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Statistical Gears and Concerns for Allied and Health Professionals

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ABSTRACT

Applied researchers, health care, and allied professionals follow any information or approach based on some statistical results and concerns about the information. Health professionals are interested in appropriate medication and real-time accurate monitoring of situations. A well-defined fact with accurate, meaningful, and easy-to-understand information is important for understanding the benefit and risk of any approach. Statisticians are playing a major and important role in defining the efficacy and accuracy of information based on statistical facts. Statisticians are also providing a key in making sure that the safety information from a study is accurate and provides adequate and acceptable information to health care professionals and policy makers for better management. Health care professionals, scientists, and policymakers have issues regarding the selection and application of appropriate statistical tools as gears, and interpretation of results; additionally, some are also facing challenges in study design, calculation of sample size, control of the bias, and significance of results. At present, the majority of the users are obtaining statistical results and information using software tools without considering the assumptions and pre-requisites for using such tools. Most of the statistical techniques are based on normal distribution; therefore, the normality of data and the nature of the population are playing significant roles in statistical results. In this article, we consider some of the important and useful tools as gears and issues for health professionals and researchers. This article also includes analytical principles and analytical methods for estimating the parameters. Consideration of these issues can benefit health care professionals and ultimately better care of patients, researchers, and policy makers.

INTRODUCTION:

Fundamental research answers the primary question of how things will work. Applied research is the study of the distribution and determinants of the associated factors in a specific area and time. Applied research is planned to provide the answer to specific questions targeted at the solution of practical problems and applied research also allows gaining new knowledge and understanding with specific objectives in the form of quality, produces, procedures or services.

Health care professionals can monitor and evaluate situations, and compare them to personal, national, and international trends, estimates, and inferences by using statistical tools and techniques. Health statistics provide the scientific numeric observations to help in the allocation of public and private funds for better management. Statistical tools provide sensitive and sensible techniques for health-associated professionals. They develop proper policies, manage the economy and social community development strategies, monitor improvements in the standard of life of the people and evaluate progress in the community by using facts.

The statistic is also used by doctors/health practitioners/epidemiologists in different avenues, such as explaining risk to patients, the intensity of the disease, accessing evidence, interpreting screening test results, and reading and publishing research. Pharmaceutical professionals are using statistics for clinical trials of drugs and drug efficacy. In other words, statistics in medicine help assess patients and provide insight into subgroups within a population. Statistics are an essential part of medical research. Researchers use statistical techniques to explain the results from experiments, clinical trials of drugs, and symptoms and risk of diseases.

Statistics is a part of mathematical analysis that uses computed models, estimation, and representations for a given set of experimental/clinical information or realistic studies. Statistics provides methodologies to collect, review, analyze and draw conclusions from observations. Health statistics are numeric information related to health. Researchers and experts from different government, private, and non-profit agencies and other organizations collect health information and other related information. They use the statistics to learn about public health and health care. Biostatistics is the development and application of statistical methods associated with biology and biological variables.

SOME BASIC TERMINOLOGY USED [1-2]:

Normal/Abnormal: When an individual can be liable to disease. In other words, an abnormality is a significant variation from commonly accepted patterns of behavior, feeling, or thought, while normality is the absence of illness otherwise called normalcy. It is not easier to draw the standard line between normal and abnormal.

Risk: Factors associated with the likelihood of disease. Risk is the probability that any activity could occur.

Cause: What factors can result in infection or sickness. Illness does not occur randomly but has a cause or multiple causes. By inspecting who is ill and who is healthy, and which risk factors they are exposed to.

Prognosis: A prediction of the probable course and outcome of an infection/illness. The likelihood of recovery from a disease or consequences of having a disease.

Diagnosis: *Diagnosis* refers both to the process of attempting to determine or identify a possible infection or sickness in other words accuracy of diagnosis or test for diagnosis.

Morbidity: The condition of suffering from a disease or pattern of a medical condition. Morbidity also discusses the medical problems caused by disease management or treatment.

Comorbidity: The simultaneous presence of two or more diseases in a patient. Generally, comorbidity describes two or more diseases that occur at the same time in a person.

Treatment: *Treatment*, therapy, or medication used to remedy health issues; *Treatment,* process, or intervention in the control of infection or sickness.

Prevention: Stopping something from occurring or happening. Prevent from infection, *Disease prevention* is a better health care management than *disease* control.

Strength: A slight or negligible association does not mean that there is not a causal impact or relation, though the higher association; the more likely that it is causal.

Consistency: Consistency is finding observed by different persons in different places with different samples that strengthen the likelihood of an effect.

Specificity: Causation is likely if a very specific population at a specific site and disease with no other likely explanation. The more specific an association between a factor and an effect is, the bigger the probability of a causal relationship.

Temporality: The effect has to occur after the cause (and if there is an expected delay between the cause and expected effect, then the effect must occur after that delay).

Biological gradient: Variations in the intensity of the exposure results in a change in the severity of the outcome. More exposure should normally lead to a larger incidence of the impact. However, in some cases, the simple presence of the factor can activate the impact.

Plausibility: A plausible mechanism between cause and effect is helpful. According to Hill, knowledge of the mechanism is limited by current knowledge.

Coherence: Coherence between epidemiological and laboratory findings increases the likelihood of an effect.

Experiment: It is the scientific procedure to determine something. Occasionally it is possible to appeal to experimental evidence.

Analogy: The effect of similar factors may be considered or comparison between effects of factors, normally for justification or clarification.

REVIEW OF LITERATURE:

The physician and health professional Hippocrates have been called the father of epidemiology [3]. Hippocrates is the first person known to have observed the relationships between the occurrence of disease and environmental influences and also coined the terms endemic and epidemic[4].

Epidemiology is closely associated with health statistics and is defined as the study of distribution and determinants of health-related states in populations and the use of this study to address health-related problems. One of the earliest theories on the origin of the disease was that it was mainly the fault of human luxury [5-7].

Health Statistics and Epidemiology both are the study of the health events, characteristics, and determinants of health patterns in a population. It is the method of public health research and helps to policy decisions and evidence-based medicine by identifying risk factors for disease and targets for preventive medicine. Statisticians are involved in the design of studies, collection and statistical analysis of data, analysis, and interpretation of results. Major disciplines of epidemiology include disease investigation, monitoring, and comparisons of treatment effects. Statisticians are also associated with several other scientific disciplines such as biology to better understand disease processes, biostatistics to make efficient use of the data and draw appropriate conclusions, and social science disciplines to a better understanding of proximate and risk factors, and their measurement.

Health-related investigation and research are becoming increasingly a matter of teamwork, not only because of the large number of people that may have to be studied and the large amount of data that have to be collected and analyzed. The Statistical technique of a research study means, planning the study scientifically so that the objectives of the study are fulfilled to facilitate meaningful interpretations of the observations collected during the research with health experts.

BASIC STUDY DESIGN AND CONCEPTS FOR INVESTIGATION [2]:

Steps for the formulation of research investigations

1. Definition and explanation of research problems include the definition of goals and objectives of the research.
2. Well-stated objectives and hypotheses.
3. The research Methodology of the particular problems must be clearly defined.
4. Ideal selection of variables for the research study.
5. Coverage of all possible subject matters associated with research objectives.
6. Well-defined study population, sample, control, sample size, and time coverage.
7. Formulation of analytical methods for the data and planning for resources.
8. Well-defined tools and techniques for data analysis.

9. Estimation of possible errors and evolving appropriate actions to rectify the errors.

Cohort Study design:

A cohort study is a study of risk factors and follows a group of people who do not have the disease and uses the correlation to determine the absolute risk of issue contraction. A cohort study is generally used in health, social, and ecological sciences. Cohort studies are largely about the life histories of sections of the population, and individual people who constitute these sections. Cohort studies can either be conducted prospectively or retrospectively.

A cohort is a group of people with some things in common. In a cohort study, two groups of people are similar in every way except that one has the risk factor or exposure being studied and the other does not /are observed. Both groups are free from the disease in question at the start of the study. The groups are gathered and observed over some time to study how many from each group develop the disease.

A prospective cohort defines the groups before the study is done, while historical studies, which are sometimes referred to as retrospective cohort, define the grouping after the data is collected.

A cohort study (longitudinal study) design collects data over long periods and measurements are taken on each variable over two or more distinct periods. This study allows to investigator to measure the change in a variable over time.

