

PEER REVIEW JOURNAL
FOR
RESEARCH AND READINGS IN
APPLIED STATISTICS
(WORLD STATISTICS DAY)

ISSN 2321-0877

SANKHYA VIGNAN

संख्या विज्ञान

NEW SERIES (NSV 16)

OCTOBER 2020

SPECIAL ISSUE

CONTENTS

<u>SPECIAL LETTER</u>		03-04
<u>EDITORIAL</u>		05
<u>ARTICLES</u>		
+ World Statistics Day	[Jayesh R. Purohit]	06-09
+ Online Education's Biggest Year 2020	[Jayesh R. Purohit]	10-12
<u>RESEARCH ARTICLES</u>		
+ Effects of Foreign Direct Investment on Indian Economy	[Rakesh Bajpai & Pradeep Prajapati]	13-27
+ Multivariate Normality Using Q-Q Plot and Chi-Square Plot	[C. D. Bhavsar]	28-43
+ Regression Analysis For Customer Relationship Management Practices and Customer Satisfaction For Private Sector Banks of Gujarat State	[Kamlesh L. Patel & Sanjay G. Raval]	44-56
+ Overview of Master Protocol In Clinical Trials	[Pinakin R. Jani & Manish B. Thaker]	57-62
<u>REVIEW ARTICLE</u>		
+ Statistical methods In Clinical Trials (III)	[Pinakin R. Jani]	63+-76
<u>BIOGRAPHY</u>		
+ Gertrude Mary Cox	[H. D. Budhbhatti]	77-78
<u>BOOK REVIEWS</u>	[Kavikumar Jacob]	79-80
<u>READERS FORUM</u>	[A. M. Patel]	81
<u>PEER REVIEW</u>		82



Published by
GUJARAT STATISTICAL ASSOCIATION



<http://www.sankhyavignan.org>

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SANKHYA VIGNAN

सांख्य विज्ञान



(Peer Review Journal For Research And Readings In Applied Statistics)

ISSN 2321-0877

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THIS LETTER IS SPECIALY FOR YOU

My dear reader/member,

Greetings of the Day !

I have great pleasure to communicate with you on the WORLD STATISTICS DAY by means of special issue of this journal SANKHYA VIGNAN. We have our very long association by means of this journal since last 16 years.

I am inclined to write this letter to you on behalf of our EDITORIAL BOARD / EDITORIAL ADVISORY BOARD to express our thanks for your whole hearted support for bringing out SV issue regularly and successfully.

These are definitely very hard and unassuming days and it becomes very difficult to pull on further due to economic conditions. As you already know, we send FREE PRINTED COPY of each issue to our members / readers as per our mailing list. Out of 400/500, print copies, hardly there remains 10/20 copies as stock. We send copies to our contributors, donors and few copies as complementary copies. Day by day, compose, printing and postal expenses are increasing. At this stage, each issue of the journal with 70/100 pages has a total cost of about Rs. 25000/- for each issue. We also send official certificates to our contributors with offprints for their papers.

Usually we have two issues (June and December) in a year but this time for the, (Corona Blessed year 2020) we are bringing out 3 issues (June, October and December). Our this October issue is a special one to celebrate WSD on 20/10/2020.

We have a mailing list which needs to be updated. Hence on this auspicious WSD, I propose the following to all our readers.

- (1) **We definitely need your academic, as well as financial support for our works ahead.**
- (2) **From January 2021, we shall stop the practice of sending printed copies to all readers.**

- (3) Of course, we shall mail digital copy to you all and also send hard copy to our contributors with certificate.
- (4) Updataion procedure is very badly needed, then and then only we can be able to send digital copy. Hence I propose the following.
- (4.1) Please send us the following details at your earliest to update our data.
(A) Full name, (B) Residential address, (C) Whatsapp mobile number (D) Email ID
- (4.2) **Please note that From January 2021, we shall send Digital copy only to all those who have given us the above information.**
- (4.3) **Even if you might have sent your above details earlier, please send it again to update the work.**
- (4.4) **Please furnish the above details Latest by 20 November 2020. Otherwise all our communication can stop immediately.**
- (5) You can supply this information by any one of the following ways.
- (5.1) **By post: Prin. A. M. Patel, 20, New Sharad Society, nr. Vijaynagar Bus Stop, Naranpura, Ahmedabad-380013. M : 9978444161**
- (5.2) By SMS/email :
(A) **Dr. Jayesh R. Purohit, M : 9909900799, email : drjayesh.purohit@gmail.com**
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(C) **Dr. Sanjay G. Raval, M : 9408867715, email : drsgraval@gmail.com**
- I am sure that you will treat this matter as urgent and give priority to send details eventhough in your busy schedule.
This will help us to update our data and serve you better.
- (6) **It is our intention to bring out 4 issues from year 2021 (instead of two issues as now).** Of course, this only depends upon our circumstances ahead.
With love and warm regards.

Yours sincerely,
Sd/-
Dr. B. B. Jani
(CE, SV Jornal)

EDITORIAL

LAMPS BURN IN EVERY HOUSE, BUT
O BLIND ONE YOU CAN NOT SEE THEM -TAGORE

We are extremely happy to present this special issue (NSV16, October 2020) as our celebration for **World Statistics Day on October 20, 2020**.

This issue contains a **special letter for our readers, two articles, four research articles, one review article, one biography, two book reviews and readers forum as usual**. Details about the same can be found in the contents.

We are highly indebted to our following referees who have spared no nerves for evaluation of the articles / papers submitted for this issue. (Names of referees are given one by one in the order of their appearance.)

- | | |
|------------------------|---------------------|
| (1) Shailesh Teredesai | (2) Ashwin M. Patel |
| (3) Jayesh R. Purohit | (4) D. K. Ghosh |
| (5) Manish B. Thaker | (6) R. G. Bhatt |
| (7) M. N. Patel | (8) H. M. Dixit |

As you know, we have our website www.sankhyavignan.org where you can give your feedback and suggestions.

We express our sincere thanks to **Shree Ashish Bhatt for website, Shree Dinesh Darji for DTP work and Shree Mehul Shah for printing work**.

Digital copy of this issue will be sent to all our readers whose email ID/Whatsapp No. are registered with us. Printed copy may follow soon. Our contributors will get offprints of their published articles along with the printed copy and certificate.

WISH YOU GOOD HEALTH, FURTHER PROGRESS AND PROSPERITY.

Our Deepawali Greetings and Best Wishes for the new year.

AHMEDABAD

EDITORIAL BOARD

Date : 20/10/2020 (WSD)

NOTE : Members of editorial board are in no way concerned with the views, opinions or ideas expressed in this issue. Authenticity responsibility lies solely with the persons presenting them.

ARTICLE

WORLD STATISTICS DAY : 20TH OCTOBER 2020

Jayesh R. Purohit*

The third **World Statistics Day** will be celebrated around the globe on **20 October 2020 (Tuesday)** with the theme “**Connecting the world with data we can trust**”. This theme reflects on the importance of trust, authoritative data, innovation and the public good in national statistical systems.

WORLD STATISTICS DAY 2020 CAMPAIGN

The celebration of World Statistics Day 2020 is a global collaborative endeavour, organized under the guidance of the United Nations Statistical Commission. The Statistics Division of the United Nations Department of Economic Affairs is the global coordinator of the campaign, defining global key messages and making available outreach resources to countries and other partners through their website.

National statistical offices act as national coordinators, translating promotional materials into national languages and organizing events and outreach efforts at national and subnational levels. International organizations play a key role in amplifying campaigns at the global and regional levels and organizing their own events.

Official Logo

Trusted data that the world can connect to is of most importance for 2020 World Statistics Day. The official logo represents this idea with a circular shape that portrays the globe, and a bar chart with a checkmark signifying trusted security.

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(I thank the referee for reviewing this article; rcd. Sep. 2020 / rvd. Oct. 2020)

History

The first World Statistics Day was celebrated on 20 October 2010 with the theme “Service, professionalism, integrity: celebrating the many contributions and achievements of official statistics”.

On 3 June 2015, the United Nations General Assembly adopted resolution 69/282, in which it designated 20 October 2015 as the second World Statistics Day and decided to celebrate the Day every five years on 20 October. The second Day was celebrated on 20 October 2015 with the theme “Better data, better lives”.

World Statistics Day is observed on October 20, once every 5 years. The coming **World statistics Day** will be celebrated on 20 October 2020. The **day** acknowledges the fundamental importance of sustainable national **statistical** capacity. **World Statistics Day** is an international day to celebrate statistics. Created by the United Nations Statistical Commission, it was first celebrated on 20 October 2010. The day is celebrated every five years.

World Statistics Day seeks to highlight the importance of reliable and timely data for informed decision-making by governments and individuals. The day also serves to promote the right to public information and raise awareness for technical investments that can aid in the data collection process. The importance of timely and reliable data means that nobody is left unaccounted for in order for policy makers to better address and overcome challenges such as education, climate change and social needs.

As of 2010, 103 countries celebrate a national Statistics Day, including 51 African countries that jointly celebrate African Statistics Day annually on 18 November.

Statistics is important for the lives of all human beings. For my case, I wish to mention when five decades ago, I was born in a family where my grandfather and father were in education field, my weight was taken and thus time to time weights and heights were maintained and I could realise the importance of statistics in my life which is true for the lives of all human beings. Worldwide its importance has been acknowledged.

It is appropriate to mention that India celebrates its Statistics Day on 29 June everywhere, the birthday of Statistician Prof Prasanta Chandra Mahalanobis, also popularly known as P.C. Mahalanobis, who was born on 29 June 1893 in Calcutta/ Kolkata and passed away on 28 June 1972, Calcutta. His greatest contribution was the formulation of the Second Five Year Plan where the emphasis was on industrialization (1956–61).

