

## REVIEW OF EPIDEMIOLOGY FOR THE NUCLEAR MEDICINE TECHNOLOGIST

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### INTRODUCTION

This paper aims to introduce the field of epidemiology to the nuclear medicine technologist. There are many instances in which epidemiology and nuclear medicine converge. Examples include research that explores the causes of disease and that which focuses on disease prevention. These investigations may examine, for example, the potential effects of ionizing radiation to occupational workers and the general public. Using epidemiologic methods, one can determine the incidence, prevalence, and predictive values concerning ionizing radiation and its possible effects. After reading this article, the nuclear medicine technologist will be familiar with (1) the history and underlying assumptions of epidemiology, (2) types of epidemiologic studies, (3) what is a valid statistical association for an epidemiologic study, (4) what is considered proper correlation of cause-and-effect relationships, and (5) definitions of epidemiologic terms.

### WHAT IS EPIDEMIOLOGY?

*Epidemiology* is the branch of medical science that deals with the study of the frequency, distribution, and causes of disease in human populations. Having origins in ancient Greek, this word roughly translates as "the doctrine of what is among or happening to people" (*epi*

means "among," *demos* means "people," and *logos* means "doctrine"). Epidemiology is a means of predicting disease within a population and, ideally, offering strategies to prevent and mitigate its occurrence. Modern epidemiology began in approximately 1854 with John Snow, a British physician. Dr. Snow postulated that cholera was being transmitted throughout the city of London by contaminated water, although he did not know the mechanism of transmission. (At that time, scientists were unaware that bacteria and viruses could cause disease.) Dr. Snow noticed a concentration of cholera deaths in an area of downtown London that was near a city water pump that citizens used for drinking water. He theorized that something in the water was causing the cholera, and that disease occurrence depended on whether the water's source was up or downstream of the River Thames, which runs through London.

To follow up on his hypothesis, Dr. Snow went literally door to door and asked residents to specify the source of their drinking water. To complicate matters, at the time in London, two water companies were servicing the city, and the water lines were entangled. Therefore, residents of even a single building might have different companies providing their water. To complicate matters further, there were also many centrally located public water pumps where people could get water and haul it home. Despite these difficulties, Dr. Snow linked the location from where a family obtained water to the probability of the occurrence of cholera. Those families that received water upstream, above the city of London, had much less likelihood of contracting cholera compared with those whose water source was downstream of London. Dr. Snow concluded that, somehow, the water downstream of London was being contaminated. Dr. Snow managed to solve the problem without the seemingly requisite knowledge of microbiology by using a *scientific*, *systematic*, and *observational* approach. Ultimately, this approach is what epidemiology is all about.<sup>1</sup>

In modern epidemiology, statistical analysis of population trends plays a large role in the scientific, systematic, and observational approach of understanding the cause-and-effect relationships associated with disease. The theory of epidemiology depends on two underlying assumptions. The first is that there is always a biological reason for disease occurrence. There must be biological plausibility for a disease. In other words, a disease must make sense, biolog-

ically speaking. For example, if one were to say that radiation makes a person glow in the dark, then there must be proof that this can happen. Conversely, if it is said that a one-time dose of radiation exposure in the neighborhood of 1000 cGy (1000 rad) can cause erythema, then there must be biological evidence that dermatitis does occur at this dose.<sup>2</sup>

The second assumption is that all human diseases have causal and preventative factors that can eventually be identified by the systematic investigation. Analysis may require examining different populations or subgroups within a population, in different places or at different times. Additionally, it is supposed that if the cause of a disease can be found and the prevention of the disease determined for a small group, then that knowledge can be applied to the larger group so that more individuals may benefit.<sup>3</sup>

## TYPES OF EPIDEMIOLOGIC STUDIES

There are three major types of epidemiologic studies: a *descriptive study*, an *analytic study*, and an *experimental study*. Each type has characteristics that distinguish them.

### DESCRIPTIVE STUDY

This study characterizes person, place, and time. Questions that might be included in this type of study are the following: Who has been affected? Where did the disease first occur? When did the illness start occurring? These questions can help to isolate a disease and find a common causative agent for an outbreak. In fighting a food-borne illness such as salmonella poisoning, an investigator conducting a descriptive study tries to pinpoint the causative agent by interviewing all those who were sickened and finding a common food that was contaminated with salmonella bacteria.