Case-Control study Design:

A case-control study is a type of another study design for health and epidemiological investigation. A case-control study is an analytical study that compares individuals who have a specific disease (known as the case) with a group of individuals without disease (known as control). Case-control studies were analyzed by testing whether or not there were significant differences between the proportion of exposed and non-exposed. These studies are used to identify factors that may contribute to a medical condition by comparing subjects who have that condition with patients who do not have the condition but are otherwise similar.

It is advantageous for the controls to come from the same population from which the cases were derived, to reduce the chance that some other differences between the groups are accounting for the difference in the exposure that is under investigation.

In this study the assumption is not necessary and that the odds ratio of exposure can be used to directly estimate the incidence rate ratio of exposure without the need for the rare disease assumption and the odds ratio of exposure can be used to estimate the relative risk. The case-control study is frequently contrasted with cohort studies, wherein exposed and non-exposed subjects are observed until they develop an outcome of interest.

The advantages of case-control studies are less costly and to carry out than prospective cohort studies as well as having the potential to be shorter in duration. Another important aspect is the greater statistical power of the type of study in several situations, given the fact that cohort studies must often wait for a sufficient number of diseases/events to occur.

The disadvantage of these studies is more difficult to establish the timeline of exposure to disease outcome in the setting of a case-control study than within a prospective cohort design where the exposure is ascertained before following the subjects over time to ascertain their outcome status. The important disadvantage in case-control studies relates to the difficulty of obtaining reliable information about an individual's exposure status over the time interval.

Cross-Sectional Study Design:

Cross-sectional study that involves observation of all population, or a representative of the population, at one specific point time and aims to provide the estimate of the subjects for the entire population. These studies are descriptive and can be used to describe the prevalence of diseases[8].

It differs from a case-control study whereas a case-control study typically includes only individuals with specific characteristics, with a sample. Descriptive research design provides data for monitoring and evaluating policies and health programs. A case-control study is especially concerned with how to answer questions such as how many, how much, how efficient, how effective, how adequate, etc. [9].

Cross-sectional studies can be thought of as providing a "snapshot" of the frequency and characteristics of the disease in a population at a particular point in time. It also measures the disease and exposure status simultaneously in a given population[10].

Some advantages of cross-sectional study are mentioned below:

- Relatively low-cost and takes up little time to conduct.
- Estimate the prevalence of output of interest because the sample is usually based on population.
- Many risk factors and parameters can be measured.
- It is very useful for public health planning, understanding of the nature of the disease, and for the making hypothesis.
- There is no loss in follow-up.

The disadvantages of cross-sectional study are difficult to interfere in causal relations and it is the only snapshot; this circumstance may provide different results if another time frame had been taken or chosen.

Case study research Design:

A case study is a research approach that is used to make a multi-factor understanding of complex issues or objectives. It is an established research design and is used in various disciplines.

Case studies aim to analyze specific issues within the boundaries of a specific environment or situation. This type of case study focuses on sensations within the contexts of real-life situations.

The qualitative case study is a research methodology that helps in the exploration of a phenomenon within some particular context through various data sources, and it undertakes the exploration through a variety of lenses to reveal multiple facets of the phenomenon.

How to prepare the Case study?

- Read and verify the case methodically and highlight relevant facts.

- Identify the key problems.
- Focus on your Analysis.
- Review course readings, discussions, outside research, and your experience.
- Select the better Solution.

There are sections in a case study:

- Outline the purpose of the case study
- Methodologies and Findings.
- Summary and Discussion.
- Conclusion.
- Recommendations
- Implementation
- References
- Appendices

Case-Control Design:

A case-control study is a type of study design especially for health or epidemiological investigation. A case-control study is an analytical study that compares individuals who have a specific disease (known as the case) with a group of individuals without disease (known as control). Case-control studies were analyzed by testing whether or not there were significant differences between the proportion of exposed and none exposed.

Case-Series Design:

Case-series may refer to the qualitative study of the experience of a single patient, or small group of patients with a similar diagnosis, or to a statistical technique comparing periods during which

patients are exposed to some factor with the potential to produce illness with periods when they are unexposed.

This study is purely descriptive and cannot be used to make inferences about the general population of patients with that disease. These types of studies, in which an astute clinician identifies an unusual feature of a disease or a patient's history, may lead to the formulation of a new hypothesis. Using the data from the series, analytic studies could be done to investigate possible causal factors. These can include case-control studies or prospective studies. A case-control study would involve matching comparable controls without the disease to the cases in the series. A prospective study would involve following the case series over time to evaluate the disease's natural history [11].

Bias in the Investigations:

Bias*: It is a systematic error in the estimate of parameters of the study. In other words, conclusions are systematically different from facts. Biasness can occur during any stage of research investigation.*

1. During the review of the study.
2. During the selection of the sample.
3. During the measurement of exposure and impact.
4. During the analysis and interpretation of observations.
5. During the publication of the research reports.

Generally three types of bias in health and epidemiological research.

Selection bias: The validity of a study is affected by selection bias. Selection bias occurs when study subjects are selected or become part of the study as a result of a third, unmeasured variable which is associated with both the exposure and outcome of interest.

Information bias: Information bias is rising from systematic error in the assessment of a variable. An example of this is memory or recall biases.

Confounding bias: Confounding has traditionally been defined as bias rising from the co-occurrence or mixing of effects of extraneous factors, referred to as confounders, with the main effect(s) of interest. In other words, if two or more factors go together effect of one may be confused with another.

Basic approaches used for presentation:

Frequency: Frequency is the number of occurrences/happening of a repeating event per unit of time.

Classification, Average, and Variation: These are simple statistical tools to describe the trend, nature, and variations in observed or experimental facts. It is very important to select the appropriate technique (Mean, Median and Mode) for average and variation (Range, Standard Deviation, Skewness, Kurtosis) according to the observations.

Ratio: It is the quantitative relation between two amounts. In other words, a ratio indicates how many times one number contains another.

Proportion: It is an equation that defines that the two given ratios are equivalent to each other. In other words, the proportion states the equality of the two fractions or the ratios.

It is a very important section of a research investigation for health-related information analysis.

Rate: A rate is a ratio between two associated quantities in different units. If the denominator of the ratio is expressed as a single unit of one of these quantities, and if it is assumed that this quantity can be changed systematically (i.e., is an independent variable), then the numerator of the ratio expresses the corresponding rate of change in the other variable.

Some important rates are birth rate, death rate, fertility rate commonly used by professionals to explain the current scenario of the community.

Birth Rates [12]: Generally, the birth rate is explained through Crude birth rate and Age-specific birth rate.

Crude Birth Rate (CBR): The crude birth rate is the number of live births in the population of a given area during a certain year. The crude birth rate is defined as the total number of live births occurring per 1,000 population divided by the total number of population.

Crude Birth Rate = [Number of live births / Estimated midyear Population] x 1,000.

Age-Specific Birth Rate (ASBR): ASBR is the number of live births to women in a specific age group for a specified area or locality and divided by the total population of women in the same age group for the same area for a specific period.

Calculation: ASBR= [No. of live births to women in a specific age group/No. of women in the same age group] x 1000

Death rates: Death rate is generally defined as Crude death rate, Age-specific death rate, Infant mortality rate.

Crude Death Rate (CDR): CDR is the total number of deaths within a population over a unit of time. In other words, crude death rate refers to the number of deaths occurring in a year per 1000 population. It is for the same area for a specified period and it is usually considered for a calendar year.

Age-specific Mortality Rate: It is a mortality rate limited to a specific age group. The numerator is the number of deaths in the particular age group and the denominator is defined as the number of persons in the specific age group in the population.

Age-standardized mortality Rate: In this case first calculate the age-specific mortality rates for each age group by dividing the number of deaths by the respective population, and then multiplying the resulting number by 100,000.

Infant mortality rate (IMR): It is the number of deaths per 1,000 live births of children under one year of age. The IMR for a given area is the number of children dying under one year of age, divided by the number of live births during the year, multiplied by 1,000.

The fertility rate is explained through Total fertility rate (TFR), General fertility rate (GFR), Gross Reproduction Rate (GRR), and Net Reproduction Rate (NRR). To explain the current and

quick changes in fertility explained through birth interval (First birth interval, closed birth interval, open birth interval, etc.).

TFR: TFR is described as the average number of children per woman which makes it an intuitive measure of fertility.

It is the number of children who would be born per woman (or per 1,000 women) if she/they were to pass through the reproduction years bearing children according to a current schedule of age-specific fertility rates.

It is calculated by adding up the average number of births per woman across five-year age groups (ASFR).