In the context of World Statistics Day, a Statement was made by Paul Cheung, Director of the United Nations Statistics Division (dated 30/9/2010) which is presented here, “Statistics are crucial to economic and social development. They generate public debate and contribute to the progress of our nations. They are indispensable to academic research and the development of businesses and civil society. Statistics ultimately serve everyone in society. We have worked hard over many decades to define and implement global statistical standards which have resulted in high quality, comparable statistics. For example, the Consumer Price Index was agreed to in 1925 at the Second International Conference of Labour Statisticians”.

The UN feels that reliable and timely statistics and indicators are more important than ever and in this regard, Ban Ki-Moon, UN Secretary-General before the UN event in 2015 stated, “On this World Statistics Day, I urge all partners and stakeholders to work together to ensure that the necessary investments are made, adequate technical capacity is built, new data sources are explored and innovative processes are applied to give all countries the comprehensive information systems they need to achieve sustainable development”.

World Statistics Day Facts & Quotes

- The coming World Statistics Day will be celebrated in 2020.
- It was not until the 19th century that statistics began to include all things related to collection, summary and analysis of data. Before the 19th century, data was mainly used to total resources, typically for military purposes and claim taxes.
- Some of the main advantages of using statistics are that you can track trends

and changes over time and track usage patterns. Some disadvantages are that they are not appropriate for being immediately understood, they must be interpreted properly, which requires technical expertise.

- In ancient times they had no statistics so they had to fall back on lies. – Stephen Leacock, a Canadian teacher, political scientist, writer and humourist.
- It is the mark of a truly intelligent person to be moved by statistics. – George Bernard Shaw, an Irish playwright, critic and polemicist.

World Statistics Day Top Events and Things to Do

- Watch a movie about the value of statistics. Some suggestions are: *Statistics* (2006), *Good Will Hunting* (1997) and *21* (2008).
- Spread awareness about the holiday by using the hashtag *#WorldStatisticsDay* *#StatsMatter* or *#TruthinStats*
- Read books about the value of statistics. Some suggestions are: *The Signal and the Noise*, *Freakonomics* and *Superfreakonomics*.
- Attend the Pizza and Puns day that will be held at Carnegie Mellon University. They are throwing a pizza party day and guests are encouraged to share statistics with themed desserts with prizes and treats for the cleverest statistics pun.

As mentioned already, this year on 20 October 2020; Tuesday, World Statistics Day will be celebrated and next World Statistics Day will be observed on 20 October 2025, Monday.

World Statistics Day References and Related Sites

www.un.org: UN Statistics

www.un.org: UN - World Statistics Day

www.un.org: UN - World Statistics Day Theme

worldstatisticsday.org: World Stats Day Org

worldstatisticsday.org: World Statistics Day Blog

ARTICLE

ONLINE EDUCATION'S BIGGEST YEAR : 2020

Jayesh R. Purohit*

ABSTRACT

This article describes briefly about the modern approach for online education which is in a way the outcome due to covid pandemic situation. Under the circumstances there can be merits and demerits of the system. Some artical points are highlighted.

Keywords

COVID 19, Infrastructure, Flexibility.

As the months go by, the changes to our lives created by the COVID-19 pandemic are proving more far-reaching than we initially thought when our governments imposed emergency measures, and they look set to continue for a long time.

In academia, where time is measured not in years or months, but by terms, semesters or trimesters, more and more institutions around the world are beginning to face the likelihood not just of finishing courses online — for which they were mostly unprepared when they started — but of having to begin the next academic year under similar conditions. At this point, 90% of students in developed countries are receiving classes online, with varying levels of excellence and satisfaction. However, as expected, things have changed significantly since March, when schools' lack of experience could be used as an excuse; but by now, they should now have a strategy and serious plans to ensure a proper learning experience to prevent their pupils forming part of a lost generation.

Academic institutions will be obliged for a long time either to teach all their classes online, or at least to offer a valid and full alternative to all students who have to follow the classes from home. Whether due to lockdown or social distancing, which will force a reduction in classroom size, everything indicates that academic activity will still take a long time to return to normal, and may end up in a very different normal to before.

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(I thank the referee for reviewing this article; rcd. May 2020 / rvd. June 2020)

How should academic institutions deal with such a scenario? First, they need to be sure that online teaching tools are not going to be the problem. The last few weeks or months could or should have been used for testing, evaluating alternatives and making decisions, but after that period, students must be offered a reasonable plan, one which allows them not only to learn online under reasonable conditions, but also to deal with the confusing interim period. The last few weeks have allowed institutions to see that, under the current technological scenario, there are many very good tools for teaching online, and that are also generally very easy to use.

Obviously, those institutions with more experience in the online environment or that had already developed a digital transformation strategy have a clear advantage, as do those that can count on their students being on the right side of the digital divide, with access to computers and high-speed connections. But from there on, the issue has to revolve around a number of specific issues:

Teaching the teachers

Online teaching tools are relatively simple to use. However, not all teachers are motivated enough to make the effort to adapt their classes to the new environment, and in many cases they will claim difficulties in doing so.

In many institutions and at certain levels of education, especially higher education, it is easy to find academics for whom teaching is not the highest priority. Getting them to understand the importance of committing to education and their students will undoubtedly be a challenge for many institutions.

Infrastructure

Teaching online is not something that can be done with a bad connection or a computer balanced on your knees. As well as bandwidth, new tools, from additional monitors to lighting fixtures, quality microphones, or even chroma key will be needed, while institutions will have to decide how much of the cost of that they will finance. Our experience is that a face-to-face class is prepared, while an *online* class is produced, almost like a television show with an audience, and with very similar philosophies as to how to encourage participation.

Conceptualizing the teaching model

Teaching online is not simply re-enacting a classroom session in front of a webcam. It requires rethinking teaching methods by understanding and taking advantage of the possibilities of certain tools, not becoming obsessed with the amount of information we

provide, combining different methods to avoid tediousness, inviting guests, and trying to share the burden and responsibility of learning with students. Nothing guarantees that a teacher who worked well in the classroom environment will be good when teaching online, and in that sense, creating spaces to share experiences and help develop skills will be essential.

Long-term approach

Most institutions and students have not yet realized this, but online teaching is no longer a poor substitute for the classroom and will result in tools and dynamics that will continue to be used when the pandemic is brought under control. In fact, knowledge transmission may be better in a medium such as the web that allows for richer interactions. Right now, a high percentage of students in business schools say that if their school starts the course in *online* mode, they will defer admission until next year. This would be a mistake. In fact, taking a portion of a course — especially if it is the first part — online can result in important skill development that many companies will appreciate in the future, and in an experience that generates even greater satisfaction than a classroom-based course. Those of us who have been offering courses in online or blended formats for many years are well aware of this.

Flexibility

Rethinking education to bring it online means acting with sufficient flexibility to reconceptualise all its elements. Class sizes will decrease, the length of sessions can be altered, assessment methodologies will evolve and interaction must be redesigned. This may be problematic for regulatory bodies, as well as for relations with students or their parents, who will see changes that will require convincing explanations, in an environment that has always been characterized by lethargy.

Some analysts are predicting that this crisis could be a catastrophe for some higher education institutions, and in some cases, they will have to hook up with technology companies to rethink their teaching methodologies. Frankly, I don't think either would be bad news: there are too many institutions in the marketplace that simply don't meet the standards students require, and education has definitely a lot to learn from technology.

But knowing the market, I believe that we will see an adjustment, whereby those who are able to evolve more quickly, who involve all stakeholders in the process, will tend to win. Education faces a serious challenge, but this is also an opportunity to get a lot of things right.

RESEARCH ARTICLE

**EFFECTS OF FOREIGN DIRECT INVESTMENT ON
INDIAN ECONOMY : AN EVALUATION**

Rakesh Bajpai⁽¹⁾ and Pradeep Prajapati⁽²⁾

ABSTRACT

The nature of Foreign Direct Investment (FDI) inflows during 2000-2015, a study period of the present article, indicates important dimensions of FDI in India impacting economic growth of India. It is observed from the results of above analysis that Trade Gross Domestic Product (GDP), Reserves GDP, Exchange rate, Ratio of External Debts to Exports (FIN Position) and Foreign Direct Investment Growth (FDIG) are the main factors affecting FDI inflows in India. The results of foreign Direct Investment Model reveal that Trade GDP, Reserves GDP, and FIN Position variables exhibit a positive relationship (pull factors) with FDI, while Exchange rate exhibits a negative relationship (restrictive forces) with FDI inflows. The study also reveals that FDI is a significant factor influencing the level of economic growth in India. The results of Economic Growth Model and Foreign Direct Investment Model reveal that FDI plays a crucial role in enhancing the level of economic growth in India. Accordingly some policy recommendations are floats in this paper.

KEY WORDS:

FDI, GDP, FDIG, Inflation.

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INTRODUCTION:

Foreign direct investment (FDI) in India has played an important role in the development of the Indian economy. It has in lot of ways facilitated India to achieve a certain degree of financial stability, growth and development. This money has endorsed India to focus on the areas that needed a boost and economic attention, and address the various problems that continue to challenge the country. From time to time various policies on FDI are also designed by Government in such a manner to promote the inward investments. Both the host and the home countries benefit a lot from such type of investments, therefore, they are directly interested in inviting FDI. India has been a major recipient of FDI in majority of sectors and different states since 1990 i.e. just before New Economic Policy. As per the assessment, the sector which attracted higher inflows was services, telecommunication, construction activities and computer software and hardware. Mauritius, Singapore, US and the UK were among the major countries for FDI in India.

We are concluding the following facts :

1. The FDI have both short – run and long – run effect on the economy. So, regulatory FDI guidelines must be formulated in order to protect developing economies from after examining the existing literature on studies concerned with exploring the determinants of FDI it has been found that these studies evaluated the various factors affecting FDI inflows in some developing and developed countries. Most of the studies have found the positive as well as significant influence of some empirical variables like GDP, per capita GDP, rate of public sector investment, terms of deposits, terms of trade, change in imports and exports, commercial interest rate, domestic investment, employment, low rate of tax, labour supply, foreign exchange reserves and low borrowing cost on FDI inflows.
2. Some theoretical variables like fiscal incentives, selective policies, infrastructure, innovative activities, level of education, strong IPR protection and labour quality have also been found to give positive impact on FDI inflows in case of developing and developed countries by above mentioned studies. The

variables such as interest rates, inflation, debt service ratio and high labour cost have been found to give negative impact on FDI inflows.

