = baseline risk + excess risk

AF = <u>risk (exposed)</u> - <u>risk (unexposed)</u>
Risk (exposed)
AF = <u>attributable risk</u>
Risk (exposed)

If population is in steady state, i.e. migration in of people is equal to migration out of the the people, then Prevalence = incidence *duration. If high prevalence implies that either disease has high incidence, low death/ cure or both. Low prevalence implies that disease has low incidence, higher rate of cure/death or both.

Odds of being a case is no. of cases in defined population during specified time divided by number of those who did not become a case in the same population and same time period. It is mostly used as measure of effect.

Measure of effect is used for etiology of disease. It aims to quantify strength of association between risk factor and outcome. It is measured as ratios or differences.

Ratio measure signifies strength of association between exposure and outcome. It is used as evidence to decide whether exposure causes outcome. Prevalence ratio, incidence ratio (risk ratio, rate ratio) and odds ratio are calculated in cross sectional, cohort and case control study respectively. If ratio is one, it implies that the risk of outcome is same in both exposed and unexposed group. There is no evidence of association. If ratio is more than one, it states that the risk of outcome is more in exposed group and there is positive association between exposure and outcome. Higher the value of ratio, shorter is the positive correlation. If rate ratio is less than one, risk of outcome is lesser in unexposed group. There is negative association between exposure and outcome i.e. exposure is positive for outcome.

Difference measure quantifies the difference in risk of outcome between exposed and unexposed group. It is used to estimate the risk that can be attributed to exposure in exposed population. It estimates the baseline excess in absence of exposure and excess risk of disease who have the factor. It is useful only if causal association exist between exposure and outcome under study.

Attributable risk is the difference measure of effect and is defined as

number of cases attributable to exposure in exposed group.

If AR > 0, it implies that the risk in exposed group is more than risk in unexposed group. No. of cases could be prevented if exposure is removed from the exposed group. If AR <0, it implies that the risk in exposed group is less as compared to unexposed group.No. of cases have been prevented by exposure in the exposure group.

Attributable fraction (AF) is the proportion of total disease in exposed group attributable to exposure.

Measures of impact are used to determine the impact or burden of disease that can be reduced if we reduces the exposure. It includes Population attributable risk.

Population attributable risk (PAR) compares the risk of outcome in the population as a whole (both exposed and unexposed persons) with the risk in unexposed group. It estimates the impact of remove or change in the exposure on the risk of outcome from population. It is the excess risk in population over and above the background risk (i.e risk in unexposed) attributed to exposure. It measures number of cases that could have been presented in entire population if exposure could be removed.

Data collection tools and management aims at providing high quality data by minimising errors as much possible and gather maximum data. It includes development of data collection tools, database for data entry followed by entry, processing and analysis. Tools for data collection should be precise and accurate. Precision/reproducibility is also known as consistency and reliability. It is defined as degree to which the results obtained is reproducible every time with nearly the same value each time it is measured .Validity is degree to which any measurement approach or instrument succeeds in describing or quantifying what it is designed to measure. Diagram show reliability and validity Methods used for data collection can be qualitative or quantative. Qualitative methods are related to quality and deals with finding out people perception, opinion, attitude, views, behaviours, cultural and social factors. Quantative methods quantify, collect and analyse the numeric data with the help of statistics eg. age, experience. Data collection can be done by questionnaire, case reports form and diaries.

Questionnaire is a research instrument which can be face to face, self administered and telephonic. It can also be based on existing validated questionnaire and can be closed or open ended. In closed ended questionnaire, respondents are to choose answers from a particular range of possible answers specified by investigator whereas in open ended questionnaire respondents provide answer on blank space with no prelisted answers.

Case report form is formed by the researcher himself or herself. It is based on technical language and questions are completed by patient, medical records and observation. Diarias are the tools particularly maintained by participants on repetitive events. Information can also be collected by electronics, smart phones and apps.

General layout of the data collection tool include theme of the study (example medications, socio demographic data), header and footer along with the coding. Header consists of the title of the study, name of the form, unique participants number, visit number in follow up study, date of visit or date of completion. Footer consist of page number and version of form.

Coding is a process of converting reported answers in CRF to numerical code that will be used for analysis either during or after interview with participant, before or while data entry. Example dates can be in American format (mm/dd/yyyy) or european format (dd/mm/yyyy).Binary variable coded 0, 1 or 1, 2 Categorical variable can be coded in 0,1,2,3 etc.For Data management, an electronic data base to be developed .Example : MS excel , access , epi – info, SPSS. Each row is identified as unique number or patient id with analyzable numeric form.

Conclusion

The knowledge of methodology enables a new research worker to do better research ability to evaluate and use research results with reasonable confidence. It also make him able to judge the adequacy of the methods by which they have been obtained and use them intelligently and efficiently. Therefore knowledge of research is must for medical students.

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