TFR = 5 X ∑ (ASFR) =

(No. of live births to women aged 15-19/ No. of women aged 15-19)+……..+ (No. of live births to women aged 45-49/ No. of women aged 45-49)

General Fertility Rate (GFR): General fertility rate is the number of live births per 1000 females of the childbearing/reproductive age group (15-45).

GFR = [No. of live births/Female population (Age 15-45)] x 1000

Gross Reproduction Rate (GRR): The GRR is the average number of daughters a woman would have if she survived all of her childbearing/reproductive years subject to the age-specific fertility rate and sex ratio at birth throughout that period. It is defined as the number of girls who are expected to be born to 1000 females passing through their childbearing years.

It is defined as the number of girls who are expected to be born to 1000 females passing through their childbearing/reproductive years. The GRR is computed by multiplying the TFR (per woman) by the ratio of female births to all births in a given year.

NRR: In population demography, the net reproduction rate, R_0, is the average number of offspring (often specifically daughters) that would be born to a female if she passed through her lifetime conforming to the age-specific fertility and mortality rates of a given year.

Net reproductive rate (r) is calculated as r = (births-deaths)/population size or to get in percentage terms, just multiply by 100. The population is so much bigger, many more individuals are added.

Birth Interval [13]:

It is a good indicator of the current change in birth patterns. Birth interval is a provided good index for the current change in human fertility behavior. It is based on fecundability and some other biological variables (Sterility, Foetal Wastage, Non-susceptible period, etc.)

Fecundability: It is defined as the probability that a non-pregnant fecund woman will conceive in one unit of the time of the exposure to the risk of conception. The unit is taken as one month which is the length of a menstrual cycle.

Sterility: A female is said to be sterile if conception is impossible physiologically.

Fetal wastage: A conception may not always result in a live birth. The outcome of the corresponding pregnancy may end in a spontaneous fetal death, induced abortion, and stillbirth.

Non-susceptible period: This is the sum of the two parts; first, gestation period and second the interval after its termination and before the resumption of the ovulation, which is known as postpartum amenorrhea (PPA) period.

Types of Birth Intervals: Various types of birth intervals discussed so far in the literature are:

First birth interval: The interval between marriages to first live birth. This interval gives the recent marital fertility performance.

Closed birth interval: This is the interval between two successive live births. This gives the actual fertility performance in between two successive birth as well as the impact of PPA and temporary separation and impact of family planning.

Open birth interval: The interval between the dates of birth of the last child to the date of the survey. This provides the latest fertility performance.

Forward birth interval: The interval between the survey date and the date of next live birth posterior to the survey date.

Epidemiology:

Epidemiology is the study of the distribution and determinants of health-related states. It is a scientific discipline with sound methods of scientific investigation. Several methods can be used to carry out epidemiological investigations. In this epidemiology the causes and other factors that influence the occurrence of disease and other health-related events as well as communicable and non-communicable diseases, chronic diseases, injuries, birth defects, maternal-child health, occupational health, and environmental health. Recently also include behaviors related to health and well-being and genetic markers for risk of disease.

Prevalence:

Portion or sub-set of a group of subjects that have the illness at a given time. In other words, prevalence is the proportion of a specific population found to be infected/affected by a medical condition at a specific time and in a specific area.

Prevalence (P) = All cases counted on a single survey of a group / All people examined

Incidence:

Sub-set or Fraction of a group of subjects is initially free of condition that develops/occurs over a period in time. Incidence is also defined as the chance of occurrence of disease in a period. Time is also a factor in incidence, generally taken as per year.

Incidence (I)= [{New cases in a period among groups (initially free from disease)} / {All susceptible people present at beginning of period}]

Diseases with similar incidence may have different prevalence because prevalence depends on the duration of the disease.

P = Incidence X Duration (T)

Duration (T) = Prevalence/Incidence

Common challenges for risk management:

Risk is the chance/probability that any activity or action could occur and harm your health. Almost everything we do has an associated risk. Living is a risky business. People will generally take risks if they feel that there is an advantage or benefit.

- Human resources for medical care.
- Medicare conditions of participation, Privacy.
- Medication/Treatment management.
- Prevention and control of infection or disease.
- Laws, regulations, standards, corporate compliance.

Calculation of Risk:

Relative Risk (RR): It is indicated that how many times more likely exposed persons are to get the disease as compared to unexposed.

RR = Incidence in exposed/Incidence in unexposed

	Disease +	Disease -	Total
Exposed	A (20)	B (30)	A + B (50)
Un-Exposed	C(10)	D(40)	C + D (50)
Total	A+C (30)	B+D (70)	A+B+C+D (100)

Relative Risk RR = [{A/ (A+B)}/ {C/ (C+D)}] = [{20/ (A+B=50)}/ {10/ (C+D=50)}]

Attributable Risk (AR):

AR = Incidence in Exposed – Incidence in Unexposed

= {20/(A+B=50)} – { 10/C+D=50)}= (2/5 - 1/5) = 1/5

Population Attributable Risk (PAR) = AR X Prevalence of risk factor in population

Odds Ratio (OR):

Odds are the probability that an event will occur and probability is the proportion of people in whom the event will occur.

OR = Odds for disease among exposed / Odds for disease among unexposed

OR = [{A/(A+C)}/ {C/(A+C)}] - [{B/(B+D)}/ {D/(B+D)}]

OR = (A x D) / (B x C) = (20 x 10) / (30 x 40) = (1/6)

Concept of Validity, Sensitivity, Specificity and Gold Standard:

Validity:

In epidemiology, validity is defined at different levels for the different fields. One way to assess the validity of findings is the ratio of false positives to false negatives [1-3].

The validity of the study depends on the degree of systematic error. Validity is generally separated into two groups:

- Internal validity is dependent on the amount of error in measurements, including exposure, disease, and the associations between these variables. Good internal validity indicates a lack of error in measurement and suggests that inferences may be drawn at least as they pertain to the subjects under study.

- External validity relates to the process of generalizing the findings of the study to the population from which the sample was drawn. This requires an understanding of which situations

are relevant or irrelevant to the generalization. Internal validity is a prerequisite for external validity.

Sensitivity

Sensitivity relates to the test's ability to identify true positive results. Sensitivity is the true positive rate [2][14]. In other words with the example of the medical test used to identify a disease. The sensitivity of a test is the proportion of people who have the disease who test positive for it.

Sensitivity = Number of True Positives / (Number of True positives + Number of False Negatives) = Probability of positive test.

For clarification:

True positive: Ill people correctly diagnosed as ill or sick (with infection)

False-positive: Healthy people incorrectly identified as ill.

True negative: Healthy people correctly identified as healthy (without infection)

False-negative: Sick people incorrectly identified as healthy.

In non-medical contexts, sensitivity is sometimes called recall. Sensitivity is not the same as the precision or positive predictive value (ratio of true positives to combined true and false positives), which is as much a statement about the proportion of actual positives in the population being tested as it is about the test.

The calculation of sensitivity does not take into account indeterminate test results. If a test cannot be repeated, the options are to exclude indeterminate samples from analysis or indeterminate samples can be treated as false negatives. A test with high sensitivity has a low type II error rate [14-15].

Specificity

The specificity of a test is defined as the proportion of patients who do not have the disease and will test negative for it. Specificity relates to the ability of the test to identify true negative results. Specificity is the true negative rate [14-15].

Calculation:

Specificity = Number of True negatives / (Number of True Negatives + Number of False Positives)

This specificity indicates the probability of a negative test. If a test has high specificity, a positive result from the test means a high probability of the presence of a disease. In other words, Specificity is the "true negative rate," equivalent to [D/B +D]. Positive predictive value (PPV) is the proportion of people with a positive test result who have the disease [A/A+ B]; Negative predictive value (NPV) is the proportion of those with a negative result who do not have the disease [D/C+ D].

Sensitivity and specificity are fixed for a particular type of test. Positive Predictive Value and Negative Predictive Value for a particular type of test depend upon the prevalence of a disease in a population. Sensitivity and specificity are inversely proportional, meaning that as the sensitivity increases, the specificity decreases and vice versa [14-15].

Concept of Gold Standard:

The gold standard is the best single test that is considered the current preferred method of diagnosing a specific disease. All other methods of diagnosing disease, including any new test, need to be compared against this ′gold′ standard. The gold standard is different for different diseases. The gold standard for any disease X may be considered outdated or not adequate, but any new test designed to replace the gold standard has to be initially validated against the gold standard. If the new test is indeed better, there are ways to prove that; following which the new test may become the gold standard [16-18].