3. Literature related with the trends of FDI, change in its pattern on account of structural transformation and change in policies and procedures regarding FDI due to liberalisation and the various economic reforms adopted by the countries with the passage of time.
4. From the review of the literature regarding determinants of FDI it has been observed that researchers agreed about the impact of many variables on FDI but there is lack of uniformity of the opinion regarding the influence of some variables like inflation, exchange rate, openness, GDP, foreign exchange reserves and long term debt on FDI inflows. This necessitates reinvestigation of factors influencing FDI in case of India.
5. After thorough investigation of the findings of various researchers it has been concluded that impact of FDI on some very important macroeconomic indicators like GDP, exports, foreign exchange reserves FDI on these variables for India and China.
6. While the literature has heeded the importance of FDI to growth and development, it also realizes that economic growth could be an important factor in attracting FDI flows. The importance of economic growth to attracting FDI is closely linked to the fact that FDI tends to be an important component of investing firms' strategic decisions.
7. Some authors argue that the adoption of new technologies and management skills requires inputs from the labour force. High- level capital goods need to be combined with labour that is able to understand and work with the new technology. Therefore, technological spill-over is possible only when there is a certain minimum, or 'threshold' level of human capital available in the host country. **(Borensztein, et al., 1998)**. This suggests that FDI and human capital are complementary in the process of technological diffusion. Other authors argue that the process of technological spill-overs may be more efficient in the presence of well-functioning markets. Under these circumstances, the

environment in which FDI operates ensures competition and reduces market distortions, enhancing the exchange of knowledge among firms (**Bhagwati, 1978; Ozawa, 1992; Balasubramanyam, et al., 1996**).

8. Some authors stress that the establishment of property rights – in particular intellectual property rights – is crucial to attract high technology FDI (**Smarzynska, 1999**). If intellectual property rights are only weakly protected in a country, foreign firms will undertake low technology investments, which reduces the opportunities for spill-over effects and improvements of productivity of domestic firms.
9. Economic Performance and economic growth of a country is influenced by multiple factors. For economies in general and developing economies in particular, Foreign Direct Investment (FDI) has been observed and argued as a significant determinant. However there remain two contrasting views.
10. Studies on role of FDI in emerging economies shows that general institutional framework, effectiveness of public sector administration and the availability of infrastructural facilities enhance FDI inflows to these nations. FDI also enhance the chances of developing internationally competitive business clusters. It is observed that countries pursuing export – led growth strategies reaps enormous benefits from FDI.
11. It is also observed that FDI have both short – run and long – run effect on the economy. So, regulatory FDI guidelines must be formulated in order to protect developing economies from the consequences of FDI flows.

It is clearly revealed from the above observations that many studies have been conducted on the issue of Foreign Direct Investment and also the main determinants of FDI in developing countries are inflation, infrastructural facilities, debts, burden, exchange rate, FDI spill-overs, stable political environment etc. In fact, the area of FDI offers such a large scope that scholars may attempt to investigate various new issues, hence, in every study one finds a different approach and different aspects which were not covered by the earlier studies. Therefore, the ultimate goal of the present research article is to analyse effects of foreign direct investment (FDI) on Indian

Economy and hence, industrial development in India, drawing the following main amongst the others objectives. The authors confess at the outset that there is still a large scope of research in this area.

Objectives of the Study:

Following are the main objectives have been drawn from the abovementioned brief review of literature;

1. To study the trends and patterns of flow of FDI.
2. To assess the determinants of FDI inflows.
3. To analyse the distribution of FDI in India.
4. To examine the relationship between FDI inflows and GDP of India.
5. To evaluate overall impact of FDI on the Economy.

Macroeconomic variables are taken into account as explanatory variables so as to have a complete understanding of the nature of inflows during 2000-2015 (study period) to analyse important dimensions of FDI in India impacting economic growth of India. Accordingly, this paper is broadly divided into four sections, as follows; Section - I gives research methodology, includes data collection, mathematical model, model building and analytical and econometric technique, Section - II entails results and findings including effects of FDI on Indian Economy, policy suggestions i.e. recommendations are included in Section - III, followed by references are covered in last section.

SECTION - I

RESEARCH METHODOLOGY:

Data Collection:

The analysis is based on primary as well as secondary data. While the primary survey provides limited information for the requisite analysis, the secondary database has been a major source of detailed firm - level and plant-level analysis. The secondary database provided a rich source of plant-level data which has been used extensively in the analysis. The Capita line database provides data on more than 14,000 Indian

listed and unlisted companies classified under more than 300 industries. The information used is based on FDI actually received.

The required data have been collected from various sources i.e. World Investment Reports, Asian Development Bank's Reports, various Bulletins of Reserve Bank of India, publications from Ministry of Commerce, Govt. of India. It is a time series data and the relevant data have been collected for the period from the year 2000 to 2015.

Mathematical Model:

To analyse the collected data the following mathematical tools were used; Firstly, to work out the trend analyses the following formula is used:

- a. Trend Analysis i.e. $w = a + bx$

where; w = predicted value of the dependent variable

a = y – axis intercept,

b = slope of the regression line (or the rate of change in y for a given change in x),

x = independent variable (which is *time* in this case).

- b. Annual Growth rate is worked out by using the following formula:

$$\text{AGR} = (X_2 - X_1) / X_1$$

Where X_1 = first value of variable X

X_2 = second value of variable X

- c. Compound Annual Growth Rate is worked out by using the following formula:

$$\text{CAGR} (t_0, t_n) = (V(t_n)/V(t_0))^{1/t_n - t_0} - 1$$

Where; (t_0) : start value, $V(t_n)$: finish value, $t_n - t_0$: number of years.

In order to analyse the collected data, various statistical and mathematical tools were used, as follows;

MODEL Building:

To examine the impact of foreign direct investment on economic growth, two models were framed and fitted. The foreign direct investment model shows the

factors influencing the foreign direct investment in India. The economic growth model depicts the contribution of foreign direct investment to economic growth. The two model equations are expressed below:

1. $FDI = f [TRADEGDP, RESGDP, R\&DGDP, FIN. Position, EXR.]$
2. $GDPG = f [FDIG]$

Where;

FDI= Foreign Direct Investment. GDP = Gross Domestic Product.

GDPG = level of Economic Growth.

TRADEGDP= Total Trade as percentage of GDP.

FDIG = Foreign Direct Investment Growth.

RESGDP= Foreign Exchange Reserves as percentage of GDP.

R&DGDP= Research & development expenditure as percentage of GDP.

FIN Position = Ratio of external debts to exports

EXR= Exchange rate

Analytical and econometric technique:

1. Regression analysis (Simple & Multiple Regression) was carried out using relevant econometric techniques. Simple regression method was used to measure the impact of FDI flows on economic growth (proxies by GDP growth) in India.
2. Further, multiple regression analysis was used to identify the major variables which have impact on foreign direct investment.
3. Relevant econometric tests such as coefficient of determination R²,
4. Durbin – Watson [D-W] statistic,
5. Standard error of coefficients,
6. t and F statistical tests were carried out in order to assess the relative significance, desirability and reliability of model estimation parameters.

SECTION - II

RESULTS AND FINDINGS:

A. Trends and patterns of FDI flows at Indian level:

1. Although India's share in global FDI has increased considerably, the pace of FDI inflows has been slower than China, Singapore, Brazil, and Russia.
2. India has considerably decreased its fiscal deficit from 5.28 percent in 2002-03 to 4 percent in 2014-15 and revenue deficit from 4.25 percent to 2.89 percent in 2014-15.
3. There has been a generous flow of FDI in India since 1991 and its overall direction also remained the same over the years irrespective of the reigning political party.
4. India has received increased commercial borrowings largely because of its rate of economic growth and stability in the political environment of the country.
5. Economic reform process since 1991 have paved way for increasing foreign exchange reserves to US\$ 251985 million in 2014-15 as against US\$ 9220 million in 2000-01.
6. During the period under study it is found that India's GDP crossed one trillion dollar mark in 2007. Its domestic saving ratio to GDP also increases from 29.8 percent in 2004-05 to 37 percent in 2014-15.
7. An analysis of last twenty four years of trends in FDI inflows in India shows that initially the inflows were low but there is a sharp rise in investment flows from 2007 onwards.
8. It is observed that India received FDI inflows of Rs.492302 crore during 2000-2015 as compared to Rs. 84806 crore during 1991-1999. India received a cumulative FDI flow of Rs. 577108 crore during 1991 to march 2015.
9. It is observed that major FDI inflows in India are concluded through automatic route and acquisition of existing shares route than through FIPB, SIA route during 2000-20015.
10. Among the sectors, services sector received the highest percentage of FDI inflows in 2015. Other major sectors receiving the large inflows of FDI apart from services sector are construction development, telecommunications, computer software and hardware, drugs and pharmaceutical and automotive industry etc. It is found that nearly 40 percent of FDI inflows are in high priority areas like

services, construction development, telecommunications, computer software and hardware etc.

