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Review Article

The understanding of epidemiology and study designs

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ABSTRACT

The goal of health care systems is to keep patients healthy by monitoring, diagnosing, and treating their illnesses. These complex systems have many objectives, such as improving the quality of health care, making healthcare accessible to all people who are in need, extending people's life span, preventing illnesses, etc. Promoting healthy lifestyles along with the prevention of illnesses to improve people's health is also a fundamental principle of public health, and now it also become a fundamental principle of health care and integrating into health and social care strategies across the world. Epidemiology is the system of ultimate reasoning focused on creating and examining theories in systematic fields such as biology, physics, behavioral sciences. Epidemiology rationalize the health-associated states and events and provide the justification for further suitable real-world public health measures. While working in the field, I observed that allied healthcare professionals lacked basic knowledge about epidemiology and related study designs. The input from this healthcare professional not only assists in building meaningful research studies but also demonstrates its powerful impact on patients' healthcare through preventive measures and study results. The goal of this article is to provide basic knowledge of epidemiology and its various study designs in a simplistic language to allied healthcare professionals working in the field. In this article, I have described a general overview of epidemiology and various study designs, along with examples. I hope this information could be beneficial for a better understanding of epidemiology to healthcare professionals working in the field.

Keywords: Epidemiology, Study design, Randomized control trials, Observational studies, Cohort studies, Cross-over studies, Case control study

INTRODUCTION

As Franklin Benjamin stated, "An ounce of prevention is worth a pound of cure." This is so correct. Prevention is better than cure, and so is the means.

Epidemiology is the fundamental science to assess the causative and aggravating factors of health-related events to restrict them in identified populations.[1]

Epi is the Greek word that means "on" or upon", the word demos mean "people," whereas logos stands for "study of". Epidemiology is a data-driven sound method of scientific inquiry, which depends on the unbiased, methodical way of compilation, evaluation, and elucidation of the study data. The epidemiologic processes are lean to focus on precise observation and accommodate comprehensible contrast groups for the review. It includes schemes from other methodical areas such as social sciences, informatics, biology, economics, biostatistics, and behavioral sciences. The epidemiology methods revolved around the frequency, pattern, and factors of health events found in the population.

Distribution

The term "frequency" is applied to the number of health events in the population and the relationship of that number to the size of the population. This subsequent rate

determines the disease prevalence across diverse populations.

The term "pattern" stands for the prevalence of health-related cases with respect to factors such as time, place, person, and differentiating cases in connection with these factors. The factor "Time" could be hourly, daily, weekly, annual, seasonal, weekday versus the weekend, etc. Similarly, the factor “Place” could be related to geographic distinction such as urban-rustic variances, location of work sites or schools, etc.

The factor “Person” could be related to age, sex, socioeconomic status, marital status, demographic, behaviors, and environmental factors, which could impact the disease or its incidents. Categorizing health events by time, place, and person are activities of descriptive epidemiology.

Determinants

Epidemiology also looks for the factor determinants. Determinants stand for any factor or trait which causes health events or impacts a change in the health status. Epidemiologists assume the cause of illness is not only random, but the illness occurs only when the person has been exposed to the precise accretion of risk causes or elements.[2,3]

To evaluate those factors, epidemiologists use analytic epidemiology and gather factors, analysis, evaluation, and depiction of illnesses. Epidemiologists evaluate if the event groups having different frequencies vary in their features such as genetics, immunology, demography, behavior, environmental or other additional possible risk factors. The accurate study results generate a satisfactory justification to guide prompt, impactful, preventive and restraint public health methods.[4]

REVIEW

Although epidemiology initially was focused on the outbreaks of transmissible illnesses, in due course of time, it stretched to take care of a variety of diseases such as chronic diseases, injuries, occupational health, environmental health, behavioral health, and widespread communicable or noncommunicable diseases. Any factor which affects the well-being of the public is understood as a health event or disease case.

The difference between a clinician and an epidemiologist is that the clinician is concerned about the health of an individual and focuses on the treatment of the patient. Epidemiologists are concerned about the combined health of the public in the community, for them, the “patient” is the “community,” not a “single patient”. Therefore, Epidemiologist focuses on various factors such as “identifying the factors or the origin of the disease in the community, number of people who are similarly exposed, the possibility of the factors which caused the diseases, the possibility for further increase or recurrence of the disease and intervention to the prevent further progression.