Applications and Issues of Normality:

Normality is one of the serious important conditions for the application of statistical techniques. In other words, testing of normality is required for most statistical procedures. Many of the statistical tools, analysis of variance, and parametric tests are based on the normal distribution. Assumptions of statistical tools and important assumptions about the normality should be taken seriously; otherwise, it is difficult to draw an accurate and reliable conclusion about the reality. In the context of correlation, regression, and parametric test based on the normal distribution under the assumption that the population from which the samples are taken is normally distributed [19-23].

Challenges of normality:

Normality can be a serious issue when the sample size is not adequate. Skewed data are problematic. The presence of kurtosis in data is also problematic, but not as much as skewed. Normality is a serious problem when there is an activity in the tails of the data set. Outliers are also problems of data in the tails are worse.

Normality of tests [20]:

Normality tests assess the likelihood that the given data set $\{x_1, \ldots, x_n\}$ comes from a normal distribution.

Null Hypothesis (H_0): The sample data are not significantly different from a normal population.

Alternative Hypothesis (H_1): The sample data are significantly different from a normal population.

Graphical test:

Generally, in the graphical test normality compares a histogram of the sample data to a normal probability curve. The empirical distribution of the data should be bell-shaped and resemble the normal distribution but it is difficult to check if the sample is small or not adequate. Lack of fit to the regression line suggests a departure from normality.

Quantile-Quantile Plot Test:

Quantile-Quantile (Q-Q) plot is a plot of the sorted values from the data set against the expected values of the corresponding quartiles from the standard normal distribution [24-25]. The points plotted in the Q-Q plot should fall approximately on a straight line and indicating a high positive correlation in the normal data. These plots are easy to interpret and also have the benefit that outliers are easily identified. In this Q-Q test, the correlation between the sample data and normal quartile measures how well the data is modelled by a normal distribution.

STATISTICAL TEST FOR NORMALITY[20][24-26]:

1. Back-of-the-envelope test:

This test is useful in cases where one faces kurtosis risk and where large deviations matter and has the benefits that it is very easy to compute and to communicate: non-statisticians can easily grasp that "6σ events don't happen in normal distributions".The simple back-of-the-envelope test takes the sample maximum and minimum and computes their z-score, or more properly t-statistic (number of sample standard deviations that a sample is above or below the sample mean), and compares it according to rule.

2. W/S Normality Test:

This test is based on t distribution and q statistics. This test requires only standard deviation and the range of the data.

$$q = w/s$$

Where q is a statistic, s is the standard deviation and w is the range of data. W/S test uses a critical range. If the calculated value falls within the range, then accept the null hypothesis. If the calculated value is outside the range then reject the null hypothesis.

3. Jarque–Bera test:

This test is based on chi-square means the goodness of fit. Jarque Bera's test is based on skewness (S_k) and kurtosis (K_u). The value of the Jarque-Bera test (JB) is compared to the critical value of Chi_Square (χ^2) with 2 degrees of freedom.

4. D'Agostino's or D Normality test:

This is a very powerful test based on the D statistic. Statistic (D) is derived through the sum of squared deviates of data (SS) and sample size. First, the data are arranged in ascending or descending order [28].

$$D = T/\sqrt{[(n^3 \text{ x } SS)]}$$

$$T= \sum [\ i -\{\ (n+1)/2\}]\ y_i$$

5. Kolmogorov–Smirnov test:

Kolmogorov–Smirnov test statistic and its asymptotic distribution under the null hypothesis were published by Andrey Kolmogorov, while a table of the distribution was published by Nikolai Vasilyevich Smirnov.

Under the null hypothesis that the sample comes from the hypothesized distribution F(y),

$$\sqrt{n}\ D_n\ \rightarrow \sup \left| B\ F(t) \right| \text{ if } n \rightarrow \infty$$

where B(t) is the Brownian bridge.

If F is continuous then under the null hypothesis $\sqrt{n}\ D_n$converges to the Kolmogorov distribution, which does not depend on *F*.

The goodness-of-fit test or the Kolmogorov–Smirnov test is constructed by using the critical values of the Kolmogorov distribution. The null hypothesis is rejected at level α if

$$\sqrt{n}\ D_n > K_\alpha$$

where K_α is found from

$$P(K \leq K_\alpha) = 1 - \alpha$$

The asymptotic power of this test is 1.

6. Anderson–Darling Test:

The Anderson–Darling test is a statistical examination of whether a given sample of data is drawn from a given probability distribution. In its basic form, the test assumes that there are no parameters to be estimated in the distribution being tested, in which case the test and its set of critical values are distribution-free. It is one of the most powerful statistical tools for identifying normality. *K*-sample Anderson–Darling test is available for testing whether several collections of observations can be modeled as coming from a single population, where the distribution function does not have to be specified. In addition to its use as a test of fit for distributions, it can be used in parameter estimation as the basis for a form of the minimum distance estimation procedure.

7. Shapiro-Wilk test:

The Shapiro–Wilk test is a test of normality in frequent statistics. The Shapiro–Wilk test utilizes the null hypothesis principle to check whether a sample y_1, ..., y_n came from a normally distributed population. The test statistic is:

$$W = (\sum a_i y_i)^2 / \sum (y_i - \bar{y})^2 \quad i = 1, 2, \ldots\ldots, n$$

Where;

y_i (with parentheses enclosing the subscript index i) is the i^{th} order statistic, i.e., the i^{th}-smallest number in the sample

$$\bar{y} = [\sum y_i]/n$$

the constants a_i given by

y_i (with parentheses enclosing the subscript index i) is the i^{th} order statistic, i.e., the i^{th} smallest number in the sample, $\bar{y}$ is the sample mean and the constants a_i are given by

$$(a_1, a_2, \ldots\ldots\ldots, a_n) = [m^T V^{-1}]/(m^t V^{-1} V^{-1} m)^{1/2}$$

and $m = (m_1, m_2, \ldots\ldots\ldots, m_n)^T$

Where, $m_1, m_2, \ldots\ldots\ldots, m_n$ are the expected values of the order statistics of independent and identically distributed random variables sampled from the standard normal distribution, and V is

the covariance matrix of those order statistics. The user may reject the null hypothesis if W is below a predetermined value.

8. Omnibus K^2 statistic:

Statistics Z_1 and Z_2 can be combined to produce an omnibus test, able to detect deviations from normality due to either skewness or kurtosis.

$$\mathbf{K^2 = Z_1(g_1)^2 + Z_2(g_2)^2}$$

If the null hypothesis of normality is true, then K^2 is approximately χ^2-distributed with 2 degrees of freedom.

Note that the statistics g_1, g_2 are not independent, only uncorrelated. Therefore their transforms Z_1, Z_2 will be dependent.

SAMPLING [27]:

Sampling is a very old concept, mentioned several times in the Bible. Pierre Simon Laplace estimated the population of France by using a sampling technique in 1786. He also calculated probabilistic estimates of the error. Alexander Ivanovich Chuprov conducted sample surveys in the 1870s [27-28]. In medical research, agricultural research, business research sampling is commonly used for gathering information about a population. The two main advantages of sampling are faster data collection and lower cost [28-29].

Sampling Techniques:

The method for the selection of individuals on which information is to be made has been described in the literature [27-29]. The following points need to be considered in the selection of individuals.

a. Investigations may be carried out on an entire group or a representative taken out from the group.

b. Whenever a sample is selected it should be a random sample.

c. While selecting the samples the heterogeneity within the group should be kept in mind and a proper sampling technique should be applied.

Sample Designs:

Some common sample designs described in the literature include purposive sampling, random sampling, and quota sampling [28-29].

Purposive Sampling

In the purposive sampling technique, sampling units are selected according to the purpose. Purposive sampling provides a biased estimate and it is not statistically recognized. This technique can be used only for some specific purposes.

Random Sampling

In this approach of sampling, each unit included in the sample will have a certain pre-assigned chance of inclusion in the sample. This sampling provides a better estimate of parameters in the studies in comparison to purposive sampling. Every single individual in the sampling frame has a known and non-zero chance of being selected into the sample. It is the ideal and recognized single-stage random sampling.

Simple Random Sampling

In the Simple random sampling method, each unit included in the sample has an equal chance of inclusion in the sample.

The simple random sampling technique provides an unbiased and better estimate of the parameters if the population is homogeneous.

Stratified Random Sampling

Stratified random sampling is a useful method for data collection if the population is heterogeneous. In this sampling approach, the entire heterogeneous population is divided into several homogeneous groups, usually known as Strata, each of these groups is homogeneous within itself, and then units are sampled at random from each of these strata.