11. India has received maximum number of financial collaborations as compared to technical collaborations.
12. FDI has gained momentum in the economic landscape of world economies in the last three decades. It had outpaced almost all other economic indicators of economic transactions worldwide.
13. FDI is considered as the safest type of external finance both by the developed and developing nations. So, there is growing competition among the countries in receiving maximum inward FDI.
14. Trends in world FDI inflows shows that maximum percentage of global FDI is vested with the developed nation. But in the last two decades, developing countries by receiving 55.5% of global FDI in 2014 as against 26% in 1980 make waves in the economics of developed nations.
15. Among developing nations of the world, the emerging economies of the Asian continent are receiving maximum share (16%) of FDI inflows as against other emerging countries of Latin America (8.7%) and Africa (2%).
16. In the last two decades, India has significantly increased its share of world FDI from 0.5% in 2001 to 3.4% in 2014.
17. China is the major recipient of global FDI flows among the emerging economies of the world. It is also the most preferred destination of global FDI flow. India is at 6th position in the category of most attractive location of global FDI.
18. It is found that FDI flows to India have increased from 12% in 1991-99 to 289% in 2000-2015.
19. In the South, East and South-East Asia block India is at 3rd place after China and Singapore in receiving FDI inflows.
20. India is the major recipient of FDI inflows in South-Asia region. It constitutes **75%** of total FDI inflows to this region.
21. It is found that China's share is 17.4% and India's share is miniscule (i.e. 3.9%) among the emerging economies of the world in the present decade. India's fiscal

deficit is reason for concern. It has increased 2.5 percent in 2007-08 to 4.1 percent in 2014-15 and revenue deficit from (-1.05) to (-2.94) percent in 2014-15.

22. India has received increased NRI's deposits and commercial borrowings largely because of its rate of economic growth and stability in the political environment of the country.
23. Economic reform and liberalization process since 1991 have paved way for increasing foreign exchange reserves to US\$ 341638 million in 2014-15 as against US\$ 42281 million in 2000-2001.
24. During the period under study it is found that India's GDP crossed one trillion dollar mark in 2007. Its domestic saving ratio to GDP also increases from 29.8 percent in 2004-05 to 37 percent in 2014-15.
25. FDI in India has increased manifold since 1991. FDI inflows in India have increased from US\$ 4029 million in 2001 to US\$ 44877 million in 2015.
26. An analysis of last eighteen years of trends in FDI inflows in India shows that initially the inflows were low but there is a sharp rise in investment flows from 2006 onwards.
27. Although there has been a generous flow of FDI in India but the pace of FDI inflows has been slower in India when it is compared with China, Russian federation, Brazil and Singapore.
28. It is also found that investors in India are inclined toward having more financial collaborations rather than technical ones.
29. Among sectors, Services sector tops the chart of FDI inflows in India in 2015. Nearly, 43.73% of FDI inflows are in high priority areas like services, Infrastructure development, telecommunication etc.
30. Mauritius is the major investing country in India during 2001-2015. Nearly 35% of FDI inflows came from Mauritius alone.
31. The other major investing countries are USA, Singapore, UK, Netherlands, Japan, Germany, Cyprus, France and Switzerland.
32. An analysis of last eighteen years of FDI inflows in the country shows that

nearly 64% of FDI inflows came from only four countries viz. Mauritius, Singapore, UK, and Japan.

33. Mauritius and Singapore are the two major countries holding first and the second position in the investor's list of FDI in India. While comparing the investment made by both countries, one interesting fact comes up which shows that there is huge difference in the volume of FDI received from Mauritius and Singapore. It is found that FDI inflows from Mauritius are nearly 3 times more than that of Singapore.
34. FDI inflows in India are concentrated around two cities i.e. Mumbai and New Delhi. Nearly 49 percent of total FDI inflows to India are concentrated in these two cities. Apart from Mumbai and Delhi, Chennai, Bangalore, Ahmedabad and Hyderabad also received significant amount of FDI inflows in the country.
35. It is observed that among Indian cities maximum foreign collaborations were received Mumbai.
36. It is observed that major investment in the above sectors came from Mauritius and investments in these sectors in India are primarily concentrated in Mumbai and New Delhi.
37. It is observed that major FDI inflows in India are concluded through automatic route and acquisition of existing shares route than through FIPB, SIA route during 2000-2015.

B. FDI and Indian Economy:

1. The results of Foreign Direct Investment Model shows that all variables included in the study are statistically significant. Except the two variables i.e. Exchange Rate and Research and Development expenditure (R&DGDP) which deviates from their predicted signs. All other variables show the predicted signs.
2. Exchange rate shows positive sign instead of expected negative sign. This could be attributed to the appreciation of Indian Rupee in international market which helped

3. the foreign firms to acquire the firm specific assets at cheap rates and gain higher profits.
4. Research and Development expenditure shows unexpected negative sign as of expected positive sign. This could be attributed to the fact that R&D sector is not receiving enough FDI as per its requirement. But this sector is attracting more attention in recent years.
5. Another important factor which influenced FDI inflows is the Trade GDP. It shows the expected positive sign. In other words, the elasticity coefficient between Trade GDP and FDI inflows is 11.79 percent which shows that one percent increase in Trade GDP causes 11.79 percent increase in FDI inflows to India.
6. The next important factor which shows the predicted positive sign is Reserves GDP
7. The elasticity coefficient between Reserves GDP and FDI inflows is 1.44 percent which implies one percent increase in Reserves GDP causes an increase of 1.44 percent in the level of FDI inflows to the country.
8. Another important factor which shows the predicted positive sign is FIN. Position i.e. financial position. The elasticity coefficient between financial position and FDI inflows is 15.2 percent i.e. one percent increase in financial position causes 15.2 percent increase in the level of FDI inflows to the country.
9. In the Economic Growth Model, the variable GDPG (Gross Domestic Product Growth i.e. level of economic growth) which shows the market size of the host economy revealed that FDI is a vital and significant factor influencing the level of economic growth in India.

In a nutshell, despite crisis in the world economy, India continued to attract substantial amount of FDI inflows. India due to its flexible investment regimes and policies prove to be the horde for the foreign investor in finding the investment opportunities in the country.

SECTION – III

MAJOR POLICY RECOMMENDATIONS:

The study suggests the policy makers to focus more on attracting diverse types of FDI and;

1. The policy makers should frame such policies where foreign investment can be utilised as means of enhancing GDP, savings, capital formation and exports; as medium of technological learning and technology diffusion and also in providing access to the external market.
2. It is suggested that the government should push for the speedy improvement of infrastructure sector's requirements which are important for diversification of business activities for balanced development of the country.
3. Government should ensure the equitable distribution of FDI inflows among states. The central government should provide business friendly environment and more freedom to states, so that they can attract FDI inflows at their own level. The government should also provide additional incentives to foreign investors to invest in states where the level of FDI inflows is quite low.
4. Government should open doors to foreign companies in the export – oriented services which could increase the demand of unskilled workers and low skilled services and also increases the wage level in these services.
5. Government must target at attracting specific types of FDI that are able to generate spill overs effects in the overall economy. This could be achieved by investing in human capital, R&D activities, resolving environmental issues, dynamic products, productive capacity, infrastructure and sectors with high income elasticity of demand.
6. The government must promote policies which allow development process starts from within (i.e. through productive capacity and by absorptive capacity).
7. It is suggested that the government endeavour should be on the type and volume of FDI that will significantly boost domestic competitiveness, enhance skills, technological learning and invariably leading to both social and economic benefits.

8. It is also suggested that the government must promote sustainable development goals through FDI by further strengthening of education, health and R&D system, political involvement of people and by ensuring safety and security of the citizens by maintaining law and order of the country.

ACKNOWLEDGEMENT:

We thank the referee (anonymous) for reviewing our paper which was helped us in its revision.

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RESEARCH ARTICLE

**MULTIVARIATE NORMALITY USING Q-Q PLOT AND
CHI-SQUARE PLOT**

C. D. BHAVSAR*

ABSTRACT

In this Paper we have used Q-Q plot and Chi-square plot for examining multivariate normality of the data related to atmospheric concentrations of air pollutants in the Los Angeles area. In our data, daily measurements on seven pollution-related variables were recorded over an extended period of time. Our immediate interest was to know whether the levels of air pollutants were roughly constant throughout the week or whether there was a noticeable difference between weekdays and weekends. A secondary objective was to check the normality of individual variables as well as the multivariate normality of the variables which have marginal normality.

Key Words:

Q-Q Plot, Chi-square Plot, Multivariate Normality

1. Introduction:

Statistical techniques are integral part of any scientific inquiry and consequently, their use is widespread. In particular, multivariate methods have been regularly applied to problems arising in the physical, social, and medical sciences. In real-world situations where multivariate techniques have proven valuable are Medicine and Health, Sociology, Business and Economics, Education, Biology, Meteorology, geology, Psychology, Sports and Environmental Studies. Marginal dot diagram can be obtained

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from the original observations or by projecting the points in the scatter diagram onto each coordinate axis. Dot diagram and scatter plots contain different kinds of information. Note that the information in the marginal dot diagrams is not sufficient for constructing the scatter plot.

2. Q-Q Plot (Powerful test for Normality):

Plots are always useful device in analysis of any type of data. Especially Q-Q plots are used to assess the assumption of normality. These plots can be performed for the marginal distributions of the sample observations on each variable. They are plot of the sample quantile versus the quantile of which one would expect to observe if the observations actually were normally distributed. When the points lie very nearly along a straight line then the normality assumption remains tenable. Normality is suspected if the points deviate from a straight line. Note that the pattern of deviations can provide clues about the nature of the non-normality. Once the reasons for non-normality are identified, corrective action is often possible. If $x_{(1)} < x_{(2)} < \dots < x_{(n)}$ represent n ordered observations then $x_{(j)}$'s are the j th sample quantiles. For standard normal distribution the quantiles $q_{(j)}$ are defined by the relation

$$P r (z \leq q_{(j)}) = \int_{-\infty}^{q_{(j)}} \phi (Z) d z = p_{(j)} = \frac{j - \frac{1}{2}}{n}.$$

Here $p_{(j)}$ is the probability of getting a value less than or equal to $q_{(j)}$ in a single drawing from a standard normal population. We are interested to look at the pairs of quantiles $(q_{(j)}, x_{(j)})$ with the same associated cumulative probability, $(j - 1/2)/n$. If the given data arise from normal population, the pairs $(q_{(j)}, x_{(j)})$ will be approximately linearly related since $\sigma q_{(j)} + \mu$ is nearly the expected sample quantile. Note that a better procedure is to plot $(m_{(j)}, x_{(j)})$, where $m_{(j)} = E(z_{(j)})$ is the expected value of the j^{th} order statistic in a sample of size n from a standard normal distribution. The calculations required for Q-Q plots are easily programmed for electronic computers. Many statistical programs available commercially are capable of producing Q-Q plots.

