Summer Training Report

By

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Acknowledgements

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Project-I: Early Detection and Diagnosis of COVID-19: Issues in Indian Response

Abbreviations

1. AIIMS: All India Institute of Medical Sciences
2. BAL: bronchoalveolar lavage
3. COVID-19: Coronavirus disease 2019
4. ELISA: enzyme-linked immunosorbent assay
5. ICMR: Indian Council of Medical Research
6. IgG: immunoglobulin G
7. IgM: immunoglobulin M
8. MERS: Middle Eastern respiratory syndrome
9. NABL: National Accreditation Board for Testing and Calibration Laboratories
10. RDT: Rapid diagnostic tests
11. RT- PCR: real-time reverse transcription polymerase chain reaction
12. SARS: Severe acute respiratory syndrome
13. SARS-CoV-2: severe acute respiratory syndrome coronavirus 2

Early Detection and Diagnosis of COVID-19: Issues in Indian Response

INTRODUCTION

Coronavirus ailment 2019 (COVID-19) is a kind of extreme intense pneumonia brought about by the novel coronavirus contamination, authoritatively named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Since it was first reported in Wuhan, Hubei Province, China in December 2019, COVID-19 has spread globally across all countries and regions.

In India, the principal instance of COVID-19 was accounted for on January 30, 2020 in Kerala. By 12:00 on July 10, 2020, there were 7,95,729 confirmed COVID-19 cases, including 21,638 deaths in India. **As of July 10, 2020, India has surpassed Russia as the country with the third-highest number of COVID-19 cases on the planet. USA is at the top with 32,20,500 total cases followed by Brazil with 17,59,103 cases.**

The WHO declared COVID-19 a pandemic and It invoked clauses of the Infectious Diseases Act of 1897, shutting down all academic institutions and commercial establishments across India.

Maharashtra is the worst affected state in India with more than 2,30,599 confirmed COVID-19 cases.

While, Tamil Nadu and Delhi have breached 1,26,581 and 1,07,051 confirmed

COVID-19 cases as on June 17, 2020In India the incidence of infection with COVID-19 is stated

to be 1.7, slightly lower than in the worst affected countries.

COVID-19 is an acute illness, but it can also

be fatal with a fatality risk of 0.5-3 per cent.

COVID-19 influences the different people in various ways. Most people who are infected can experience mild to moderate disease and recover without hospitalization.

Most common symptoms:

- fever
- dry cough
- tiredness

Less common symptoms:

- aches and pains
- sore throat
- diarrhea
- conjunctivitis
- headache
- loss of taste or smell
- a rash on skin, or discoloration of fingers or toes

Serious symptoms:

- difficulty breathing or shortness of breath
- chest pain or pressure
- loss of speech or movement

For average , it takes 5-6 days for someone to show signs to get infected with the virus, but it can take up to 14 days. Specific therapeutic drugs and vaccines against COVID-19 are currently under development; therefore, early detection and immediate isolation of COVID-19 positive cases is recommended. Additionally, People who come into contact with the infected person need to be quarantined to avoid the spread of the disease. To prevent exponential growth in the number of cases and to contain this pandemic, there is need for more testing in all countries, including India. To tackle this demand, Indian government has allowed two different methods for testing of COVID-19, namely the real-time reverse transcription polymerase chain reaction (RT- PCR), and the rapid antigen detection test.

Indian Council of Medical Research (ICMR) has set certain guidelines for diagnosing COVID-19. The RT-PCR test should only be conducted by a laboratory with a National Accreditation Board for Testing and Calibration Laboratories (NABL) accreditation. RT-PCR, and rapid antigen detection tests are recommended by Indian government. Those who test negative in the rapid antigen test should then be RT-PCR screened to rule out infection. WHO has issued COVID-19 testing guidelines that describe all the required safety measures while performing laboratory tests. Biological specimens such as nasopharyngeal swabs, sputum, other lower respiratory tract secretions, blood, and feces can detect COVID-19. Currently, upper respiratory tract nasopharyngeal swab is the preferred method for

collecting sample for COVID-19 detection

Over the last few months, the outbreak of COVID-19 has had a significant effect on clinical microbiology laboratories. This review deals with the present issues and challenges for diagnosing
COVID-19. COVID-19 's pathological characteristics are very similar to those seen in Severe Acute Respiratory Syndrome (SARS) infections, and in the Middle East (MERS) coronavirus infections.