The sample size in each stratum varies according to the relative importance of the strata in the population. The technique of drawing this stratified sample is known as Stratified Sampling. Sampling will then be conducted separately in each stratum. Strata or Subgroups are chosen because the evidence is available that they are related to the outcome. The selection of strata will vary by area and local conditions. After stratification, sampling is conducted separately in each stratum. In a stratified sample, the sampling error depends on the population variance within the stratum but not between the strata.

Multistage Random Sampling:

In Multistage random sampling, units are selected at various stages. The sampling designs may be either the same or different at each stage. Multistage sampling technique is also referred to as cluster sampling, it involves the use of samples that are to some extent clustered. The principal advantage of this sampling technique is that it permits the available resources to be concentrated on a limited number of units of the frame, but in this sampling technique, the sampling error will be increased.

Systematic Random Sampling:

In this method of sampling, the first unit of the sample is selected at random and the subsequent units are selected systematically. If there are N units in the population and n units are to be selected, then R = N/n (the R is known as the sampling interval). The first number is selected at random out of the remainder of this R (Sampling Interval) to the previously selected number.

Quota sampling:

In quota sampling, the population is first segmented into mutually exclusive sub-groups, just as in stratified sampling. Then judgment is used to select the subjects or units from each segment based on a specified proportion.

It is this second step that makes the technique one of non-probability sampling. In quota sampling, the selection of the sample is non-random. The problem is that these samples may be biassed because not everyone gets a chance of selection.

Sample Size:

Sample and sample size are important for research investigation. Generally, a large sample size leads to an increase the accuracy when assessing unknown parameters. In some circumstances, the increase in precision for bigger sample sizes is minimal or less. Techniques for estimating sample size mainly on the design and measure of the study. There are separate methods for calculating sample size for different study designs.

Calculation of Sample Size [29]:

Using a Census for Small Populations

One approach is to use the entire population as the sample. Although cost considerations make this impossible for large populations, a census is more attractive for small populations (e.g., 200 or less). A census eliminates sampling error and provides data on all the individuals in the population. In addition, some costs such as questionnaire design and developing the sampling frame are "fixed," that is, they will be the same for samples of 50 or 200. Therefore, the entire population would have to be sampled in small populations to achieve a desirable level of precision.

Using a Sample Size of a Similar Study

Another approach is to use the same sample size as those of studies similar to the plan. Without reviewing the methods used in these studies may run the risk of repeating errors that were made in determining the sample size for another study. However, a review of the literature in this discipline can provide supervision about typical sample sizes that are used.

Using Published Tables

A third way to determine sample size is to rely on published tables, which provide the sample size for a given set of criteria. Sample sizes would be necessary for given combinations of precision, confidence level, and variability. Israel (1992), presented two tables for the selection of sample size (Table No. 1 and 2) [30]. Please note two things. First, these sample sizes reflect the number of *obtained* responses and not necessarily the number of surveys mailed or interviews planned (this number is often increased to compensate for non-response). Second, the

sample sizes in Table No. 2 presume that the attributes being measured are distributed normally or nearly so. If this assumption cannot be met, then the entire population may need to be surveyed.

Table No. 1: Sample Size for ± 5% and ± 10% Precision Levels where Confidence Level is 95% and P=0.5.

Size of Population	Sample Size (n) for precision (e)	
	± 5% (0.05)	± 10% (0.10)
1,000	286	91
2,000	333	95
4,000	364	98
5,000	370	98
7,000	378	99
9,000	383	99
10,000	385	99
15,000	390	99
20,000	392	100
25,000	394	100
50,000	397	100
100,000	398	100
>100,000	400	100

Table No. 2: Sample Size for ± 5% and ± 10% Precision Levels where Confidence Level is 95% and p=0.5.

Size of Population	Sample Size (n) for Precision (e) of:	
	± 5%	± 10%
100	81	51
150	110	61
200	134	67
250	154	72
300	172	76
350	187	78
400	201	81
450	212	82
500	222	83

Some techniques for Calculation of sample size:

1. Required Sample sizes for hypothesis tests by Cohen's d and Power

Calculating the sample size requires yielding a certain power for a test, given a predetermined Type I error rate α [28-29]. This can be estimated by pre-determined tables for certain values, by Mead's resource equation, or, more generally, by the cumulative distribution function as follows:

The desired statistical power of the trial is shown in the column to the left.

Cohen's d (= effect size), which is the expected difference between the means of the target values between the experimental group and the control group, is divided by the expected standard deviation.

Table No. 3:

Cohen's d	POWER							
	.25	**0.5**	**0.6**	**0.7**	**0.8**	**0.9**	**0.95**	**0.99**
0.20	84	193	246	310	393	526	651	920
0.50	14	32	40	50	64	85	105	148
0.80	06	13	16	20	26	34	42	58

2. Determination of sample size for laboratory animal study based on Mead's resource equation

Mead's resource equation is often used for estimating sample sizes of laboratory animals, as well as in many other laboratory experiments [31]. It may not be as accurate as using other methods in estimating sample size, but gives a hint of what is the appropriate sample size where parameters such as expected standard deviations or expected differences in values between groups are unknown or very hard to estimate [32].

3. Determination of sample size by a cumulative distribution function

Let X_i, i = 1, 2, ...,n be independent observations taken from a normal distribution with unknown mean μ and known variance σ^2. Let us consider two hypotheses, a null hypothesis:

$$H_0 : \mu = 0$$

and an alternative hypothesis:

$$H_1 : \mu = \mu^*$$

for some 'smallest significant difference $\mu^*>0$. This is the smallest value for which we care about observing a difference. Now, if we wish to reject H_0 with a probability of at least 1-β when H_1 is true (i.e. power of 1-β), and second reject H_0 with probability α when H_0 is true, then we need the following:

If Z_α is the upper α percentage point of the standard normal distribution, then

$$\mathbf{P}\ \ \mathbf{x} > \mathbf{Z_\alpha \sigma} / \sqrt{\mathbf{n}}\quad H_0] \ = \boldsymbol{\alpha}$$

and hence,

Reject H_0 if our sample average sample mean is more than $\mathbf{Z_\alpha \sigma / \sqrt{n}}$

is a decision rule for a 1-tailed test.

Now we wish for this to happen with a probability of at least 1-β when H_1 is true. In this case, our sample average will come from a Normal distribution with mean μ^*. Therefore, we require

$$\mathbf{P [x > Z_\alpha \sigma / \sqrt{n} \quad H_1] = 1 - \beta \quad where\ x = sample\ mean}$$

Through careful manipulation, this can be shown to happen when

$$\mathbf{n \geq [\{\Phi^{-1} (1-\beta) + Z_\alpha\} / (\mu^* / \sigma)]^2}$$

Where **Φ** is the normal cumulative distribution function.

The formula for Calculating A Sample for Proportions:

Cochran (1963) described the formula to the representative sample for proportions of the large sample [27].

$$\mathbf{n_0 = Z^2 p q / e^2}$$

This is valid where n_0 is the sample size, Z^2 is the abscissa of the normal curve that cuts off an area α at the tails (1 - α equals the desired confidence level is 95%), **e** is the desired level of precision, p is the estimated proportion of an attribute that is present in the population, and q is 1-p. The value for Z is found in statistical tables which contain the area under the normal curve.

To illustrate, suppose we wish to evaluate a state-wide Extension program in which individuals were encouraged to adopt a new practice/drug. Assume there is a large population but that we do not know the variability in the proportion that will adopt the practice; therefore, assume p = .4 (maximum variability). Furthermore, suppose we desire a 95% confidence level and ±5% precision. The resulting sample size is:

$$\mathbf{n_0 = Z^2 p q / e^2 = (1.96)^2 (0.4) (0.6) / (0.05)^2 = 369}$$

Finite Population Correction for Proportions (If small population)

If the population is small then the sample size can be reduced slightly. This is because a given sample size provides proportionately more information for a small population than for a large population. The sample size (n_0) can be adjusted as:

$$\mathbf{n = n_0 / [1 + \{(n_0 - 1) / N\}]}$$

Where n is the sample size and N is the population size.

Suppose new treatment only affected 1,000 individuals. The sample size that would now be necessary is shown as:

$$\mathbf{n = n_0 / [1 + \{(n_0 - 1) / N\}]}$$

$$\mathbf{= 369 / [1 + \{(369 - 1) / 1000\}] = 270}$$

This adjustment can substantially reduce the necessary sample size for small populations and also known as population correction.