The steps leading to Q-Q plot are (i) Order the original observations to get

$x_{(1)}, x_{(2)}, \dots, x_{(n)}$ and their corresponding probability values $(1-1/2)/n, (2-1/2)/n, \dots, (n-1/2)/n$, (ii) Calculate the standard normal quantiles $q_{(1)}, q_{(2)}, \dots, q_{(n)}$ and (iii) Plot the pairs of observations $(q_{(1)}, x_{(1)}), (q_{(2)}, x_{(2)}), \dots, (q_{(n)}, x_{(n)})$ and examine the “straightness” of the outcome. Note that the Q-Q plots are not particularly informative unless the sample size is moderate to large; for instance, $n > 20$. There can be quite a bit of variability in the straightness of the Q-Q plot for small samples, even when the observations are known to come from a normal population. The straightness of Q-Q plot can be measured by calculating the correlation coefficient of points in the plot. A powerful test of normality based on the correlation coefficient r_Q for the Q – Q plot is defined as follow.

$$r_Q = \frac{\sum_{j=1}^n (x_{(j)} - \bar{x})(q_{(j)} - \bar{q})}{\sqrt{\sum_{j=1}^n (x_{(j)} - \bar{x})^2} \sqrt{\sum_{j=1}^n (q_{(j)} - \bar{q})^2}}$$

We reject the null hypothesis of normality at level of significance α if r_Q falls below the appropriate value in the table of “Critical points for the Q - Q Plot Correlation Coefficient test for Normality”.

3. Examine Bivariate Normality:

We would like to check on the assumption of normality for all distributions of 2, 3, ..., p dimensions. However, for practical purpose it is sufficient to investigate the univariate and bivariate distributions. If the observations were generated from a multivariate normal distribution, each bivariate distribution would be normal and the contours of constant density would be ellipses. The scatter plot should confirm to this structure by exhibiting an overall pattern that is nearly elliptical. If the scatter plot of pairs (x_1, x_2) is nearly elliptical then bivariate normality is tenable. Contours of constant density for the p-dimensional normal distribution are ellipsoids defined

by \underline{x} such that

$$(\underline{x} - \underline{\mu})' \Sigma^{-1} (\underline{x} - \underline{\mu}) = c^2.$$

These ellipsoids are centred at μ and have axes $\pm c \cdot (\lambda_i e_i)$, where " $e_i = \lambda_i e_i$, $i = 1, 2, \dots, p$. If we choose $C^2 = \chi_p^2(\alpha)$, where $\chi_p^2(\alpha)$ is the upper $(100\alpha)^{\text{th}}$ percentile of a chi-square distribution with p degrees of freedom, leads to contours that contains $(1 - \alpha)100\%$ of the probability. Specifically, for a p -dimensional normal distribution, the solid ellipsoid of \mathbf{x} values satisfying

$$(\underline{x} - \underline{\mu})' \Sigma^{-1} (\underline{x} - \underline{\mu}) \leq \chi_p^2(\alpha)$$

has probability $(1 - \alpha)$. Moreover for the set of bivariate outcomes \underline{x} such

that
$$(\underline{x} - \underline{\mu})' \Sigma^{-1} (\underline{x} - \underline{\mu}) \leq \chi_p^2(0.5)$$

has probability $(1 - 0.5) = 0.5$. Thus we should expect roughly the same percentage, 50% of sample observations to lie in the ellipse

$$(\underline{x} - \bar{\underline{x}})' S^{-1} (\underline{x} - \bar{\underline{x}}) \leq \chi_p^2(0.5); \forall \underline{x}$$

where we have replaced μ by its estimate $\bar{\underline{x}}$ and Σ^{-1} by its estimate S^{-1} . If not, the normality assumption is suspect.

4. Methodology:

We consider the data for 42 measurements on air-pollution variables namely Wind, Solar radiation (SR), CO, NO, NO₂, O₃ and HC recorded at 12:00 noon in the Los Angeles area on different days. We Plot the marginal dot diagrams for all the variables to check individual normality of the variables under study. The mean vector $\bar{\underline{x}}$, sample variance-covariance matrix S_n and sample correlation matrix R are obtained for the Los Angeles data. Interpretation of the entries in R to observe the association between the variables are discussed.

Plots are important in data analysis. Although it is impossible to simultaneously plot all the measurements made on several variables and study the configurations, plots of individual variables and plots of pairs of variables can still be informative. Overall shape of scatter plot provides information on symmetry and possible outliers for each individual characteristic. The scatter plots can be inspected for patterns and unusual observations.

Further we construct a Q-Q plot for the solar radiation measurements and carry out a test for normality based on the correlation coefficient r_Q . We let $\alpha=0.01$ and use the entry corresponding to $n = 42$ in the Table of critical points for the Q-Q plot correlation coefficient test for normality. We also examine the pairs $(x_5, x_6) = (\text{NO}_2, \text{O}_3)$ for bivariate normality. For this, we calculate generalized distances $(x_j - \bar{x})'S^{-1}(x_j - \bar{x})$; $j = 1, 2, \dots, 42$ where $x_j' = (x_{5j}, x_{6j})$. Then we determine the proportion of observations $x_j' = (x_{5j}, x_{6j})$; $j = 1, 2, \dots, 42$ falling within the approximate 50% probability contour of a bivariate normal distribution and construct a chi-square plot of the calculated generalized distances.

Table- 1: AIR POLLUTION DATA

Sr.No.	x1	x2	x3	x4	x5	x6	x7
	Wind	SR	CO	NO	NO2	O3	HC
1	8	98	7	2	12	8	2
2	7	107	4	3	9	5	3
3	7	103	4	3	5	6	3
4	10	88	5	2	8	15	4
5	6	91	4	2	8	10	3
6	8	90	5	2	12	12	4
7	9	84	7	4	12	15	5
8	5	72	6	4	21	14	4
9	7	82	5	1	11	11	3
10	8	64	5	2	13	9	4
11	6	71	5	4	10	3	3
12	6	91	4	2	12	7	3
13	7	72	7	4	18	10	3
14	10	70	4	2	11	7	3
15	10	72	4	1	8	10	3
16	9	77	4	1	9	10	3
17	8	76	4	1	7	7	3
18	8	71	5	3	16	4	4
19	9	67	4	2	13	2	3
20	9	69	3	3	9	5	3
21	10	62	5	3	14	4	4
22	9	88	4	2	7	6	3
23	8	80	4	2	13	11	4
24	5	30	3	3	5	2	3
25	6	83	5	1	10	23	4
26	8	84	3	2	7	6	3
27	6	78	4	2	11	11	3
28	8	79	2	1	7	10	3
29	6	62	4	3	9	8	3
30	10	37	3	1	7	2	3
31	8	71	4	1	10	7	3
32	7	52	4	1	12	8	4
33	5	48	6	5	8	4	3
34	6	75	4	1	10	24	3
35	10	35	4	1	6	9	2
36	8	85	4	1	9	10	2
37	5	86	3	1	6	12	2
38	5	86	7	2	13	18	2
39	7	79	7	4	9	25	3
40	7	79	5	2	8	6	2
41	6	68	6	2	11	14	3
42	8	40	4	3	8	5	2

It is good statistical practice to plot pairs of variables and to visually inspect the pattern of association. We can observe that the patterns of air pollutants Wind, NO, CO and HC are symmetric while patterns of solar radiation, O₃ and NO₂ are random. Some outliers are present in observed HC, O₃, NO₂ and NO.