The investigator would first establish who was sickened. Factors such as age, race, sex, occupation, social economic status, and the level of immunity to disease would all be scrutinized. Did only children get sick? Was it any particular group of children based on any of the above factors? Likewise, the investigator would determine where the illness first appeared. Is there a common eating place for all of these people such as a lunch room, cafeteria, restaurant, picnic, ballpark? Geographically, were all these people at the same place at a particular time? Where do they live, work, go to school, or travel to? Also, the investigator would try to determine when an illness occurred, who was exposed, and by what transmission or vector they contracted the illness. Through a descriptive study technique, asking the appropriate questions may enable the investigator to determine, retrospectively, the causative agent of the disease. With this information, an investigator may also be able to suggest ways to prevent a future outbreak. For example, if salmo-

nella food poisoning is found to be the causative agent, then an investigator should be able to say, through careful interviewing of those affected, that the egg salad at the annual summer picnic was the cause of the outbreak.<sup>4</sup>

### ANALYTIC STUDY

The type of epidemiologic study technique that is probably the most recognizable is the analytic study. Analytic studies are the classic case/control and cohort studies. An analytic study attempts to determine factors associated with a disease by calculating estimates of risk. This type of study would likely be used if the goal is to determine if, for example, occupational radiation exposure results in long-term health effects.

In this situation, the first thing an investigator would look for is a higher prevalence of any disease among a group of people identified as being exposed to radiation in an occupational setting. A study involving a nuclear medicine technologist would most likely be concerned with radiation exposure, but analytic studies can also be performed in a number of other settings. In other industries, researchers may examine such factors as exposure to coal dust, harmful vapors, and loud noises. Investigators also look at risk quantitatively by asking how risk of disease might vary according to the timing and dose of radiation. Like descriptive studies, analytic studies hope to offer suggestions concerning disease prevention.

There are three main types of analytic studies: the *case/control study*, the *prospective cohort study*, and the *retrospective cohort study*. In the case/control study, a case is a group of subjects who have a certain, specified disease. This case group is compared with a control group (a group without disease) with respect to the exposure of interest. This comparison is an effort to isolate the causative agent by determining what common exposure the case group may have had versus the control group.

For example, it may be discovered that workers from a particular chemical plant develop leukemia at a number higher than that of the general population. The workers from the chemical plant are compared with plant workers from other companies. Investigators would try to determine if there is a difference in exposure between the two groups. The best case/control studies try to eliminate all but one variable between the two groups, although this ideal is typically not possible with human populations. However, researchers do try to control for any factors that are known to be associated with the disease being studied. For example, if an association between asbestos and lung cancer is being considered and it is known that older individuals are more likely to have cancer, the study must be designed so that both of the groups examined contain individuals of similar ages.

Cohort studies can be of two types: they either start in the present and await outcomes in the future (prospective studies), or the outcomes are measured in the present on groups of people who can be categorized as having had

certain characteristics in the past.

The prospective cohort study follows two groups of individuals. One group might be those whose work situation results in exposure to a possible harmful agent and a second group (considered the control group) that has had no exposure. These studies are ongoing studies of workers presently in an occupation. For example, a study might be designed to determine if low-dose radiation exposure is the causative agent for a particular disease, such as leukemia, in a certain work force, such as nuclear submarine naval shipyard workers. A control group might be established from the secretaries in the naval office, who are workers who do not receive any radiation exposure. The health of each group could then be followed over a time period, perhaps 20 years, with follow-up surveys and examinations. If disease develops in the exposed group versus the control group, then a causative agent may be determined. This type of study is quite expensive and is therefore used sparingly. However, it is one of the best studies overall because all data, from beginning to end, are utilized by the researcher.<sup>5</sup>

The Framingham Study is a good example of a prospective cohort study.<sup>6</sup> It began in 1948 in the Massachusetts town of Framingham. All men aged 45 to 59 were asked to participate by giving a history of their health habits, being examined physically, and giving blood samples. The participants were then reviewed every two years until they died, and disease events were categorized according to the health behaviors elicited in the histories. A similar study for women is the on-going Harvard Nurses Health Study, begun in 1976 and followed up since then. Much of what is known about how health behaviors affect disease and death have come from these (and similar) studies.