A Simplified Formula for Proportions:

Yamane (1967) provides a simplified formula to calculate sample sizes [33]. This formula was used to calculate the sample sizes in Tables No. 2 and 3 and is shown below. A 95% confidence level and p = 0.5 are assumed.

$$\mathbf{n = N / [1 + N (e)^2]}$$

Where n is the sample size, N is the population size, and e is the level of precision. When this formula is applied to the above sample, we get.

$$\mathbf{n = N / [1 + N (e)^2]}$$

Rao (1985) presented another calculation for sample size under different circumstances in a simple manner [12]. These determinations are also more useful for medical or clinical research investigations.

a. When it is a field survey to estimate the prevalence rate of a specific event or cases or disease the sample size is calculated by the formula:

$$\mathbf{n = 4\ p\ q\ /\ L^2}$$

where n is the required sample size, p is the approximate prevalence rate for which the survey is to be conducted. The knowledge of this is to be obtained from previous surveys or pilot surveys. q = 1 – p and L is the permissible error in the estimate.

For calculation

If p = 40% (0.4) and q = 1 – p = 0.6 or 60% and 5% permissible error in the estimate. So L = 5% of 40% is 2. Therefore, $n = (4 \times 40 \times 60) / (2)^2 = 2400$

If p = 60% (0.6) and q = 1 – p = 0.4 or 40% and 5% permissible error in the estimate. So L = 5% of 60% is 3. Therefore, $n = (4 \times 60 \times 40) / (3)^2 = 1067$

Similarly, the calculated sample size for different levels are presented in Table No. 4.

Table No. 4

Prevalence		**Permissible error in the estimate**	
		5%	**10%**
p (%)	**1 - p = q (%)**	**Required Sample**	**Required Sample**
0.5	99.5	318400	79600
01	99.0	158400	39600
05	95.0	30400	7600
10	90.0	14400	3600
25	75.0	4800	1200
50	50.0	1600	400

b. When conducting research investigation on quantitative data, the sample size is calculated by the given formula:

$$\mathbf{n = t_\alpha^2 s^2 / \varepsilon^2}$$

Where n is the desired sample size, s is the standard deviation of observations, ε is permissible in the estimate of mean and t_α is the value of at 5% level of significance.

For calculation

If from the pilot it is known the mean is 15gm.% with 1.2 gm.% standard deviation and permissible error 0.5 gm.%. So $t_{0.05} = 2.0$.

Therefore, required sample size:

$$n = [(2.0)^2 \times (1.2)^2] / (0.5)^2 = 23$$

(c) In clinical trials usually there will be two groups one experimental and the other control group. To estimate the size of the sample for each group, the difference in the response rates of the two groups is to be taken into consideration and the sample size is estimated from the following formula:

$$n = 2\, t_\alpha^2 s^2 / d^2$$

where n is the required sample size for each group, s is the pooled standard deviation of the two groups and d is the anticipated smallest difference in the estimates for the two groups and t_α is usually taken as a 5 % level of significance.

For Calculation

If d is the smallest anticipated difference in the rise of mean between two groups is 2%, pooled standard deviation s = 2.5 gm.% and $t_{0.05}$= 2.

Therefore, required sample size

$$n = [2 \times (2)^2 \times (2.5)^2] / (2)^2 = 13$$

The appropriate sample size for a population-based survey is determined largely by three important factors:

(i) Estimated prevalence of the variable of attention.

(ii) Desired level of confidence.

(iii) Adequate margin of error.

Similarly, sample size can be calculated based on a margin of error in confidence interval especially for estimation of the population mean.

Z x **(s** /√**n)** where **s** is the standard deviation. If fluctuations in the estimate of the population mean is **ε.**

$$\mathbf{Z} \times \mathbf{(s}/\sqrt{\mathbf{n}}\mathbf{)} < \boldsymbol{\varepsilon} \text{ Therefore, } \mathbf{n} = [\mathbf{Z}^2 \times \mathbf{S}^2] / \boldsymbol{\varepsilon}^2$$

For calculation, if standard deviation 0.4 gm and fluctuation in the estimated mean is 3 gm. with 98% confidence interval. Therefore minimum sample size will be **n= 305**

Concepts to Minimize the Sample Size

Browner et al. (2001) presented several strategies to minimize the sample size [34]. These strategies are discussed in the following paragraphs. The statistical tests that incorporate the use of continuous values are mathematically more powerful than those used for proportions, given the same sample size. In a radiological diagnosis is expressed in terms of a binary result, such as the presence or absence of a disease, it is natural to convert continuous measurements into categories [35].

Use of More Precise Measurements

In the research investigation or survey any way to increase the precision or decrease the variation of the measurement process. For some types of research, precision can be increased by simply repeating the measurement. More complex equations are necessary for studies involving repeated measurements in the same individuals, but the basic principles are similar [28-29].

Use of Paired Measurements

The paired *t*-test is more powerful for a given sample size than are unpaired tests because, in paired tests, each measure is matched with its control. For example, instead of comparing the average lesion size in a group of treated patients with that in a control group, measure the change in lesion size in each patient after treatment allows each patient to serve as his or her control and yields more statistical power. The additional power and reduction in sample size are due to the

standard deviation being smaller for changes within individuals than for overall differences between groups of individuals [36].

Use of Unequal Group Sizes

The sample size is statistically most efficient if the two groups are equal in size, benefit is still gained by studying more individuals, even if the additional individuals all belong to one of the groups. For example, it may be feasible to recruit additional individuals into the control group even if it is difficult to recruit more individuals into the non-control group. More complex equations are necessary for calculating sample sizes when comparing means [37] and proportions [38] of unequal group sizes.

Extension of the Minimum Expected Difference

The minimum expected difference that has been specified is unnecessarily small, and a larger expected difference could be justified, especially if the proposed study is a preliminary one. The results of a preliminary study could be used to justify a more ambitious follow-up study of a larger number of individuals and a smaller minimum difference [36].

TESTING OF HYPOTHESIS [28]:

Testing of Hypothesis: Parametric Test and Non-Parametric Test: Understanding of fundamentals and terminologies used in the testing of hypothesis are very and selection of tests and applications challenging for health professionals.

Hypothesis: A hypothesis is a proposition temporarily accepted as true in the light of what is, at the time, known about a phenomenon. It is a tool for action in the search for truth. Lundberg defines a hypothesis as “a tentative generalization, the validity of which remains to be tested”. In basic stages, the hypothesis may be any hunch, guess an imaginative idea which becomes a basis for investigation [39].

Characteristics of Hypothesis [28][39]:

The important characteristics of usable hypothesis are given below-

i. The hypothesis should be empirically testable.

ii. The hypothesis should be conceptually clear and simple.

iii. The hypothesis should be specific.

iv. The hypothesis should be related to the body of theory.

v. The hypothesis should be related to available techniques.

The usefulness of Hypothesis:

i. Hypothesis acts as a guide.

ii. Hypothesis spells out the differences between precision and haphazard, between fruitful and fruitless research.

iii. It provides the direction to research, identifying which factor is relevant, it also prevents irrelevant information and literature.

iv. It links up related factors and information is fully understandable.

v. Hypothesis serves as a framework for drawing meaningful conclusions.

Construction of statistical hypothesis:

The first basic step in hypothesis testing is to state the null hypothesis ($H_{o)}$ which follows logically from the alternative hypothesis (H_1) [40, 41]. Alternative hypothesis defines the research statement in positive terms [40]. Acceptance or rejection of null hypothesis based on our statistical testing parametric or non-parametric methodologies [28]. If null hypothesis (H_0) is accepted, then H_1 must be rejected and vice versa due to that hypothesis is mutually exclusive. If H_0 is accepted, this concludes that no statistical differences exist and if any differences in groups or observations are due to only chance or due to sampling fluctuations. On other hand, if H_0 is rejected or H_1 is accepted this indicates that a significant difference exists and the differences are not only due to chance or sampling fluctuations.

Hypothesis Testing and Statistical Error:

There are two types of error or incorrect conclusions possible in hypothesis testing and possibilities in which the statistical test falsely indicates that significant differences exist between

the two or more groups and also analogously to wrong positive results. Rejection of null hypothesis ($H_{0)}$ when it is true is called as Type I error and acceptance of null hypothesis (H_0)when it is false and it is known as Type II error and Type II error is more harmful than Type I error [39].

The probability of Type I error is known as the level of significance and the probability of Type II error is known as the power of the test [39]. By convention, statistical significance is generally accepted if the probability of making a Type I error is less than 0.05, which is commonly denoted as $p < 0.05$ [39]. The probability of Type II error is more difficult to derive than the probability of Type I error, as it is not one single probability value. The probability of Type II error is often ignored by the researcher [3, 8]. The probability of Type I error and probability of Type II error are inter-related[39].