OBJECTIVE

The objective of this literature review was to explore the current understanding of various diagnostic approaches to detect COVID-19 and the most effective and useful method.

METHOD

MEDLINE, PUBMED, and Mesh databases were searched and publications on COVID-19 laboratory testing were reviewed. This study presents the current status of best practices for detecting COVID-19 as well as future perspective on diagnostic approaches.

FINDINGS

RAPID TESTING OF COVID-19.

In response to the growing COVID-19 pandemic and the shortage of laboratory-based molecular testing capacities and reagents, several diagnostic assay manufacturers have developed and started to sell quick and easy-to-use equipment or devices to facilitate testing outside the laboratory setting. Such basic test kits are based on either the detection in respiratory samples of SARS-CoV-2 viral proteins (e.g. sputum, throat swab) or the detection in blood or serum of human antibodies produced in response to SARS-CoV-2 infections.

RAPID DIAGNOSIS OF COVID-19

1. Rapid diagnostic tests (RDT) kit based on antigen detection

RDT may detect the presence of SARS-CoV-2 viral proteins (antigens) expressed in an individual. If enough concentration of the target antigen is present in the sample, binding to specific antibodies attached to a paper strip contained in a plastic enclosure and generating a visually detectable signal, typically within 30 minutes. The identified antigen(s) are expressed only when the virus actively replicates; thus, these tests are ideally suited to diagnose acute or early COVID-19 infection. How well the test performs depends on many factors, including the period after the onset of the disease, the concentration of the virus inside the specimen, the nature of the specimen obtained and how it is handled, and thus, the exact composition of the reagents inside the test kits. Based on the experience with antigen based RDTs for other similar respiratory diseases, it is expected that the sensitivity of these tests varies from 34% to 80%.

2. Rapid diagnostic tests based on antibody detection

Another type of rapid diagnostic test is marketed for COVID-19. This test detects the presence of antibodies in the blood of a person who is suspected of having SARS-CoV-2. Antibodies take several days to weeks to become detectable after an infection. Response strength depends on several factors, including age, nutritional status, disease severity, and certain drugs or infections that suppress the immune system. Studies suggest that most patients develop an antibody response within the second week of infection.
This means that COVID-19 diagnosis using antibody response will not be possible during the early phases of the infection, resulting in delayed clinical intervention and increased possibility of disease transmission. Antibody detection tests targeting COVID-19 can also cross-react with other pathogens, including other human coronaviruses. And give false-positive results. RDTs have been evaluated for predicting a patient's resistant to reinfection with SARS-CoV-2. Currently, no proof is available to support the possibility.

Tests to detect antibody reactions to COVID-19 in the population are important for the development of vaccines and predict their effectiveness. Furthermore, rapid antibody tests can be used for disease surveillance, help measure the extent of infection in a community, and predict the attack rate within a population.

Such tests have little clinical diagnostic value, as they can not diagnose an acute infection rapidly. Some clinicians used these tests to detect antibody response to a suspected diagnosis of COVID-19 disease in cases where molecular testing was negative. Based on the current data, WHO is not recommending the use of antibodies to detect rapid patient care diagnostic tests.

DIAGNOSTIC APPROACHES FOR COVID-19 IN INDIA

Enzyme-linked immunosorbent assay (ELISA)

Recently the ICMR has approved ELISA test kits produced by two companies for COVID-19 detection. Those were the first approved ELISA test kits other than those that use the patented ICMR technology and attach choices available to detect SARS-CoV-2 infection to the basket. The ELISA test is of two types depending on the antibody tested (immunoglobulin G [IgG] or immunoglobulin M [IgM]). IgG antibodies develop later in the infection stage whereas IgM antibodies are detectable early in the infection stage.