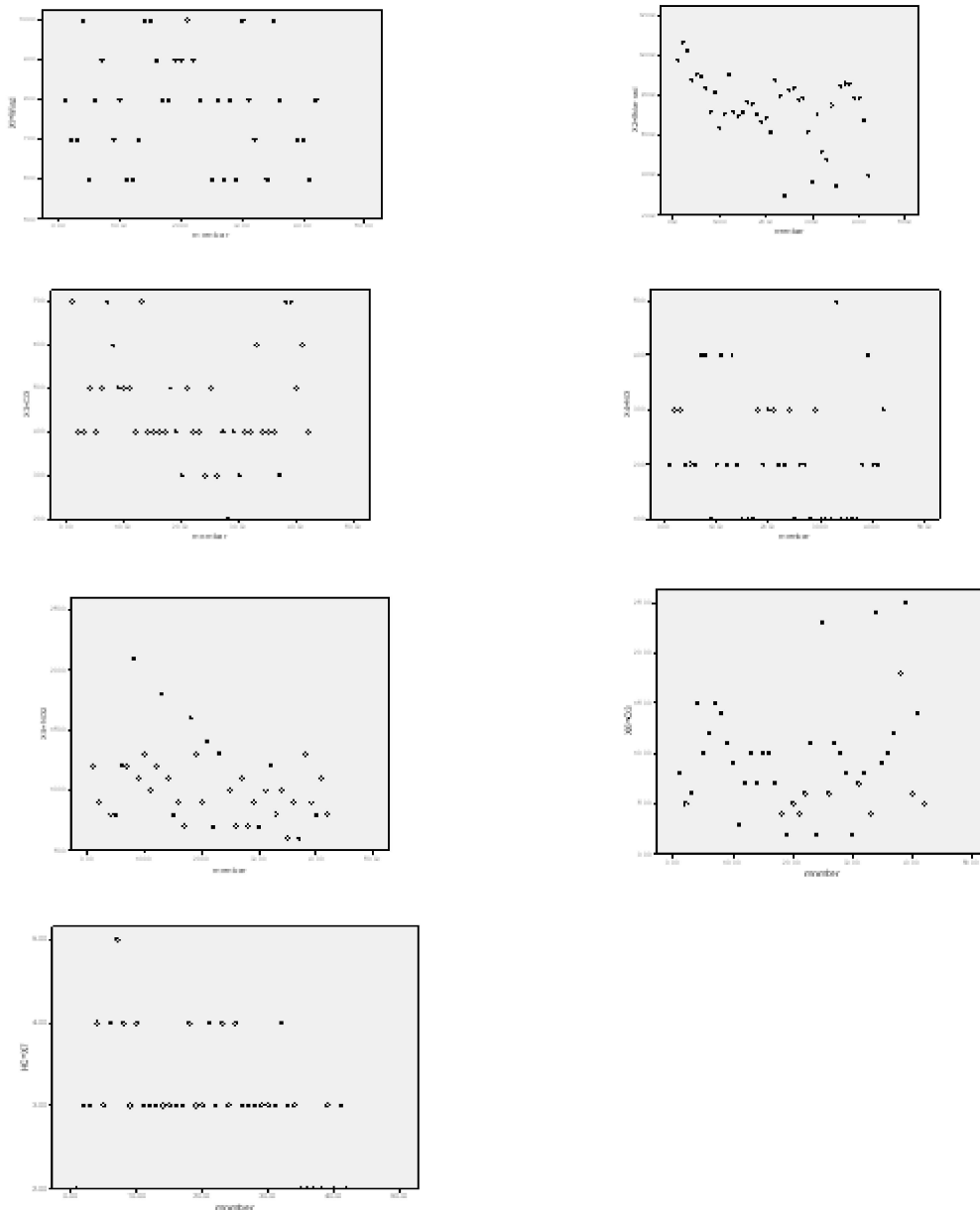


Figure-1. Marginal Scatterplots for air pollution data from table-1

Table- 2: Descriptive Statistics

	N	Range	Mean	Variance
Wind	42	5.00	7.5000	2.500
Solar rad	42	77.00	73.8571	300.516
CO	42	5.00	4.5476	1.522
NO	42	4.00	2.1905	1.182
NO2	42	16.00	10.0952	11.064
O3	42	23.00	9.4048	30.979
HC	42	3.00	3.0952	.479
Valid N (listwise)	42			

Table- 3: Correlation Matrix

		Wind	Solar rad	CO	NO	NO2	O3	HC
Wind	Pearson Correlation	1	-.101	-.194	-.270	-.107	-.254	.156
	Sig. (2-tailed)		.523	.219	.084	.501	.105	.324
	N	42	42	42	42	42	42	42
Solar rad	Pearson Correlation	-.101	1	.183	-.074	.089	.319(*)	.052
	Sig. (2-tailed)	.523		.247	.643	.577	.039	.744
	N	42	42	42	42	42	42	42
CO	Pearson Correlation	-.194	.183	1	.502(**)	.558(**)	.411(**)	.166
	Sig. (2-tailed)	.219	.247		.001	.000	.007	.293
	N	42	42	42	42	42	42	42
NO	Pearson Correlation	-.270	-.074	.502(**)	1	.312(*)	-.134	.235
	Sig. (2-tailed)	.084	.643	.001		.044	.398	.135
	N	42	42	42	42	42	42	42
NO2	Pearson Correlation	-.107	.089	.558(**)	.312(*)	1	.157	.431(**)
	Sig. (2-tailed)	.501	.577	.000	.044		.320	.004
	N	42	42	42	42	42	42	42
O3	Pearson Correlation	-.254	.319(*)	.411(**)	-.134	.157	1	.154
	Sig. (2-tailed)	.105	.039	.007	.398	.320		.329
	N	42	42	42	42	42	42	42
HC	Pearson Correlation	.156	.052	.166	.235	.431(**)	.154	1
	Sig. (2-tailed)	.324	.744	.293	.135	.004	.329	
	N	42	42	42	42	42	42	42

- * Correlation is significant at the 0.05 level (2-tailed).
- ** Correlation is significant at the 0.01 level (2-tailed).

The correlation between solar radiation and O_3 and NO and NO_2 are significant at 5% level while the correlation between CO and (NO, NO_2 , O_3) are significant at 1% level. The same strategies of association between the variables can also be observed in the following combined scatter plot for all the pollutants.

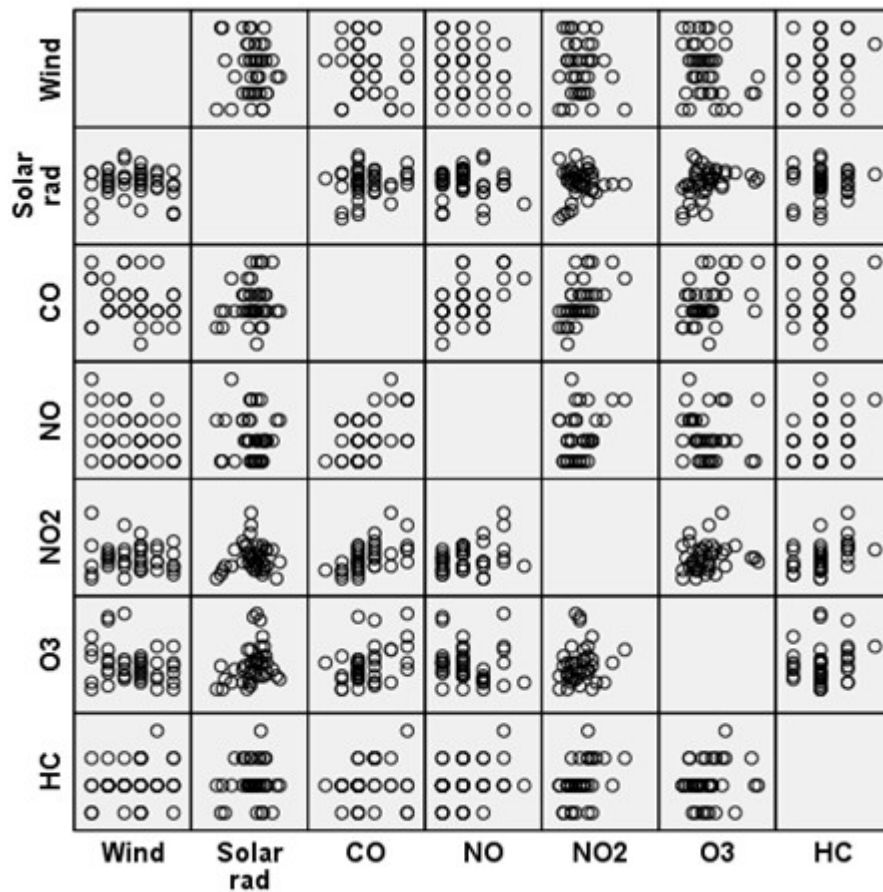


Figure-2. Combined Scatter plot for all the pollutants

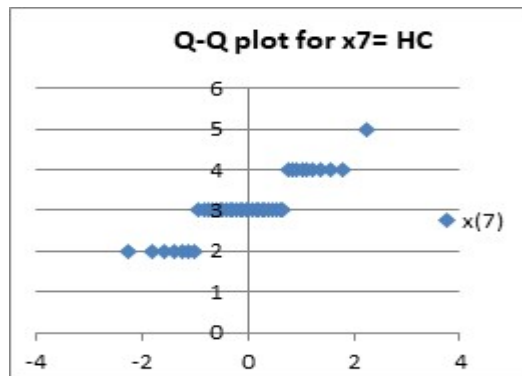
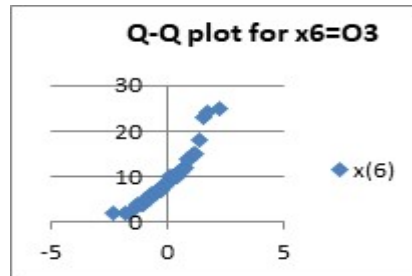
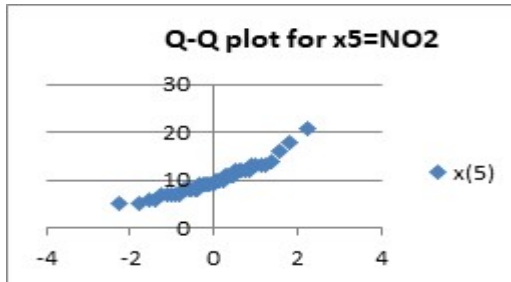
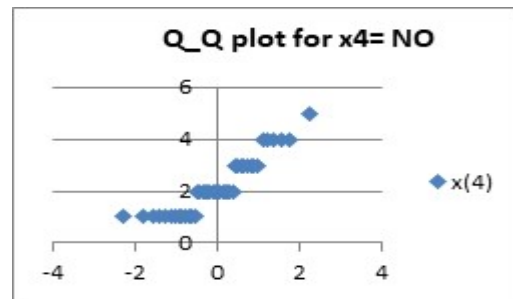
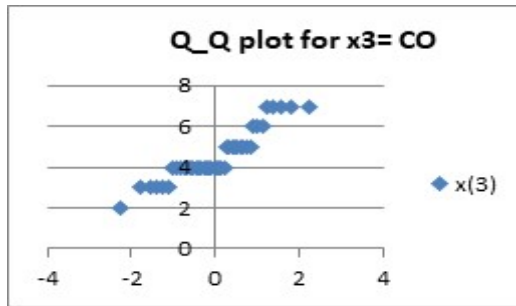
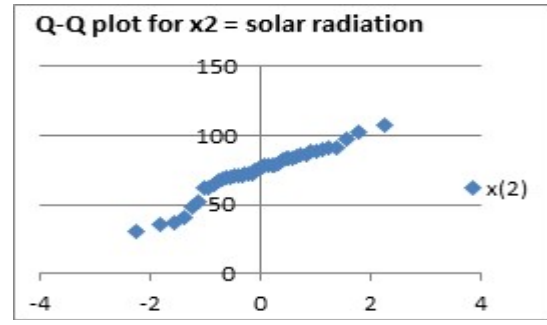
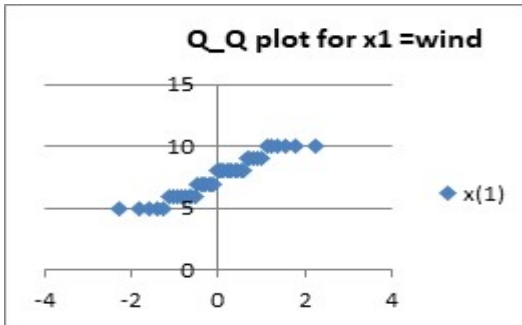


Figure-3. Q – Q plot for all the Air pollutants

A test of normality at the 10% level of significance is provided by referring $r_Q = 0.996$ to the entry in table-5 for critical points for Q-Q plots, corresponding to $n = 40$ and $\alpha = 0.10$ in the following table. Note that this entry is 0.9771. Since $r_Q > 0.9771$, we do not reject the hypothesis of normality for solar radiation. Note that we can also visualize the normality of the Solar radiation from Q-Q plot, as it is near to straight line.