Statistical Power:

Statistical power indicates mathematically the probability of not making a Type II error. The probability of making II error and if sample size increases and power also increases [39]. Power is similar to sensitivity in hypothesis testing. The sensitivity indicates the probability that the diagnostic test can detect disease when it is present. Power indicates the probability that the statistical test can detect significant differences, when in fact such differences truly exist.

Concept of p-value: The p-value is the chance to observe the effects as big as those seen in the study if there is no difference between the groups or treatments. The p-values help to assess whether this apparent effect is likely to be actual or could just by chance or sampling fluctuation. The p-value gives the magnitude of difference present between populations. In the calculation of p-values, first, assume that no true difference between the two groups/treatments. The p values allow the assessment of findings that are significantly different or not statistically different. If the p-value is small, the findings are unlikely to have arisen by chance or sampling fluctuation, reject the null hypothesis. If the p is large, the observed difference is plausibly chance finding, we do not reject the null hypothesis. By convention, a p-value of less than 5% is considered small or significant. Sometimes p-value is less than 1% or 0.01, called as highly significant [28] [39].

Confidence Interval: Confidence interval, like p values, provides a guide to help the interpretation of research findings in the light of the probability. Confidence interval describes the different information from that arising in the hypothesis test. The confidence interval provides a range about the observed effect size. The formal definition of the confidence interval is a range of values for a variable of interest constructed so that this range has a specified probability is called the confidence level, and the end points of the confidence interval are called the confidence limits [39][42]. By conventional, confidence interval at 95% corresponds to hypothesis testing with p values, with a cut-off for p is less than 0.05 [39].

One-tailed and two-tailed tests [39]: A test of any statistical hypothesis where the alternative hypothesis is one-tailed (right-tailed/left-tailed) is called a one-tailed test.

For example, A test for testing the mean of a population

Null Hypothesis (H_0): $\mu = \mu_0$ against the alternative hypothesis

Alternative Hypothesis (H_1): $\mu > \mu_0$ (Right tailed test) or H_1: $\mu < \mu_0$ (Left tailed test)

A test of statistical hypothesis where the alternative hypothesis is two-tailed such as

H_0: $\mu = \mu_0$ against the alternative hypothesis

H_1: $\mu \neq \mu_0$ (two-tailed test) where $\mu < \mu_0$ and $\mu > \mu_0$

Degree of freedom: The number of independent variates which make up the test statistic is known as the degree of freedom. The degree of freedom, in general, is the total number of observations less the number of independent constraints imposed on the observations.

Parametric test: Parametric statistics is a part of inferential statistics that assumes that the data have come from a type of probability distribution and makes inferences about the parameters of the distribution [42]. The most well-known elementary statistical methods are parametric [43]. Parametric tests have more statistical power. Generally speaking, parametric methods have more assumptions than non-parametric methods [44-45].

Non-parametric test: Nonparametric tests are those data that do not assume a prior distribution. This is mainly the case when we do not know a lot about the sample we are studying and making

a priori assumptions about data distributions might not give us accurate results and interpretations. There are many advantages of using nonparametric statistics. Non-parametric statistics are usually wider in scope as compared to parametric statistics that assume a distribution.

There are also some disadvantages of nonparametric statistics. The main disadvantage is that the degree of confidence is usually lower for these types of studies. This means for the same sample under consideration, the results obtained from nonparametric statistics have a lower degree of confidence than if the results were obtained using parametric statistics.

Applications of parametric test:

Student's t-Test [45]

'Student' derived a new distribution in 1908 and the test statistic is known as t. The value of t is dependent upon the sample size 'n' and for each value of n-1, (degree of freedom used for estimating the standard deviation of the sample). The student's t-test is a statistical method that is used to test if two sets of data differ significantly.

(i) t-test or t statistics is calculated as a ratio of the difference between the two means to the standard error of the difference. The t-test is applicable for small samples ($n < 30$) and quantitative data.

$$t\text{-test} = (\text{Mean of X} - \text{Mean of Y}) / s_{md}$$ where X and Y are two samples mean.

s_{md} is the standard error of the difference of two sample means.

where: $s_{md} = s_d / \sqrt{n}$

In the actual research experiment, the observations may be carried out on two independent samples one known as the control group and the other known as the treated group. In such cases, the comparisons are defined as unpaired comparisons.

(ii) t-test for comparing paired observation - In this case t-statistics is [Mean of d / s_{md}] with (n-1) degree of freedom. Whereas the mean of 'd' is the difference in the values of the variable before and after exposure or treatment and n is the number of observations in the sample.

$S_{md} = s_d / \sqrt{n}$, where s_d is the standard deviation of the values of d_i. For the calculation of $s_d = \sqrt{[(d_i - \text{Mean of } d)^2 / (n-1)]}$

After the computation of t-statistics compares the value with the t distribution table at α (conventionally, 1% or 5%) level of significance with (n-1) degree of freedom.

In the other situation, for comparing the means of two independent sample t-statistics is equal to (Mean of X – Mean of Y) / s_{md} with $(n_1 + n_2 -2)$ degree of freedom. Here s_{md} is the estimated standard error of the difference between the two sample means.

$$S_{md} = \sqrt{[(n_1 + n_2)/ (n_1 . n_2)]}*[\{(n_1 – 1) s_1^2 + (n_2 – 1) s_2^2 \}/(n_1 + n_2 – 2)]$$

where s_1^2 and s_2^2 are the standard deviations of the two samples and n_1 and n_2 are their respective sample sizes.

If in experiment two sample sizes are equal $(n_1 = n_2)$. Therefore,

$$s_{md} = [(s_1^2 + s_2^2)/ n] \text{ and degree of freedom is } (2 n -2).$$

Z-Test

Z-test is a statistical test where normal distribution is applied and is used for dealing with problems relating to large samples when $n \geq 30$ where n = sample size

Uses of Z-Test's for Different Purposes: There are different types of Z-tests each for a different purpose. Some of the popular types are outlined below:

1. z test for a single proportion is used to test a hypothesis on a specific value of the population proportion.

Statistically speaking, we test the null hypothesis H_0: $p = p_0$ against the alternative hypothesis H_1: $p \neq p_0$ where p is the population proportion and p_0 is a specific value of the population proportion we would like to test for acceptance.

2. z test for difference of proportions is used to test the hypothesis that two populations have the same proportion.

3. z -test for a single mean is used to test a hypothesis on a specific value of the population mean.

Statistically, to test the null hypothesis H_0: $\mu = \mu_0$ against the alternative hypothesis H_1: $\mu \neq \mu_0$ where μ is the population means and μ_0 is a specific value of the population that we would like to test for acceptance.

Unlike the t-test for a single mean, this test is used if $n \geq 30$ and population standard deviation are known.

4. z test for single variance is used to test a hypothesis on a specific value of the population variance.

Statistically speaking, we test the null hypothesis H_0: $\sigma = \sigma_0$ against H_1: $\sigma \neq \sigma_0$ where σ is the population means and σ_0 is a specific value of the population variance that we would like to test for acceptance.

In other words, this test enables us to test if the given sample has been drawn from a population with specific variance σ_0. Unlike the chi-square test for single variance, this test is used if $n \geq 30$.

5. z test for testing equality of variance is used to test the hypothesis of equality of two population variances when the sample size of each sample is 30 or larger.

Assumptions

Irrespective of the type of z-test used, it is assumed that the populations from which the samples are drawn are normal.

F-test:

Any statistical test that uses F-distribution can be called an F-test. It is used when the sample size is small i.e. $n < 30$. However, one assumption of the t-test is that the variance of the two populations is equal - here two populations are the population of heights of male and female students. Unless this assumption is true, the t-test for difference of means cannot be carried out.

The F-test can be used to test the hypothesis that the population variances are equal.

F-test for different purposes

There are different types of F-tests each for different purposes. Some of the popular types are outlined below.

1. F-test for testing equality of variance is used to test the hypothesis of equality of two population variances.

2. F-test for testing equality of several means. Test for equality of several means is carried out by the technique named Analysis of Variance (ANOVA).

To test if there are significant differences among the three levels of the drug in terms of efficacy, the ANOVA technique has to be applied. The test used for this purpose is the F-test.

3. F-test for testing the significance of the regression is used to test the significance of the regression model. The appropriateness of the multiple regression models as a whole can be tested by this test. A significant F indicates a linear relationship between Y and at least one of the Xs.