RT-PCR

Although ELISA is quick and relatively inexpensive, the usage is restricted to population forecasts which may guide policy decisions. The worldwide test used for individual diagnosis and treatment of COVID-19 is RT-PCR. It was previously used to diagnose Ebola and Zika. The procedure includes taking swabs from nasal or oral tracts, extracting the viral RNA in a printer-like unit, and amplifying it for SARS-CoV-2 detection. RT-PCR is expensive, although free in government labs. The cost of a single RT-PCR test at Rs 4,500 for private laboratories had been fixed by the ICMR until the end of May; however, the cap for private laboratories was removed later, enabling states to set their own prices. The ICMR assessed 97 RT-PCR kits from different manufacturers, of which 40 have been approved so far. In addition to nasal or oral swabs, the RT-PCR sample may be collected using the bronchoalveolar lavage (BAL) method, in which a bronchoscope is passed to obtain fluid from the lungs or sputum. Sputum or BAL has a higher viral load than nasal or oral swabs, which allows viral identification more likely.

TrueNat

This is a private test, which works on the same principle as RT-PCR, but with a smaller

kit and faster outcomes. Commonly used for checking for tuberculosis and HIV. Recently TrueNat was approved by the ICMR for COVID-19 screening and validation. If a sample tests negative, it must be treated as negative; if it tests positively, a second test, called confirmatory assay of the RdRp gene, must be carried out. The TrueNat computer is compact and lightweight, runs mainly on batteries and delivers results within 60 minutes. This involves taking swabs at the nasal or oral levels. There are over 800 machines throughout India to test for TB; hence the government will not need to invest in machines any further.

In an attempt to meet the increasing demand for coronavirus disease (COVID-19) research, India set up the first mobile laboratory. The laboratory can be deployed in remote and inaccessible areas of the country where no such facility exists, even as the total COVID-19 testing capability has reached three lakh swab samples per day. The mobile laboratory belongs to the category of biosafety level 2 (BSL-II), which a team from Andhra Pradesh MedTech Zone Limited created in eight days' time.

BSLs are ranked from one to four and are classified according to the species with which the researchers deal. BSL-I is the least hazardous while BSL-IV poses the highest risk to safety. Each level builds on the previous category, adding more strata of barriers and constraints. The organisms include viruses , bacteria, parasites , fungi, etc. SARS-CoV-2, causing COVID-19, is part of BSL-II category.

Health screening and submission of a self-declaration form with travel history are also compulsory for all passengers returning from the restricted countries.

Summarizing the diagnostic tests including their runtime and cost associated with each test of COVID-19.

THE TESTS, THEIR RUNTIME AND THEIR COST

	RT-PCR	Rapid Antibody	ELISA	TrueNat
Use	To diagnose	For surveillance, to detect exposed population	For surveillance, to detect exposed population	To diagnose
Time taken to test	3 hours	30 minutes	60 min	60 min
Cost	Earlier capped at at ₹4,500, now no price cap	₹600	Not fixed	₹1,000-1,500

ISOLATION AND QUARANTINE AT THE AIRPORTS IN INDIA BASED ON SARS-COV-2 SCREENING AND TESTS

Beginning on 4 March, India required uniform screening for incoming travelers at the airports. At 21 airports, including those in Delhi, Mumbai, Kolkata, Chennai, Bengaluru,

Hyderabad and Cochin, thermal screening has been installed to check for COVID-19 symptoms. Standard screening for flights from China, Hong Kong , Singapore, and Thailand at the ear-marked aero-bridges for the purpose was required.
In addition, screening initiatives were introduced throughout India at 12 major seaports and 65 minor seaports and land frontiers.