The retrospective cohort study looks at two groups of individuals who have similar working conditions. One group has been exposed to a factor that is under suspicion of contributing to disease, whereas the other group has not. The incidence of disease in each group is then compared to determine whether the exposure in question could be a factor. This comparison is done retrospectively, or after the fact, and can be done after the patient has contracted the disease or even after death. Researchers conducting such a study might consider if a possible exposure during the life of an individual caused a certain disease or death.

One way of collecting data for this type of study is by reviewing death certificates. For example, to determine if chronic low-dose radiation exposure causes life span shortening, an examiner might look at the dosimetry reports and death certificates of deceased radiation workers and compare their age at death to those of workers who were not exposed to occupational levels of radiation. Furthermore, if a correlation is made that a given radiation exposure over the life of an individual has resulted in life span shortening, this information could be used to develop policies that could benefit employees still

working in the field.

## EXPERIMENTAL STUDY

An experimental study is a search to develop strategies for altering the natural history of a disease. Intervention studies are used to identify early stages of a disease, and this information may then be used to reduce the risk factors for a particular disease. An example is a study that focuses on cigarette smoking and whether quitting smoking reduces an individual's chance of getting lung cancer. These studies evaluate the degree to which different forms of therapy or diagnostic tests, such as nuclear medicine examinations, improve the prognosis for a patient.

An example would be using a multi-gated heart study to stage possible heart damage before and during some types of chemotherapy treatment. Also, an experimental study might be used to verify that a new radiopharmaceutical is safe to use by comparing the effects from the drug with the effects from a placebo. All *investigational new drugs* must go through an experimental study of some sort before routine human use is allowed.<sup>7</sup>

## EVALUATION OF A VALID STATISTICAL ASSOCIATION

How can it be determined if an epidemiologic study is statistically valid? Three main factors must be considered. These factors can affect any type of study that is done. They are *chance*, *bias*, and *confounding* factors.

Chance is the possibility that random variations in data may make inferences drawn from a study invalid. This concept is one familiar to nuclear medicine technologists because radiation decay is a random process. In nuclear medicine, techniques such as using a small, well-defined window around an energy peak reduce random error. However, we cannot eliminate the element of chance that will always be present in dealing with the random decay of radioisotopes. Likewise, all epidemiologic studies have the potential of random error. The question is whether or not enough error is present to invalidate the conclusion drawn from the study. Statistical tests such as chi-square analysis, t-tests, or p-values can help to determine the accuracy of the results.

## P-VALUE

P-values are commonly used to test hypotheses. In the research literature, results of statistical tests are usually reported using the p-value. The p-value provides an objective measure of the strength of evidence that the data supply in favor of the hypothesis.

A p-value is the probability of getting a result as extreme or more extreme than the one observed if the proposed hypothesis is correct. A small p-value provides evidence

against the hypothesis because data have been observed that would be unlikely if the hypothesis were correct. Thus we reject the hypothesis when the p-value is sufficiently small.

Generally, a p-value of 0.05 is the standard. By convention, in medical research, if the p-value is less than or equal to 0.05, it is assured that there is no more than a 5% (1 in 20) probability of a result that is affected by chance. Therefore, if the p-value is less than or equal to 0.05, the association between exposure and disease is considered statistically significant. Alternatively, if the p-value is greater than 0.05, by convention it is considered that chance cannot be excluded as a likely explanation, and the findings are considered not statistically significant.

In summary, a p-value less than 5% indicates that random error is not likely to affect the results to a great extent, whereas a p-value greater than 5% implies that random error could be affecting the results. Similarly, the relative error (the standard deviation divided by the mean) should always be included in a study. If not, it is difficult to determine if the variation observed is due to chance or random error.

Another factor that can affect random error is the *sample size* of a study. If too few samples or individuals are included in a study, it could be deemed invalid because there is not enough information to work with mathematically. A large enough sample size, properly randomized, is necessary for mathematical analysis to be accurate. This practice helps to eliminate random error. To illustrate, if a random sample of American teenagers contained just two individuals, one a blonde and one a redhead, then a conclusion might be drawn that 50% of teenagers in America have red hair. Clearly, sample size is an important aspect of a study's accuracy.