Table- 4: Descriptive Statistics for Solar radiation

	Mean	Std. Deviation	N
Solar rad	73.8571	17.33539	42
quantile	.0000	$r_Q = .99694$	42

Table- 5: Critical points for the Q-Q plot correlation Coefficient test for Normality

sample size	significance level α		
	0.01	0.02	0.03
n	0.01	0.02	0.03
5	0.8299	0.8788	0.9302
10	0.8801	0.9198	0.9351
15	0.9126	0.9389	0.9503
20	0.9269	0.9508	0.9604
25	0.941	0.9591	0.9665
30	0.9479	0.9652	0.9715
35	0.9538	0.9682	0.974
40	0.9599	0.9726	0.9771
45	0.9632	0.9749	0.9792
50	0.9671	0.9768	0.9809
55	0.9695	0.9787	0.9822
60	0.972	0.9801	0.9836
75	0.9771	0.9838	0.9866
100	0.9822	0.9873	0.9895
150	0.9879	0.9913	0.9928
200	0.9905	0.9931	0.9942
300	0.9935	0.9953	0.996

Table- 5: One-Sample Kolmogorov-Smirnov Test

		Wind	Solar rad	CO	NO	NO2	O3	HC
N		42	42	42	42	42	42	42
Normal Parameters(a,b)	Mean	7.5000	73.8571	4.5476	2.1905	10.0952	9.4048	3.0952
	Std. Deviation	1.58114	17.33539	1.23372	1.08736	3.32624	5.56583	.69175
Most Extreme Differences	Absolute	.148	.132	.267	.236	.129	.149	.317
	Positive	.138	.090	.267	.236	.129	.149	.317
	Negative	-.148	-.132	-.186	-.137	-.081	-.092	-.279
Kolmogorov-Smirnov Z		.958	.855	1.728	1.531	.836	.966	2.052
Asymp. Sig. (2-tailed)		.317	.458	.005	.018	.487	.308	.000

We can observe that the p-values for Wind, Solar radiation, NO₂ and O₃ are greater than .05; and hence our hypothesis of normality is accepted for these air pollutants while p-values are less than .05 for CO, NO and HC; hence the normality assumption is suspected for the data corresponding to those variables. Note that for Solar radiation Q-Q plot as well as $r_Q = 0.996$, gives support to normality.

Now to check Bivariate normality of two air pollutants $x_5 = \text{NO}_2$ and $x_6 = \text{O}_3$, we calculate generalized distances $(x_j - \bar{x})'S^{-1}(x_j - \bar{x})$ where $x_j' = (x_{5j}, x_{6j})$; $j = 1, 2, \dots, 42$. Further we determine the proportion of observations x_j 's, $j = 1, 2, \dots, 42$ falling within the approximate 50% probability contour of a bivariate normal distribution.

5. Calculation of generalized distances $(x_j - \bar{x})'S^{-1}(x_j - \bar{x})$:

We have $X = (10.0952, 9.4048)$ and the sample variance covariance matrix S and S^{-1} for $\mathbf{x} = (x_5, x_6)$ are as follows.

$$S = \begin{pmatrix} 10.8004 & 2.8424 \\ 2.8424 & 30.2409 \end{pmatrix} \text{ and } S^{-1} = \begin{pmatrix} 0.094937 & -0.00892 \\ -0.00892 & 0.033906 \end{pmatrix}.$$

From the table of Chi-square values, we have $\chi_2^2(.5) = 1.39$. Any observation $\mathbf{x} = (x_5, x_6)$ satisfying

$$\begin{pmatrix} x_5 - 10.0952 \\ x_6 - 9.4048 \end{pmatrix}' \begin{pmatrix} 0.094937 & -0.00892 \\ -0.00892 & 0.033906 \end{pmatrix} \begin{pmatrix} x_5 - 10.0952 \\ x_6 - 9.4048 \end{pmatrix} \leq 1.39$$

is on or inside the estimated 50% contour. Otherwise the observation is outside this contour. The first pair of observations in our case is $x_1' = (x_{51}, x_{61}) = (12, 8)$. In this case, we have the generalized distance is

$$\begin{pmatrix} 12 - 10.0952 \\ 8 - 9.4048 \end{pmatrix}' \begin{pmatrix} 0.094937 & -0.00892 \\ -0.00892 & 0.033906 \end{pmatrix} \begin{pmatrix} 12 - 10.0952 \\ 8 - 9.4048 \end{pmatrix} = 0.4591 < 1.39$$

and this point falls inside the 50% contour. We calculate generalized distance for all the observations and arrange them in ascending order as shown in the following table.

Table- 6: Generalized Distances

Number	Generalized_Distance	G_Distance_Ascending
1	0.459105468	0.137529528
2	0.685635752	0.137529528
3	2.548157581	0.1382414
4	1.6874984	0.1382414
5	0.451047071	0.153333097
6	0.484590503	0.192850919
7	1.215740501	0.312621686
8	11.1110155	0.451047071
9	0.1382414	0.451047071
10	0.827583127	0.459105468
11	1.380852206	0.459105468
12	0.622266643	0.484590503
13	5.860210192	0.622266643
14	0.312621686	0.68251953
15	0.451047071	0.685635752
16	0.137529528	0.685635752
17	0.972783759	0.719492408
18	4.870109457	0.804632358
19	3.044019483	0.827583127
20	0.685635752	0.909920079
21	2.814620352	0.954438805
22	1.11452469	0.972783759
23	0.804632358	1.11452469

24	3.650477895	1.11452469
25	6.290921524	1.205133601
26	1.11452469	1.215740501
27	0.1382414	1.380852206
28	0.954438805	1.568160096
29	0.153333097	1.6874984
30	2.359618152	2.010232913
31	0.192850919	2.359618152
32	0.459105468	2.548157581
33	1.205133601	2.814620352
34	7.248461211	2.86041333
35	1.568160096	3.044019483
36	0.137529528	3.650477895
37	2.010232913	4.870109457
38	2.86041333	5.860210192
39	8.665156876	6.290921524
40	0.68251953	7.248461211
41	0.719492408	8.665156876
42	0.909920079	11.1110155

From the above table we can observe that 27 of these distances are less than 1.39, a proportion $[(27/42)] = 0.64$, of the data falls within the 50% contour. If these observations were normally distributed, we would expect about half, or 21, of the observations to be within this contour. This difference $(0.64-0.50 = 0.14)$ in proportion would ordinarily provide evidence to accept the notion of bivariate normality; however, our sample size of 42 is not too small to reach this conclusion.

6. Construction of a chi-square plot:

Computing the fraction of the points within a contour and subjectively comparing it with the theoretical probability is a useful, but rather rough, procedure. A somewhat more formal method for judging the joint normality of a data set is based on the

squared generalized distances $d_j^2 = (x_j - \bar{x})' S^{-1} (x_j - \bar{x}), j=1,2,\dots,n$

where x_1, x_2, \dots, x_n are the sample observations. The procedure we are about to describe is not limited to the bivariate case. It can be used for $p \geq 2$. When

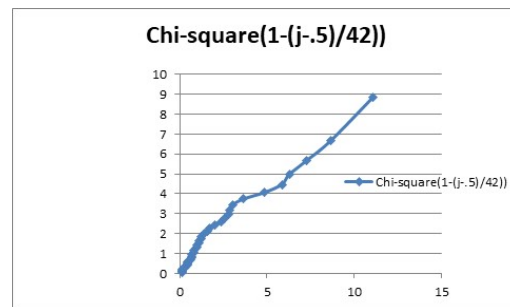
the parent population is multivariate normal and both n and $n-p$ are greater than 25 or 30, each of the squared distances $d_1^2, d_2^2, \dots, d_n^2$ should behave like a chi-square random variable. Although these distances are not independent or exactly chi-square distributed, it is helpful to plot them as if they were. The resulting plot is called a chi-square plot, or gamma plot, because the chi-square distribution is a special case of the more general gamma distribution. The steps to construct the chi-square plot are (i) Order the squared distances $d_j^2; j = 1, 2, \dots, n$ from smallest to largest as $d_{(1)}^2 \leq d_{(2)}^2 \leq \dots \leq d_{(n)}^2$, (ii) Graph the pairs $(d_{(j)}^2, \chi_p^2((j-1/2)/n))$ where $\chi_p^2((j-1/2)/n)$ is the $(100(j-1/2)/n)$ percentile of the chi-square distribution with p degrees of freedom. A plot should resemble a straight line. A systematic curved pattern suggests lack of normality. One or two points far to the right of the line indicate large distances, or outlying observations, that merit further attention.