Descriptive epidemiology can detect the frequency of health events by place, time, and person in the population and establish theories about the causes of these frequencies and associated factors which increase the possibility of health events. To test these theories, epidemiologists need to use analytic epidemiology. Analytic epidemiology is focused on the factors such as finding the causes and their effects, measuring the correlation between exposing factors and outcomes' results, examine the assumption about contributory relationships. It has been stated that epidemiology never confirms that a particular aspect causes a particular health event; instead, it provides necessary data to correct preventive restraint actions. The critical feature of analytic epidemiology is a contrast group, it compares the exposure history of disease subjects with a suitable comparison or control group.[2,5]

Example, in 2003, a significant occurrence of hepatitis struck Pennsylvania. It was evaluated that before the onset of symptoms, all affected case patients ate at a specific restaurant. The case group patients who got symptoms and the control group patients who did not get symptoms were asked which food they consumed at a particular restaurant around the same period. It has been found that out of several menu items, 94 % of patients and 39 % of the control group people ate Salsa. The investigation concluded that green onion, one of the ingredients of Salsa, was the source of infection.[6]

When it is found that persons with a specific feature are more prone to get affected with the disease than those without the part, then the features assumed to be related to the condition and those features could be 1. demography factors like race, sex, age 2. constitutional factors such as blood group, immune status, etc., 3. behavioral habits.4. other circumstances and the surrounding environment of an affected person.[2] Understanding the causes of illnesses enables health officials to create proper deterrence and restraint actions and guide further research associated with the grounds of the diseases.

Epidemiology studies are classified as follows: Descriptive epidemiology, analytic epidemiology, descriptive epidemiology study types-case report, case series, incidence, cross-sectional and ecologic, analytic epidemiology study types- experimental studies, clinical trial, community trial, observational studies, cohort-prospective study and retrospective study, case-control and other.

In this article, we described the most commonly used epidemiology studies.

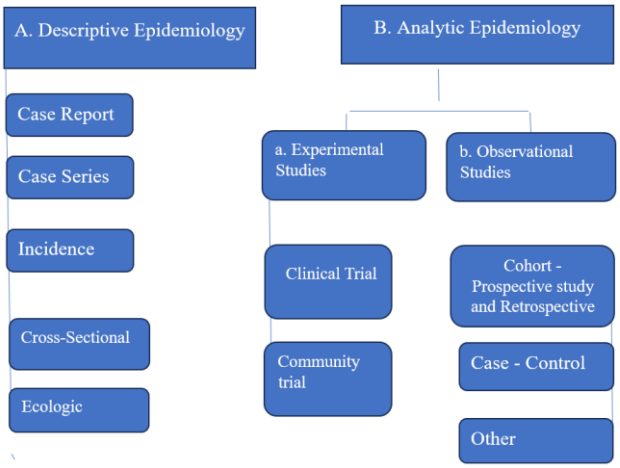

Figure 1: Classification of epidemiology studies.

EXPERIMENTAL STUDIES

Experimental studies include clinical trials or community trials with exposing agents called interventions. The intervention consists of any agent, such as an investigational product, test, or any other intervention, which could be part of the causation, prevention or treatment, or treatment of a health event or a study indication. The investigator traces study participants or communities throughout the trial to identify the effects of the intervention. To avoid confounding and to reduce selection bias randomization method is used, which ensures the study includes similar experimental and control groups. For example, a clinical trial of a new investigational product for a specific indication could consist of a random assignment of the participants into various groups, such as 1. Experimental group, in which participants receive treatment with new investigational products, and 2. Control group where participants could receive no treatment, a placebo, or another approved standard of care treatment depending on the study objective. The investigator follows up with all study subjects and compares the effect of the intervention on various groups on the study indications, which is called an outcome of interest. Randomized control trials are expensive and often face issues such as premature drop out of the study subjects, crossovers of study treatments, and subject non-compliance, which affects study data integrity and quality conduct of the clinical trials. RCT is considered the gold standard of study design for evidence-based medicine.[6,7]

OBSERVATIONAL STUDIES

In the observational study, the researcher observes and measures the characteristics of a group of individuals without changing anything about them. Researchers do not control the treatments or enroll subjects in experimental groups. There is only observation and measurement of variables of interest and investigation of the relationships between them. The researcher detected illness status and exposed elements for each participant.

For example, researchers are conducting an observational study on how depression affects the performance of an individual. It is not possible to assign individuals to the depression and control groups randomly. Researchers can enroll study subjects with and without depression to perform the activity and compare the results.