Epidemiologists assign a power to a study based on the size and randomness of the sample; the higher the power, the better the statistical validity. The sample size needed to arrive at an accurate analysis in any particular study depends on what is being investigated.

The second factor that can affect the validity of a study is *bias* or *systematic error*. Once again, this concept should be familiar to nuclear medicine technologists, because one of the reasons daily quality control is performed on the cameras is to ensure that no systematic error causes the equipment to run improperly. In nuclear medicine, errors can be due to an operator failure, such as leaving the camera set on  $^{57}\text{Co}$  when it should be set on  $^{99\text{m}}\text{Tc}$ . This type of error will result in the camera being biased.

An epidemiologic study can also have an *operator bias*. The way a study is designed can greatly affect its outcome. Studies in which the observer and/or subjects are kept ignorant of the group to which the subjects are assigned are called *blinded studies*. When both the observer and subjects are kept ignorant, the study is termed a *double-blind study*. The purpose of blinding is to eliminate

sources of bias.

How a study is designed may affect who is eligible to be in the study, how the results are interpreted, and may therefore, affect the outcome of the study. *Selection bias* is bias in assignment that arises from study design rather than by chance. Selection bias can occur when the study and control groups are chosen so that they differ from each other by one or more factors that may affect the outcome of the study.

Another form of bias is called *recall bias*. This bias occurs when an event in someone's recent past affects their response to a question. For instance, if someone gets salmonella poisoning and sees a news report that salmonella is spread by eating contaminated chicken, that person may believe that the chicken sandwich he or she had for lunch the previous day is the cause of the disease. If an investigator trying to determine the source of an outbreak of salmonella poisoning asks this person, "What do you believe caused your illness?" that person is likely to respond, "It must be the chicken I ate for lunch yesterday." This could, in turn, bias the investigation, because the person may have also had egg salad but failed to mention it because he or she was convinced that the chicken was the cause. An interviewer must be careful in framing a question, perhaps asking instead, "Can you tell me everything you ate yesterday?"

There are many types of bias or systematic errors (such as selection bias, observational bias, interviewer bias, and recall bias) that could be introduced into any study and thus skew the results.<sup>8</sup>

The third factor that affects the validity of the statistical association is *confounding*, which is an inadvertent mix of variables: exposure, disease, and some other variable that may also be associated with the disease. For instance, a study may focus on a group of coal miners to look for links between lung disease and working in the mines, but their history of cigarette smoking might not be considered. Smoking would be a confounding variable in the study.

Confounding is a common problem in studying humans. All humans are exposed to a great many outside variables that may affect health. Unlike many types of animals, humans cannot be studied in a strictly controlled environment in which only one variable is altered between two different study groups. This problem is one reason why there are so many conflicting studies about what is good or bad for human populations. For example, one day the media reports that beta-carotene is good for human health;<sup>9</sup> the next day another study reports that the opposite seems to be true.<sup>10</sup>

Another factor that can affect validity is the *comparability* of the control group. For instance, if a study is performed with 100 case subjects and 100 control subjects, it is fairly simple to find control subjects that are well matched to the case subjects. However, if the study attempts to evaluate small changes and therefore requires a larger sample size, such as 1000 in each group, it becomes much more

difficult to find a control group that is well matched to the case group.

Epidemiologists continue to explore ways to improve human studies. Mathematical algorithms that take into account multiple variables have improved study accuracy. However, the majority of studies done today are still plagued by some confounding factors that must be considered. In reviewing studies, one should look carefully at the study design to see how possible confounding factors are addressed by the investigators.<sup>11</sup>

## JUDGEMENT OF CAUSE-AND-EFFECT RELATIONSHIPS

There are many considerations that must be addressed before a true cause-and-effect relationship can be established between a possible causative agent and a disease. Correlation does not always imply causation. Three main areas to examine are (1) strength of the association, (2) biologic plausibility/temporality, and (3) reproducibility.

### STRENGTH OF ASSOCIATION

The term *strength of the association* refers to the probability that a particular agent or activity is highly correlated with the incidence of a particular disease. For instance, there is a high correlation that cigarette smoking increases one's risk of heart disease and lung cancer. The stronger the association, the less likely that the proposed effect is due merely to some unsuspected or uncontrolled confounding variable. The relative risk of certain exposures may indicate a high strength of association. The higher the relative risk value, the greater the association.