Assumptions

Irrespective of the type of F-test used, one assumption has to be met. The populations from which the samples are drawn have to be normal. In the case of the F-test for equality of variance, a second assumption has to be satisfied in that the larger the sample variance has to be placed in the numerator of the test statistic. Like t-test, F-test is also a small sample test and may be considered for use if the sample size is < 30.

Testing

In attempting to reach decisions, we always begin by specifying the null hypothesis against a complementary hypothesis called the alternative hypothesis. The calculated value of the F-test with its associated p-value is used to infer whether one has to accept or reject a null hypothesis.

If the associated p-value is small i.e. (<0.05) we say that the test is significant at 5% and one may reject the null hypothesis and accept the alternative one.

On the other hand, if the associated p-value of the test is >0.05, one may accept the null hypothesis and reject the alternative. Evidence against the null hypothesis will be considered very strong if the p-value is less than 0.01. In that case, the test is significant at 1%.

Uses

The main use of F-distribution is to test whether two independent samples have been drawn for the normal populations with the same variance, or if two independent estimates of the population variance are homogeneous or not since it is often desirable to compare two variances rather than two averages. For instance, college administrators would prefer two college professors grading exams to have the same variation in their grading. For this, the F-test can be used, and after examining the p-value, inference can be drawn on the variation.

Assumptions

To perform an F-test of two variances, the populations from which the two samples are drawn must be normally distributed. The two populations are independent of each other.

If the two populations have equal variances, then s_1^2 and s_2^2 are close in value and F is close to 1. But if the two population variances are very different, s_1^2 and s_2^2 tend to be very different, too.

Nonparametric tests and applications [12][45]:

Chi-Squared Test

The Chi-square test is based on the χ^2 distribution. It has a large number of applications in applied research. Generally, it is used to test the goodness of fit, to test the independence of attributes, and to test the homogeneity of independent estimates of the population variance.

It has to be noted that the Chi-square goodness of fit test and test for independence of attributes depend only on the set of observed and expected frequencies and degrees of freedom. These two tests do not need any assumption regarding the distribution of the parent population from which the samples are taken.

Since these tests do not involve any population parameters or characteristics, they are also termed nonparametric or distribution-free tests.

A Chi-Squared test gives an estimate of the agreement between a set of observed data and a random set of data that you expected the measurements to fit.

Chi-Squared (χ^2)

The Chi-squared calculation involves summing the distances between the observed and random data.

$$\chi^2 = \Sigma \ [(\text{Observed} - \text{Expected})^2 / \text{Expected}]$$

Calculation of expected frequencies in 2 x 2 table.

Table No. 5

			Total
	a E(a)	b E(b)	(a + b)
	c E (c)	d E(d)	(c + d)
Total	(a+c)	(a +d)	N=a+b+c+d

E(a) = (a+b)(a+c) / N E(b) = (a+b)(b+d) / N

E (c) = (a+c)(c+d) / N E(d) = (b+d)(c +d) /N

χ^2 test ={ $[O(a) - E(a)]^2/E(a)$} + {$[O(b)- E(b)]^2/E(b)$ +{ $[O(c) - E(c)]^2$ /E(c)}+{ $[O(d) - E(d)]^2$ / E(d)}

with (2-1)(2-1) degree of freedom with α (Conventionally, 0.05 or 0.01) level of significance.

In other derivation,

Table No. 6

Gender	With disease	Without Disease	Total
Male	a	b	a+b
Female	c	d	c+d
Total	a+c	b+d	G

χ^2 test = { (a d – b c)^2 G}/ (a+b)(c +d) (a+c)(b+d) at 1 degree of freedom.---------(i)

Signed Test: The significance of the difference between the two procedures can be tested using by usual χ^2 test calculated as follows.

$$\chi^2 = (\left| a-b \right| -1)^2 / n \text{ with one degree of freedom.}$$

Where a and b are the number of + (sign) and - (sign) respectively and n=(a+b). All zero differences are omitted for calculation, therefore n is always equal to (a+b). Probability p obtained from χ^2 distribution table and conclusion about significance will be made.

Wilcoxon Signed-Rank Test

The Wilcoxon Signed Rank Test is a non-parametric statistical test for testing a hypothesis on a median. The test has two versions: "single sample" and "paired samples / two samples".

Single Sample

The first version is the analog of the independent one-sample t-test in the nonparametric context. It uses a single sample and is recommended for use.

Paired Samples

The second version of the test uses paired samples and is the nonparametric analog of the dependent t-test for paired samples.

This test uses two samples but they must be paired. Paired samples imply that each observation of one sample has a unique corresponding member in the other sample.

However, the test has certain assumptions notable among them being normality. If this normality assumption is not satisfied, one would have to go for the nonparametric Wilcoxon Signed Rank Test.

Wilcoxon Signed Rank Test is that it neither depends on the form of the parent distribution nor on its parameters. It does not require any assumptions about the shape of the distribution. For this reason, this test is often used as an alternative to t test's whenever the population cannot be assumed to be normally distributed. Even if the normality assumption holds, it has been shown that the efficiency of this test compared to the t-test is almost 95%.

$$\text{Test statistic } z = (\left| \mu - T \right| - 1/2)/\sigma$$

Where, T= smaller rank sum, $\mu = n (n+ 1)/4$, $\sigma = \sqrt{\{(2n +1)/4\}}$ and n=number of pairs of observations.

Probability p is obtained from the normal distribution table corresponding to the value of calculated z for the comparison and significance.

Mann-Whitney U-Test:

The Mann-Whitney U-test is used to test whether two independent samples of observations are drawn from the identical distributions. An advantage of this test is that the two samples under consideration may not necessarily have the same number of observations.

This test is based on the idea that the particular pattern exhibited when the 'm' number of X random variables and 'n' number of Y random variables are arranged together in increasing order of magnitude provides information about the relationship between their parent populations.

Assumptions

The test has two important assumptions. First, the two samples under consideration are random and are independent of each other, as are the observations within each sample. Second, the observations are numeric or arranged by ranks.

Calculation:

First, the observations in the samples are arranged in the order of magnitude taking all the observations in both the sample together. A proper tag is made to distinguish the observations of the two samples separately. Then the ranks are assigned to the combined observations. Whenever there are common observations, the average of the ranks is given to them. Then the sum of ranks

of each of the samples is calculated separately. The smaller rank-sum out of the above two is referred to the prepared table (Mann-Whitney Table) which gives the maximum sum of ranks required for the rejection of null hypothesis, under the different probability levels. If the calculated smaller rank-sum is less than the tabulated value the null hypothesis is rejected. When the two samples are of unequal size the smaller ranks sum is corrected as,

$T_2 = n_1 (n_1 + n_2 + 1) – T_1$, where T_1 is the rank sum of a sample with a smaller number of observations, n_1 and n_2 are the numbers of observations in a bigger sample. T, the smaller of T_1 and T_2 is referred to in the mentioned table. For values of n_1 and n_2 greater than 20, the normal approximation is followed and Z is calculated as follow,

$Z = (|\mu\text{-}T| - 1/2) / \sigma$ where, $\mu = n_1(n_1 + n_2 + 1) /2$ and n_1 is smaller sample size than n_2. The calculated value is referred to the table of normal distribution and p value is obtained [12] [45].

CONCLUSION:

Medical and applied research is directly associated with the development and progress of a nation. Medical science is the study of the distribution and determinants of health-related events in a specific population. Health research is directly associated with the collection of information related to health and family welfare. Medical data analysis makes a significant contribution to emerging population-based health management and community development.

Modern and advanced medical research is linked with better management of standards. It needs multiple sets of skills with different specialties. In the advanced medical database, research requires appropriate research design and statistical tools to provide unbiased results, conclusions, and appropriate interpretation. This article describes the basic terminologies, statistical concepts, and techniques for the unbiased estimation of parameters. Testing of hypothesis describes the significance of results with the help of parametric and non-parametric techniques, as emphasized simply. These tests are valid for any kind of research data, and especially, for quantitative and qualitative data. These have brought the difficult concept of fundamentals as well as parametric and nonparametric techniques within the reach of all researchers and professionals. The availability of computational power naturally makes it all the more important that the researcher accurately applies statistical approaches. The statistical tests for normality are also very useful for valid results. Careful consideration of normality will hopefully result in more meaningful

studies whose results and interpretations are based on sound scientific principles. This article discussed the importance of these measures and highlighted how one should use these measures in our day-to-day applied research.

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