Another example of an observational study: The validity of the influenza vaccine in the pregnant women group in Lao, 2014-2015 found that the group of influenza vaccine recipient pregnant women had nearly 20% reduced risk of having a preterm baby during high flu season and it prevented up to 1 in 5 preterm births.[8,9]

Cohort studies and case-control studies are the most common type of observational studies, and cross-sectional study is the third type.[5]

According to some researchers, cross-sectional studies are more common and usually is the starting point for a theory due to their simplicity and low cost.

COHORT STUDY

It includes retrospective and prospective study types.

A cohort follow-up study is also called a prospective cohort study as after the study participant is enrolled, they are prospectively followed up over time to establish the incidence of the outcomes of interest. In this case, the epidemiologist collected data for the study participants who are exposed or not exposed to the factors. Participants are then followed up to see if they develop the concerned disease throughout duration of study.

The unexposed group provided approximate disease occurrences in the beginning and during the study in the community. If the disease frequency significantly varies in the exposed group compared to the unexposed group, the exposure factor is supposed to be associated with the disease. The period of tracing participants differs, during epidemics or pandemics, epidemiologists conduct relatively short studies and studies related to chronic illnesses such as cancer, cardiovascular, HIV, and follow-up studies could be of longer durations. For example, Framingham Heart, a long-running cohort study, recruited approximately 5,209 participants in 1948 Framingham, MA. This study has established significant data for cardiovascular risk factors and an understanding of heart health. Subsequently, in 1971 and 2002, second and third cohorts began, which enable the researchers to study the correlation between genetic factors and cardiovascular health risks.[5,10,11]

In a retrospective cohort study, the exposing factor and the outcomes already occurred, and the researcher evaluates and compares incidence rates in the exposed and unexposed groups. This study design is usually used to evaluate disease investigation in groups of people such as schools, workplaces, etc. In 2004, in a residential

facility in Pennsylvania, there was an outbreak of cyclosporiasis. In order to find out the source of infection, a retrospective cohort study was conducted, and it was concluded that the intake of snow peas was implicated as the cause of cyclosporiasis occurrence.[12]

Another example, in U. K., Millennium cohort study follows 19,000 babies who were born between 2000 and 2001. This study is researching health data of parents and investigating child behavior and their cognitive development along with a series of social factors.[11]

For example, a study on the effect of smoking: This study evaluates the impact of smoking, its risks for developing various diseases, and how to evaluate smoking as a risk factor compared to other factors. This study design sounds more ethical as it enrolls a study participant who is an existing smoker, and it does not expose the participant to smoking for the sake of the study's purpose.

Advantages of this study design

Cohort studies are vigorous forms of medical research. Scientists study groups of people before contracting the disease to establish cause-and-effect relationships. In addition, this study can gather a range of data for various research purposes. Can examine multiple outcomes which could be related to multiple exposures. Ability to examine the change in exposure and outcome during the course. Great for investigating rare exposures.

Limitations of this study design

Retrospective studies could be less expensive than prospective studies, but if the study objective and available data are not coherent, then the studies could be less useful. Costly and time-consuming. Not useful to study rare diseases due to the restricted patient population. Can cause bias due to the study conduct error. Difficult to evaluate the reasoning behind the impact of the factor.[13,14]

To summarize

Cohort study objectives - Rule out if the exposing factor is supposed to be related to the disease. Patient selection-study participants who are exposed and not exposed to the exposing factors. Time perspective-retrospective or prospective. Selection of controls - unexposed study participants who are not exposed to the exposing factors.

CASE-CONTROL STUDY

This study is commonly used to examine the factors associated with diseases or outcomes. The case-control study starts with a group of cases, which are the individuals.

In this study there are two groups of patients. The first group of patients with the outcome of interest, a disease condition, the group is called as the case group. The second group of patients without a disease condition called as the comparison group or control group. The crucial step of this study is to find a suitable comparable control group that can provide a sound assessment of the factors or the expected number of factors in that population.