ISSUES OF RAPID TESTING KITS IMPORTED FROM CHINA

India has imported five lakh rapid antibody testing kits from two Chinese companies – Wondfo Biotech and Livzon Diagnostics. These kits were distributed to many states who has increasing cases of COVID-19. However, the test results were inaccurate as reported by the Rajasthan and West Bengal governments. Although China claims that the test kits are fine, several Indian states and foreign countries have raised concerns regarding the quality of these imported test kits. China claimed that all the test kits are fine. Initially, the ICMR asked all states to put the use of rapid testing kits on hold, later they suggested using these kits only for surveillance purpose. The two Chinese manufacturers claimed that the kits are being exported worldwide and work properly.

The companies advised healthcare workers to follow the user manuals properly and handle the kits accordingly. The two companies claimed that the product must be stored and used as per the instructions given in the user manual for correct results. The instructions in their manuals include correct storage temperatures, the deadline to use the kit after opening it, storage guidelines and testing methods.

ICMR RECOMMENDS ANTIGEN-BASED TESTING KIT FOR FASTER DIAGNOSIS

The ICMR has suggested the use of COVID-19's first antigen-based test kits to allow for faster diagnosis at lower levels and without laboratory sample analysis.
A private biotechnology company, SD biosensor, is developing the antigen test kit and it has been validated by All India Institute of Medical Sciences (AIIMS) , New Delhi. It is able to detect the presence of SARS CoV-2 in the sample collected via nasal swab. Maximum duration for interpreting a positive or negative test through the antigen-based kit is 30 minutes.

By comparison, the RT-PCR test takes at least 2–5 hours including the time taken to transport samples. The kit's assessment showed that it has a very high specificity or the capacity to identify true negatives ranging from 99.3% to 100%.
While no confirmatory tests are required for samples testing positive, ICMR recommends that those that test negative should be screened for RT-PCR to rule out infection.1,10,24,491 tests have been done as on July 9th ,2020 in India.

CONCLUSION

RT-PCR is currently the frontline gold standard tool for COVID-19 diagnosis. The RT-PCR procedure takes at least 2–5 hours including the time taken to transport the sample.

DISCUSSION

Effective diagnosis of COVID-19 is important for treating and preventing diseases. Chest CT imaging could be a more accurate, realistic, and rapid method of diagnosing and assessing COVID-19 compared with RT-PCR.

The viral nucleic acid test per RT-PCR assay plays a critical role in assessing hospitalization and isolation for individual patients according to the latest diagnostic criteria. However, the management of the disease outbreak was detrimental to the inadequate sensitivity, inadequate consistency and relatively long processing times. Furthermore, several external factors can affect RT-PCR test results, including sampling operations, specimen source (upper or lower respiratory tract), timing of sampling (different time of development of disease), and detection performance of the kit.

The newly launched antigen detection kit is highly sensitive (99.3%–100%), and its cost is approximately ten times less than RT-PCR.

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Report on Online Course

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Project 2: ONLINE COURSE- DATA ANALYTICS FOR LEAN SIX SIGMA

HOURS

Approximately 15 hours to complete.

LEARNING METHODOLOGY

Video lectures, cases, Assignments, and Reading material.

WEBSITE/ ORGANIZATION

https://www.coursera.org

COURSE DESCRIPTION

- Data analytics techniques that are typically useful within Lean Six Sigma improvement projects.
- To analyze and interpret data gathered within such a project.
- Use of Minitab to analyze the data.
- Learnt what Lean Six Sigma is.
- Learnt to use data analytics tools and interpretation of the outcome.
- Use of Statistics for data analysis.

OBJECTIVE

Objective of this course is to learn the data analytics techniques that are typically useful within Lean Six Sigma improvement projects.

KEY LEARNINGS

- Statistics
- Lean Six Sigma
- Data Analysis
- Minitab

- WEEK-1 (9 videos, 1 Practice quiz, 1 Graded Quiz)

Data and Lean Six Sigma- Introduction about Lean Six Sigma and the software Minitab which is used for data analytics.