### BIOLOGIC PLAUSIBILITY

*Biologic plausibility* means that there must be some proof that the cause of a disease can happen biologically. For instance, the amount of hair an individual has is not related to intelligence. A biologic explanation of a causative agent must always be actually associated with a correlation to make it plausible.

Related to biologic plausibility is the concept of *temporal plausibility*, or *temporality*. Temporality is the simplest of the cause-and-effect relationship criteria. An exposure from a purported disease-causing agent must always precede the onset of a disease in a logical, biologically sound progression. In other words, an individual cannot get a disease before an exposure that causes that disease and an expected induction period has lapsed. When evaluating a study, it is important to be sure that the science behind the question asked is appropriate and makes sense, biologically and temporally, with exposure and disease onset.

## REPRODUCIBILITY

Reproducibility is an important factor to assess to determine if a cause-and-effect relationship is valid. A group of studies must consistently get similar results. If one study alone says that smoking causes lung cancer, and other researchers are not able to reproduce the study and get the same results, then the conclusions inferred from the study are considered invalid. However, if 30 or 40 studies all get the same results, then a more probable cause-and-effect relationship has been established.

## DEFINITIONS OF EPIDEMIOLOGIC TERMS

There are a great many terms specific to the field of epidemiology. The following section defines and explains some of the more common terms.

*Cohort*—a group of individuals who share common factors. Nuclear medicine technologists might be a cohort of occupationally exposed, chronic low-dose radiation workers.

*Prevalence*—the proportion of a population that is affected by a disease at a given point in time. Prevalence is usually expressed as the number of all existing cases (old and new) at a given point divided by the total population being sampled. For example, if a survey is being done to estimate the number of prostate cancer cases in a community of 1000 men, and if 50 men were currently under treatment and an additional 25 men were detected on the day of the survey, then

$$\text{Prevalence} = \frac{50 + 25}{1000} = 0.075$$

or 7.5% of the men in the community had prostate cancer at the time of the survey. The prevalence rate equals 7.5% in this community.

*Incidence*—the number of new cases of diseases or in a population divided by the sum of time periods of observation for all individuals in the population. Therefore, for the above example,

$$\text{Incidence} = \frac{25 \text{ new cases}}{\text{the number of patients screened in one day}}$$

If 100 patients had been screened in one day, the incidence rate equals 0.25, or 25% for that day. If the time period is expanded to include all 1000 men in the community screened in a month, then

$$\text{Incidence} = \frac{25 \text{ new cases}}{1000 \text{ men over a month}}$$

and the incidence rate would be 0.025, or 2.5% over the entire screening period. One should always look

for the time period involved when looking at incidence rates.

An analogy to illustrate the difference between prevalence and incidence may be found in looking at damage from storms. The prevalence of tornado damage in the South Central United States is higher than the prevalence of tornado damage in the Northeast. However, this statement says nothing about a possible natural anomaly that could increase the incidence rates of tornadoes in one season in the Northeastern United States. Another analogy can be found in the stock market. The prevalence is that the average yield over a long term is somewhere around 7% overall. The incidence of one stock earning or losing over the short term, however, is different. Therefore, one should look at prevalence and incidence rates carefully and determine trends. The prevalence would be expected over a long period, but the incidence can represent a single event. These are important terms to understand when looking at epidemiologic studies.

*Relative Risk*—a comparison of two groups or populations. Relative risk is a generic term that looks at incidence when comparing two groups. In analytic studies such as case/control, retrospective, and prospective studies, this analysis would be utilized to see if one group has a higher incidence of a disease than the other, based on what they were or were not exposed to. For example, the risk of getting lung cancer for coal miners who were both exposed to radon and were smokers is higher than the risk of radon-exposed workers who were not smokers. The relative risk is determined by comparing one group over the other. In this case,

$$\text{Relative Risk} = \frac{\text{Incidence of Disease in Smokers}}{\text{Incidence of Disease in Nonsmokers}}$$

*Person-Years*—the total time of all contributing subjects in a dynamic population in a study. For example, if you study the cancer rate for ten technologists over a period of 20 years, you would have 200 person-years (10 x 20).