While comparing these two groups if it is found that the number of exposed factors among the case group is notably more than the number of exposed factors in the control group, then the diseases are understood to be related to that exposing factor and the researcher can hypothesize that the exposure may be linked to the outcome of interest.[14]

For example, the study of diarrhea related to contaminated water is an example of a case-control study. The critical step in this study is to find a suitable comparable control group that can provide a good approximation of the baseline or expected factor. Another example of a case control study is "Risk factors for amyotrophic lateral sclerosis US case-control study." The etiology of amyotrophic lateral sclerosis is still not clear, but this study reported advanced chances of confirming an amyotrophic lateral sclerosis diagnosis for people who narrated experiences of head trauma, hobbies that involve lead, painting, employment in mechanics, construction, severe electrical burn.[15,16]

Another example, a case-control study in which the data was gathered from a Kaposi's Sarcoma group of patients and compared them to a group of patients who are similar but who do not have Kaposi's sarcoma. Exposing factors in both groups are collected to see if any exposure is more common in case group than in control group. The researcher found that case-group patients are more likely to have HIV than control group. Therefore, it concludes that HIV could be a risk factor for Kaposi's sarcoma.[17,18]

Advantages of this study design

Excellent efficacy in studying rare diseases or rare outcomes. Cost-effective and less time-consuming as compared to cohort studies. Useful when the risk factors or exposure data is less known or expensive to obtain or if there is a longer period of interval between exposing factor and outcome of interest.

Disadvantages of this study design

Prone to selection bias and observation bias. They are inefficient for rare exposures.

To summarize

Case control study objectives- To examine the factors associated with diseases or outcomes. If it is found that the number of exposed factors among the case group is significantly more than the number of exposed factors in

the control group, then the diseases are considered to be related to that exposed factor. Patient selection-Two groups of patients. The first group of patients with a disease condition called as the case group. The second group of patients, which is similar to the first group but without a disease condition, called as the comparison group or control group. Time perspective-Retrospective study. Selection of controls- The group without a disease condition is called as the control group.

CROSS-SECTIONAL STUDY

In this study, there is a concurrent measurement of exposures and health outcomes of an enrolled group of people. The cross-sectional study intends to assess the occurrence of health events at a specific point in time without the limitation of the length of the disease. For example, in a cross-sectional study of hypertension, many participants could be chronic hypertensive patients, and some may be recently diagnosed with hypertension.

For example, several cross-sectional studies have been conducted to assess the incidence of HIV in antenatal and genitourinary medicine clinics.

The cross-sectional study is frailer than the cohort or case-control study in logical interpretation because this study typically cannot extract risk elements for the occurrence of the disease from the risk elements for the existence of the disease.

The cross-sectional studies are utilized to record the health outcome in a community, such as health outcomes of chronic conditions, health behaviors, smoking, health status, and the frequency of vaccination against influenza, etc. Hence, it could be a perfect method for descriptive epidemiology research.

Advantages of this study design

Comparatively less expensive, easy to conduct with no ethical issues. Several outcomes and exposures can be assessed to generate hypotheses. Effective for confirming initial evidence for future advanced study.

Limitations of this study design

Inability to measure the incidence. Difficult to investigate and interpret the association between outcomes and risk factors. Prone to nonresponse and recall bias. Not a great fit to study rare diseases.[17-19]

To summarize

Cross-sectional study objectives-To study a single moment in time, not to study long-term trends. Patient selection-The researcher selects a sample population to collect data to determine the prevalence of a disease or issue. Evaluation is done at the specified time in a population. Time perspective-Study a single moment in time. Selection of controls-Do not require a control group as the population studied is not selected based on exposure.

CASE-CROSSOVER STUDIES

Case-crossover studies are helpful in examining the risk factors, causes, specific events, activities, or influences in an individual. The design is self-matched and uses each case as its control. For each person, there is a fixed case window and a control window which represents two different durations of time during which the person was a case, and the person was not a case. The effect of event exposure is compared during these two different window periods. Understanding the activity or trigger is an essential step in understanding etiology, which makes a person susceptible to the disease. The knowledge can be used to prevent illness through trigger reduction, minimization of baseline risk, or a focused intervention to reduce risk at a time when the disease is more likely to occur.

Establishing the control and case elements period is a critical and challenging feature of a case-crossover study. For example, the study of "Alcohol intake, meals, and the risk of road traffic accidents" concluded that every unit of acute alcohol ingestion increases the danger of road traffic collision compared with the permissible maximum alcohol allowed in some countries.

"The study also concludes that meal consumption is not related to the risk of road traffic accidents, but united effects of meal consumption with sleepiness need more clarification.

As comparison to the case-control studies and cohort studies in which subjects are selected based on the outcome status and based on the exposure status, this design measures the exposures and outcome at the same time, which is relevant to the study question.