1.Introduction to Lean Six Sigma- It is a methodology for process improvement, and it makes use of data and data analytics. Lean Six Sigma is a data-driven approach to process improvement.

2.DMAIC- The acronym stands for 1. Define, 2. Measure, 3. Analyze, 4. Improve, 5. Control. It is a step wise procedure in Lean Six Sigma for process improvement. Someone leading the Lean Six Sigma project is called a Belt.

3.Selecting Critical to Quality Test (CTQ)- In Lean Six Sigma, the CTQ is the metric which is used to change. It is often called Y-variable or dependent variable or outcome variable.

4.Units and Measurement definition- Units are things which we collect data on. Example - Objects, People. Units are always stored in the rows of the data set.

5.Sampling- Collecting a representative sampling and Minitab is used to make a random sample population.

6.Organizing data- Data can be organized in a structured way using units and variables. Variables are properties we measure, and It is always stored on the column.

- **WEEK-2(8 Videos, 1 Practice Quiz, 1 Graded Quiz)**

Understanding and visualizing data – Differentiating numerical and categorical variables. Visualizing data of both single variables and two variables using appropriate graphs.

1.Numerical & Categorical data- Numerical data known as quantitative data has been divided into discrete and continues. Categorical data known as qualitative has been divided into
ordinal, nominal and binary data. Numerical data contains more information than categorical data

2. Descriptive analysis- Descriptive statistics are only available for numerical data. It summarizes features from a collection of information such as mean, median, Range, Standard deviation, Variance, Interquartile range etc.

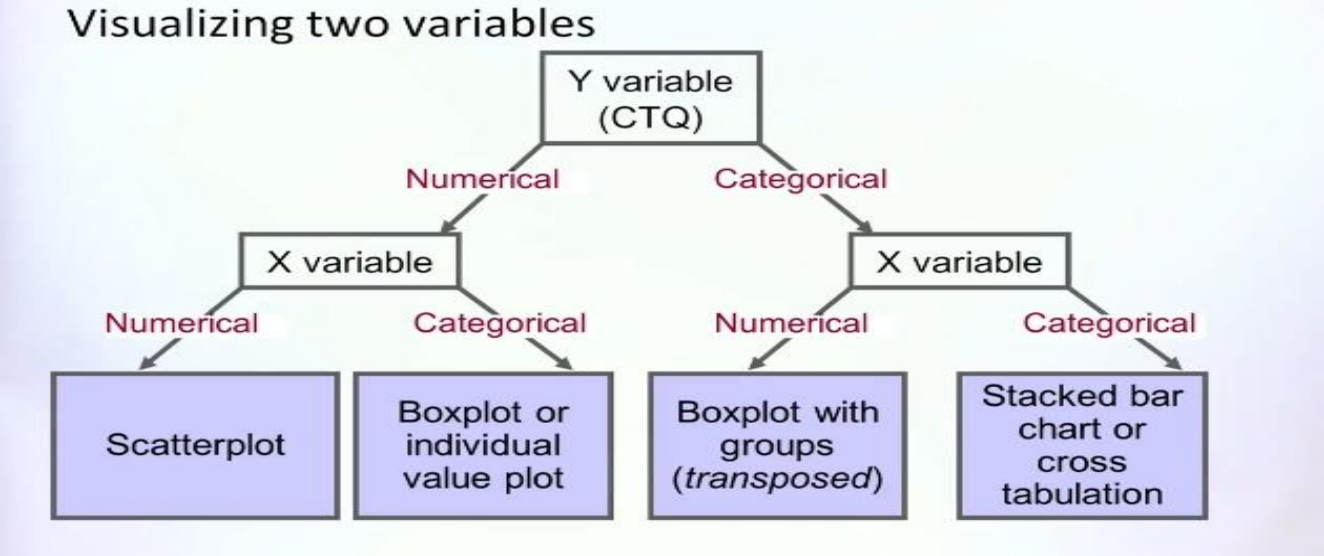
3.Visualizing numerical data- The histogram and boxplot are the graphs for the numerical data. The histogram shows the variable and gives information about the data distribution. A box plot gives information about the spread in our data and outliers.