The next four epidemiologic terms are related. They are primarily used in screening and diagnostic tests.

*Sensitivity*—the proportion of those with disease who had a positive clinical test.

*Specificity*—the proportion of those without disease who had a negative clinical test.

*Positive Predictive Value*—those who have a disease and tested positive for it divided by all who tested positive even if they did not have the disease.

*Negative Predictive Value*—those who had a negative test and who did not have disease divided by all who tested negative even if they have a disease.

In other words, the positive and negative predictive values indicate how well a particular test truly determines if a disease is or is not present. There are indications, usually, whether a particular test will have a good or bad predictive response, but sometimes these

pretest indicators can be wrong. In nuclear medicine, it is known that a bone scan is very sensitive in detecting any abnormal bone growth. However, it is not very specific in consistently revealing the nature of that increased activity. A good patient history can help to determine if recent events like surgery, broken bones, or deep bruises could be the reason for increased uptake of the radiopharmaceutical. It cannot be automatically assumed that the increased uptake is metastatic disease. If a good patient history is not taken, there could be an increase in false positive results. Likewise, the positive predictive value of the bone scan would decrease. It is important to always determine if any study has a good positive and negative predictive value. This determination tells physicians whether the test or study is valid and trustworthy. This is a hallmark that is used to determine what will be considered a "gold standard" in testing.<sup>12</sup>

## EXAMPLE OF A NUCLEAR MEDICINE RESEARCH STUDY

Many studies have been and continue to be done in nuclear medicine to test the soundness of protocols applied to nuclear medicine scans. Most of these studies utilize epidemiology in some manner. The following synopsis of a research study illustrates how epidemiologic concepts are used.

A study by Milavetz, Miller, Hodge, et al. looked at the accuracy of single photon emission computed tomography (SPECT) myocardial perfusion imaging in patients with stents in native coronary arteries. At the defined level of restenosis using angiography of greater than 70% narrowing of a coronary artery as a restenosis event, there was an improved accuracy using SPECT to detect a significant stenosis in a stented artery. The approximate derived number of results from patients admitted into the study was that 32 patients had disease and had a positive SPECT, 1 patient had the disease but had a negative SPECT, 4 patients did not have the disease but tested positive under SPECT, and 8 patients had a negative SPECT and did not have the disease. (Thus, in Table 1, A = 32, B = 4, C = 1, and D = 8.) Thus, the approximate derived sensitivity, specificity, positive predictive value, and negative predictive values are, respectively, 97%, 67%, 89%, and 89%, showing that this study could predict with a good accuracy a restenosis event (approximately 89%, which is the same as the positive predictive value).<sup>13</sup>

**TABLE 1. The Variables Useful in Determining the Sensitivity, Specificity, and Predictive Values of a Clinical Test**

	Proof of Disease (ie, Surgery)	
	Disease Present	Disease Not Present
Positive Clinical Test	A	B
Negative Clinical Test	C	D

Sensitivity =  $A/(A + C)$ ; Specificity =  $D/(B + D)$

Positive Predictive Value =  $A/(A + B)$ ;

Negative Predictive Value =  $D/(C + D)$

## SUMMARY

Epidemiology is a branch of science that affects all of us in some way. Through good research studies using biostatistics and epidemiology, humankind benefits from knowledge concerning the cause of disease that is gradually built as more and more studies are validated through strength of association and reproducibility. Through these studies, researchers can also discover preventive measures to avoid disease entirely.

Research studies in nuclear medicine utilize epidemiology. By understanding epidemiologic and biostatistical methods, individuals become better consumers of scientific literature. It is the hope of this author that this brief overview of epidemiology provides the tools for nuclear medicine technologists to better understand the research literature.