Advantages of **case-***crossover study*

Reduce the risk of confounding as the interventions are assessed on the same participants. Reduced need for study participants as compared to randomized controlled trials. Blinding can be maintained by using stratification methods.

Limitations of case-crossover study

Mostly useful in studying chronic diseases. Risk of carry-over effects of the previous intervention impacting the effects of the next intervention and eventually study results. Possibility of a type II error. The study design includes two treatment periods prolonging the study duration. In the case of non-compliant patients who don't complete all the stages of the study, statistical analysis becomes more complicated, affecting the study results.[20,21]

To summarize

Case-crossover study objectives- The crossover trials consist of two study periods. This means that they usually take up more time. It is a great study design that can be used to compare interventions on a few participants when studying chronic diseases. Patient selection-chronic disease therapeutic clinical trials with multiple interventions. Time perspective-longitudinal studies.

Selection of controls-each patient acts as his or her control, meaning that they receive both the study drug as well as the placebo or standard of care treatment.

ECOLOGICAL STUDIES

To measure the prevalence and incidence of diseases including rare diseases ecological studies are commonly used in the public health research.[13] In this study the study data are evaluated at the group level or population level rather than the individual level, this is because either individual data is unavailable, or the study requires the population-level or group-level effect of factors on a disease condition.

Although these studies are inexpensive and easy to carry out using routinely collected data. The studies are subject to the ecological fallacy as the unit of observation is not a person, instead, it is an entire population, and the group level data link is assumed to be true for everyone. For example, in an ecological study, investigators collected the overall meat consumption by various nations. The investigator then divides the total national meat consumption of each country by the total population of that country. The study shows a strong trend that countries with a low rate of colon cancer also have low meat consumption and the prevalence of colon cancer gradually increases as meat consumption rises in those countries. However, as we know ecological study doesn't collect individual person data such as individual risk factors or individual outcome data such as, genetic causes or other dietary or nondietary factors contributing to colon cancer. Hence, we cannot co-related meat consumption as the risk factor for colon cancer. That's means we don't know if an individual affected with colon cancer was exposed to meat consumption and we also don't know if the people who consume most meat are the ones who affected by colon cancer, this is referred to as ecological fallacy.

Study design serves as a significant factor in defining the logical value of a research study hence, being aware of the fundamental study design theories will help clinicians in practicing evidence - based medicine. Study design should be thoroughly understood before beginning the project as choosing an incorrect study design may challenge study rationality. The inaccuracies in the study designs are very difficult to correct after the study is over. Therefore preventative meticulous preparation is required which includes prospective critical thinking of the issues to avoid weak inferences or unpersuasive results and various steps to ensure the research question is adequately addressed.[22-24]

Advantages of ecologic studies

Quick and inexpensive as the accumulated data is typically available. Beneficial for early assessment of the association. Compare the outcome of interest among broader populations and sites.

Limitations of ecologic studies

Do not represent data individually referred to as ecological bias or fallacy. An apparent association or lack of association between exposing factors and outcome could be misleading.

To summarize

Ecological study patient selection-Generally, it is recommended that ecological studies should be conducted on a representative sample of all patients in a geographical region or group of interest. Ecological study objectives- The objective of this study design is to examine the relationship between an exposure and outcome at the population level. Time perspective-Retrospective study design. Selection of controls-Ecological studies do not have control groups because they are conducted at the population level and not at the individual level.

CONCLUSION

Promoting healthy lifestyle along with the prevention of ill health to improve people's health is a fundamental principle of public health. Now it also become a fundamental principle of modern health care and integrating into health and social care strategies across the world. It will be highly beneficial if the range of healthcare professionals involved in healthcare has a sound understanding of various concepts involved in interventional and non-interventional studies, such as their goals, objectives, study designs, and methods. Public health aims to find out the cause of illness for preventative and protective measures and improve public health. The health professionals include clinicians, investigators, epidemiologists, nurses, pharmacists, research associates, research coordinators, therapists, and all other allied healthcare workers working directly and indirectly in patient healthcare. Being aware of epidemiology study designs used in public health will enable them to efficiently contribute to study conduct, health care research data collection, and spreading knowledge of this topic to the patients and the general population. Sound knowledge and input not only assist in building meaningful research studies but also demonstrate its powerful impact on patients' health care through preventive measures, study results, and it's approved advanced interventions on an ongoing basis.

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