4.Visualizing categorical data- Pie chart, Bar chart and Tally table are used for visualizing categorical data. A pie chart shows us how often each category occurs. A bar chart also gives the same information, but it is easy to identify which category occurs most often. A Tally Table gives the exact numbers.

5.Pareto Analysis- It is a chart in which Pareto principle can be seen and it counts how often each cause on the x-axis occurs. It can be helpful to differentiate the major and minor causes of the problems.

6.Visualizing two variables-

The graph to visualize two variables depends on the type of data.



- **WEEK-3(7 Videos, 1 Explanation Quiz, 1 Practice Quiz, 1 Graded Quiz)**

Using Probability Distributions- Usage of probability distributions and Quantifying uncertainty.

1.Population versus Sampling- The population is a collection of all units of interest, example all customers of a company. The sample is a subset of the population, example all male customers of a company.

2.Estimation and Confidence Interval- Estimates the unknown population parameters and uses confidence interval to quantify the uncertainty. Confidence Interval gives the boundaries where the population mean will lie in between with a certain level of confidence.

3.Probability distribution- The normal distribution is the most often seen probability distribution while in Lean Six Sigma projects, both Weibull distribution and Lognormal distribution are also relevant.

4.Probability Plot- It is a tool used to determine which distribution to be used for modelling the population. It can be used to spot data anomalies. Depends upon the data which lies on the straight line, it can be classified into good fit and poor fit.

5.Empirical CDF- It is used in the analyze phase of the project and it is used to calculate percentages.

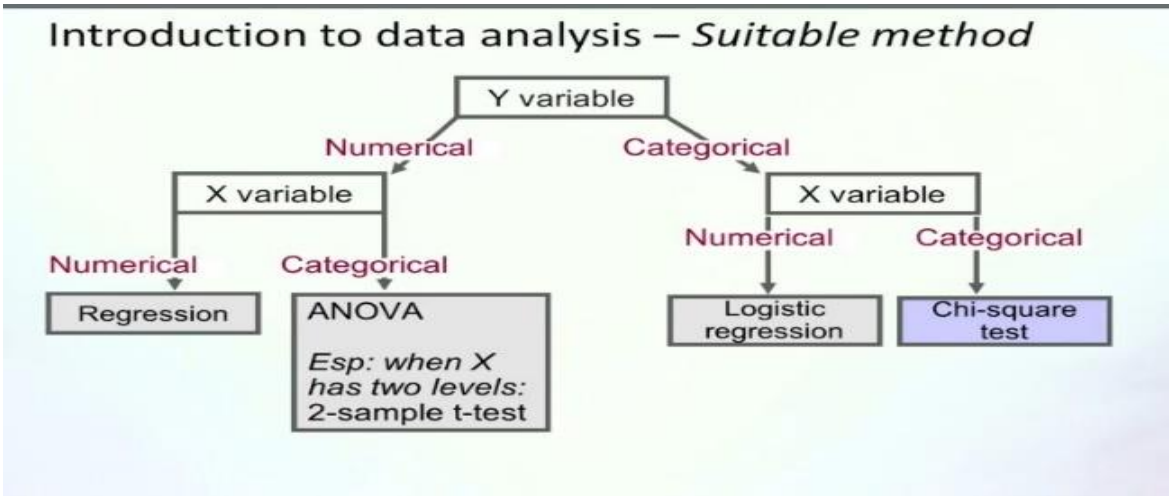
6.Properties of Normal distribution- It is symmetrical looks like a bell shaped. It is even called Gauss curve. The shape of the distribution is determined by the parameters location parameter (μ) and dispersion parameter (σ).