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## REVIEW OF EPIDEMIOLOGY FOR THE NUCLEAR MEDICINE TECHNOLOGIST POST TEST

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1. **Epidemiology is defined as the study of**
  - a. humans.
  - b. biologic affects of drugs in humans.
  - c. human population trends.
  - d. the frequency, distribution, and causes of disease in humans.
2. **Which British physician, investigating the cause of a cholera outbreak, is credited with beginning modern epidemiology?**
  - a. John Snow
  - b. Louis Leakey
  - c. Jonas Salk
  - d. Louis Pasteur
3. **The approach of modern epidemiology is often described as**
  - a. hypothetical, analytical, and mathematical.
  - b. scientific, systematic, and observational.
  - c. historical, biochemical, and innovative.
  - d. statistical, cumulative, and quantitative.
4. **One underlying assumption of epidemiology is that**
  - a. biostatistics are never wrong.
  - b. there is always some biologic reason disease occurs.
  - c. a properly designed study will always reveal a cause-and-effect relationship.
  - d. a good positive predictive value can always be obtained.
5. **A characteristic of a descriptive study is that**
  - a. strength of association is not necessary.
  - b. cause-and-effect are clearly established.
  - c. it calculates estimates of risk.
  - d. questions pertain to person, place, and time.
6. **An example of a type of analytic study is**
  - a. case/control study.
  - b. one that develops strategies for altering the natural history of a disease.
  - c. a food-borne illness study.
  - d. one that looks for a link between geographic location and multiple sclerosis.
7. **A control group is**
  - a. a group of subjects in whom researchers control the amount of exposure to the agent in question.
  - b. a name for the group of formulas used to test the accuracy of a specific study design.
  - c. a comparison group of persons without the disease being studied.
  - d. the name of the group of subjects who do not complete the study.
8. **The best case/control studies**
  - a. use only male subjects.
  - b. try to eliminate all but one variable between the case and control groups.
  - c. take place after the fact.
  - d. use only subjects under 40 years of age.
9. **What type of study starts in the present time and awaits outcomes in the future?**
  - a. An experimental study
  - b. A prospective study
  - c. A retrospective study
  - d. A descriptive study
10. **Reviewing death certificates is most likely to be part of what type of study?**
  - a. A retrospective cohort study
  - b. A prospective cohort study
  - c. A descriptive study
  - d. An experimental study
11. **Which of the following is NOT a factor in the evaluation of a valid statistical association?**
  - a. Confounding
  - b. Chance
  - c. Bias
  - d. Dose-response
12. **P-values are used to**
  - a. evaluate whether the proper sample size was used.
  - b. provide an objective measure of the strength of evidence that the data supplies in favor of the hypothesis.
  - c. blind the subjects, so that researchers are unaware if they are in the case or control group.
  - d. select the appropriate study design for the situation.
13. **A p-value equal to 5% indicates that**
  - a. random error is not likely to have had a significant effect on the results.
  - b. random error may be affecting the results.
  - c. the relative error is unacceptably high.
  - d. the standard deviation is great.
14. **To assess the sample size and randomization of a study, epidemiologists assign a**
  - a. standard deviation.
  - b. relative error ratio.
  - c. power.
  - d. random error ratio.
15. **A study that is designed in which both the observer and subjects are kept ignorant of the group to which the subjects are assigned is called**
  - a. a blind study.
  - b. a double-blind study.
  - c. an age-adjusted study.
  - d. a case-controlled study.
16. **A form of bias in which an event in someone's past affects how that person responds to a question is called**
  - a. selection bias.
  - b. statistical bias.

- c. age bias.
  - d. recall bias.
- 17. Before a cause-and-effect relationship can be determined, all of the following must be considered EXCEPT**
- a. strength of the association.
  - b. severity of the disease.
  - c. biologic plausibility/temporality.
  - d. reproducibility.
- 18. An example of a real biologic/temporal plausibility is that**
- a. hair color affects intelligence.
  - b. height affects mathematical ability.
  - c. one may get a virus after being exposed to it.
  - d. one may get a virus just before exposure to it.
- 19. An example of a cohort is a group of individuals who**
- a. share one factor only.
  - b. share common factors.
  - c. do not share any common factors.
  - d. fall outside a study's selection criteria.
- 20. A good positive predictive value indicates that a study is**
- a. good at detecting false positives.
  - b. not a study to be used as a gold standard.
  - c. not good at accurately predicting the occurrence of disease.
  - d. good at accurately predicting the occurrence of disease.



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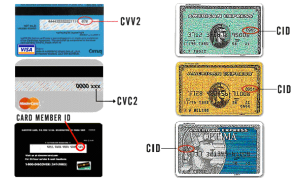
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