- **WEEK- 4(9 Videos, 2 Explanation Quiz, 2 Practice Quiz, 1 Graded Quiz)**

Introduction to Testing -Modeling CTQ and influence factors and selecting appropriate tool for data-based testing of the models.

1.Introduction to data analysis – In the Lean Six Sigma project, the main intension is to know whether CTQ is related to the influence factor or not. The suitable method depends on the type of data that is the CTQ and the influence factor is categorical or numerical variable.

2.Hypothesis Testing – This is done to find the effect between the variables. The null hypothesis and alternate hypothesis stated have to be checked in accordance with the P-value. If the P- value is smaller than 0.05, reject null hypothesis. If P-value is larger than 0.05, do not reject null- hypothesis.



3.Causality- It is about the cause & effect of relationships, example if x variable changes y variable also changes. So, the relationships should be interpreted judiciously in order to avoid mistakes.

Testing numerical Y and categorical X- Establishing relationship between numerical Y variable (CTQ) and categorical influence factors (X variables).

4.Introduction to ANOVA- It stands for analysis of variance. It is used to study the relationships between numerical Y and categorical X variable. It consists of 2 steps, 1. Organize data, 2. ANOVA and 3. Residuals. The two assumptions of ANOVA are, 1. The distribution should be normal and there will not be any outliers.

5.ANOVA analysis – The hypothesis test using p-value is done to find the significant relationship between the variables. The R-square value gives the relevancy of the influence factor.

6.ANOVA residual analysis- This is done to validate the assumptions underlying ANOVA. To validate the assumptions, it must be checked that the residuals are normally distributed and the there are any outliers or other irregularities present.

7.Kruskal-Wallis Test- This is a non-parametric test used us an alternative to ANOVA when the assumptions are not met.

8.Two sample t-test – This is used to analyze the difference between the means of two groups. The P-value obtained can be used to calculate whether the mean difference is coincidental or truly significant.

9.Test for equality of variances-This is used to test the variability across groups as variation shows the consistency of the variables. The hypothesis test shows the consistency of the variance.

- **WEEK-5(8Videos, 3 Explanation Quiz, 2 Practice Quiz, 1 Graded Quiz)**

Testing: numerical Y and numerical X- Statistical tests to relate a numerical Y variable (CTQ) and numerical X variable (influence factor).

1.Correlation- It shows the strength of relationship between two numerical variables. It is always between the value -1 and +1. A negative correlation shows that the variables are correlated in the opposite direction. Correlation of 0 means there is no relation between the variables.

2.Regression- This is a statistical method to test weather two numerical variables are related or not by calculating the best fitting line. Regression analysis is about finding the values of a and b from the formula y= a+ BX. Regression analysis consist of 4 steps which are, 1. Make a fitted line plot to visualize the data, 2. Perform main Regression analysis, 3. Perform residual analysis, 4. Calculating the prediction interval.

3.Regression Analysis- The hypothesis shows the significant relation and the R square shows the strength of the relationship.

4.Regression Residual analysis- If the residuals are normally distributed and shows no outliers or irregularities then the assumptions can be proved. If not, then the quadratic regression model can be used.

5.Regression prediction interval- This can be used to determine the level of influence factor, which ensures a certain CTQ performance.

6.Quadratic Equation-This is used when the linear regression analysis is not meeting the assumption. A curved line fits to the data instead of a straight line.

Testing categorical Y- Testing relationship between a Y and a X variable, when Y variable (CTQ) is categorical.

7.Chi- Square analysis- It is used to find the relation between a categorical Y and categorical X variables. This has two steps, 1. Cross tabulation of data, 2. Chi-square analysis and p-value. The p-value shows the significance of relationship between the variables.

8.Logistic Regression- It is used to find the relation between a categorical Y and numerical X variables. This consists of 3 steps,1. Enter data in event/trial format, 2. Make fitted line plot, 3.P-value. The p-value shows the significance of relationship between the variables.