Table- 7: Ascending Generalized Distances and Chi-square values

Number - j	dj_square	Chi-square(1-(j-.5)/42))
1	0.137529528	0.023952382
2	0.137529528	0.072735288
3	0.1382414	0.122737893
4	0.1382414	0.174022754
5	0.153333097	0.226657371
6	0.192850919	0.280714716
7	0.312621686	0.336273845
8	0.451047071	0.393420589
9	0.451047071	0.452248359
10	0.459105468	0.512859059
11	0.459105468	0.575364147
12	0.484590503	0.639885875
13	0.622266643	0.70655871
14	0.68251953	0.775531063
15	0.685635752	0.84696723
16	0.685635752	0.921049776
17	0.719492408	0.997982343
18	0.804632358	1.077993024
19	0.827583127	1.161338397
20	0.909920079	1.248308623
21	0.954438805	1.339233377
22	0.972783759	1.434489485
23	1.11452469	1.534510347

24	1.11452469	1.639797778
25	1.205133601	1.750937487
26	1.215740501	1.8686185
27	1.380852206	1.993659241
28	1.568160096	2.127041938
29	1.6874984	2.269959866
30	2.010232913	2.423881948
31	2.359618152	2.590645166
32	2.548157581	2.772588722
33	2.814620352	2.972755639
34	2.86041333	3.19520691
35	3.044019483	3.445533196
36	3.650477895	3.731734883
37	4.870109457	4.065843052
38	5.860210192	4.467184443
39	6.290921524	4.9698133
40	7.248461211	5.642757773
41	8.665156876	6.66440902
42	11.1110155	8.861633598

A plot of the ordered squared distances $d_{(1)}^2 \leq d_{(2)}^2 \leq \dots \leq d_{(n)}^2$ versus $\chi_p^2((1-1/2)/n)$, $\chi_p^2((2-1/2)/n), \dots, \chi_p^2((n-1/2)/n)$ respectively, is nearly a straight line which suggest the bivariate normality of two variables $x_5 = \text{NO}_2$ and $x_6 = \text{O}_3$. Note that by considering the same steps we can check the normality for all $p \in \{2, \dots, 6\}$.



7. Acknowledgements

I thank the referee for reviewing my paper which has helped me to revise thoroughly the earlier draft of this paper.

8. Reference:

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RESEARCH ARTICLE

**REGRESSION ANALYSIS FOR CUSTOMER RELATIONSHIP
MANAGEMENT PRACTICES ON CUSTOMER SATISFACTION FOR
PRIVATE SECTOR BANKS OF GUJARAT STATE**

Kamlesh L. Patel⁽¹⁾ and Sanjay G. Ravl⁽²⁾

ABSTRACT

Customer relationships management (CRM) has been central to strategic decision making in all business organizations. Companies recognize the value of customer relationships for sustainable growth and development. Customer Satisfaction is one of the unavoidable factors to maintain customer relationship mainly in the banking sector. Therefore, the current study focuses on the outcome of CRM practices on Customer Satisfaction in the Gujarat Banking sector. The objective of the study is to examine the relationship between service quality of CRM practices and Customer Satisfaction with the help of SERVPERF scale and also test the significance impact of quality dimensions on customer satisfaction. This paper has revealed that quality dimensions Assurance, Empathy and Responsiveness have significantly impacted on customer satisfaction while dimensions Reliability and Tangibility are positively related with customer satisfaction but not significantly impacted on customer satisfaction.

Keywords:

Customer Relationship Management (CRM), Customer Satisfaction, SERVPERF

1. INTRODUCTION:

In today's highly competitive environment, companies should look at their

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customers from different angles. The dynamics of the changing business around the world are characterized by strong competition, the luxury of many options, the demand for published customers, government laws and the extremely unstable socio-economic environment.

All these changes have transformed today's banking sector from traditional to modern banking sector. Customers are emerging as potential partners in the central phase of banking activities, their growing power and skill to get what they want anywhere, anytime is forcing a drastic change in traditional marketing strategies. Globalization and global dynamics are forcing business organizations to change their strategies. Customer experience is becoming an important aspect of corporate existence.

2. REVIEW OF LITERATURE:

2.1 Service Quality of CRM:

CRM is the most professional approach for maintaining and building customer relationships. CRM is not only a pure business; it also improves the quality of strong personal relation between customers and organization. Developing this type of relationship takes the business to new levels of success. Once this personal relationship is established, it is very simple for the organization to categorize the actual needs and interests of the customers. It is believed that the more sophisticated strategies are involved in deploying CRM; business will be much more fruitful. Organizations should seriously think about investing in tools for the functioning of CRM systems in their workplaces (Choi, Wan, & Siti, 2013).

2.2 Customer Satisfaction:

Satisfaction of old customers recommends other customers to take your services. Study found that a company that develops a new customer is six times more likely to retain an old customer in terms of costs. Therefore, cultivating loyal customers through customer satisfaction is the main competitive advantage of starting a business.

If customer needs are ignored or disregarded, advanced technologies do not allow businesses to move forward. CRM implementation is not just installing software; it is essential to change the overall management around customer relationships (Fangfang, 2014).

Instead of making more returns from any transaction, Banks can increase their profits by increasing their relationships with their customers over a period of time. In order to survive in a dynamic business environment, the similarities between services as well as situations with different factors are taken into account, which means that the quality of services varies from one bank to another. Therefore, it is imperative that the service providers meet or exceed the target customers' expectations of quality of service (Sheik, Manohar, & Manikandan, 2016).

CRM is required in any organization as a result of profitability, revenue, and meeting customer needs. What CRM offers is great customer satisfaction. An effective CRM will lead to customer satisfaction and if the customer is satisfied, positive words lead to word of mouth and loyalty. In fact, this helps to benefit the business as well as more revenue and profit. Therefore, research is an attempt to adopt two important variables that affect CRM, namely consumer satisfaction and consumer loyalty (Khedkar, 2015).

CRM is a complex and multifaceted phenomenon surrounded by a variety of factors. Owing to this complexity, many different variables have been used to measure CRM. Continuous improvement to achieve high levels of customer satisfaction has been confirmed to be a determining factor in improving organizational performance and competitive advantage. Based on the review, we believe that CRM is generally conceived based on three main parameters, Service Quality (SQ), Service Access (SA), and Complaint Handling (HC). In most studies, these three parameters have been found to have a significant effect on customer satisfaction and loyalty (Saeed & Haslinda, 2017).

3. SERVPERF SCALE:

Despite the wide recognition, acceptance, and application of the SERVERQUAL

scale, some researchers have argued for its approach in conceptual and operational terms (Cronin and Taylor 1992; Carmen, 1990). It is argued that economical, statistical, and psychological theories do not support SERVERQUAL patterns. Moreover it has been argued that it is not appropriate to use differences of expectations and performance as a measure of service quality because the perception of service quality is based on customer attitudes, while customer satisfaction is already based on the difference between expectations and performance measures. Therefore, they have chosen that the level of service quality should be evaluated in terms of the service performance i.e SERVPERF (Emmanuel, 2018). However SERVPERF recognizes the generic dimensions of SERVQUAL as Reliability, Assurance, Tangibility, Empathy and Responsiveness, as the five fundamental dimensions of service quality. (Jain & Gupta, 2004)

3.1 Reliability:

Reliability refers to customer behaviour and treatment issues that are related with the level of services, the demonstration of services when they are first provided, timely services, and error-free record keeping (Byun & Cheong, 2017).

3.2 Assurance:

Assurance is defined as the courtesy and knowledge of workforce, and their skill to encourage confidence in customers (Parasuraman, Zeithaml, & Berry, 1994). They have also stated that Assurance reflect the attitudes and manners of employees and their skill to provide friendly, confidential, courteous and competent service to customers.

3.3 Tangibility:

It is the physical image of the service that customers will use for quality assessment. Tangibility is related with the physical facilities, equipment and machines used to provide the service, as well as the representations of services such as

statements, debit and credit cards, speed and efficiency of transactions. Tangibility include some privileges like external appearance, bank counters, overdraft facilities, timing of bank and speediness and effectiveness of dealings (Parasuraman, Zeithaml, & Berry)

3.4 Empathy:

Empathy is the dimension of a business relationship that allows both parties to feel the dimensions from the other person's perspective. Empathy is an attempt to understand one's wishes and goals (Leo, Alan, Oliver, Jeeny, & Raymond, 2002).

3.5 Responsiveness:

Responsiveness is the dimension that determines the enthusiasm to help customers and to afford prompt service. Service instructions such as "What can I do for you" clearly explain the significance of customers. It is also concerned in understanding customer wants, wishes, convenient operation time, care provided by employees, attention to problems and customer safety (Arun Kumar, Tamilmani, Mahalingam, & Mani, 2010)

4. OBJECTIVES OF THE STUDY:

This study has been conducted with the following objectives:

- (1) To investigate whether the service dimensions of CRM Practices are related to Customer satisfaction in private sector banks of Gujarat state.
- (2) To investigate the impact of service dimensions of CRM practices on Customer Satisfaction in private sector banks of Gujarat state.

5. RESEARCH METHODOLOGY:

Gujarat is located on the west coast of India and has the longest coastline among any state in the country. Gujarat is one of the most important industrial states of India. Gujarat is considered as the oil capital of India, Owing to the existence of

a large refining capacity established by private and public sector companies (IBEF, 2020). Gujarat has one of the best banking networks in the country and the state's banking business is supported by successful commerce, trade and industries. Gujarat is one of the major industrial states in India (Banking Frontiers, 2016).

The study is intended to examine the level of service quality of CRM practices in ICICI bank, AXIS bank and HDFC bank of Gujarat state. Population of this study is customers of these private sector banks of Gujarat. Data were collected from randomly selected customers through the administration of a structured questionnaire. Statistically collected data are to be analyzed with SPSS 20. Statistical analysis will be performed to achieve the objectives of this study. The questionnaire consists of six items of Reliability, five items of Assurance, eight items of Tangibility, seven items of Empathy, six items of Responsiveness and five items of Customer Satisfaction and questions along with relevant personal information. Pearson's method was used to explore the relationship between quality level of CRM practices and customer satisfaction. Multiple linear regressions were used to find the significant cause of these variables on customer satisfaction. The reliability of the scale items was verified using Cronbach's alpha statistics.

5.1 Research Model:

An extensive range of CRM practices are used to enhance customer satisfaction, however most of these practices are adopted by private sector banks of Gujarat which stimulate customer satisfaction. This research examines the level of quality of CRM services in private banks in Gujarat. We measure the level of service quality of CRM practices by independent variables such as Reliability, Assurance, Tangibility, Empathy and Responsiveness. On the basis of these variables the conceptual model represented in Figure 1 has been made.

Service Quality Dimensions of CRM Practices (Independent Variables)

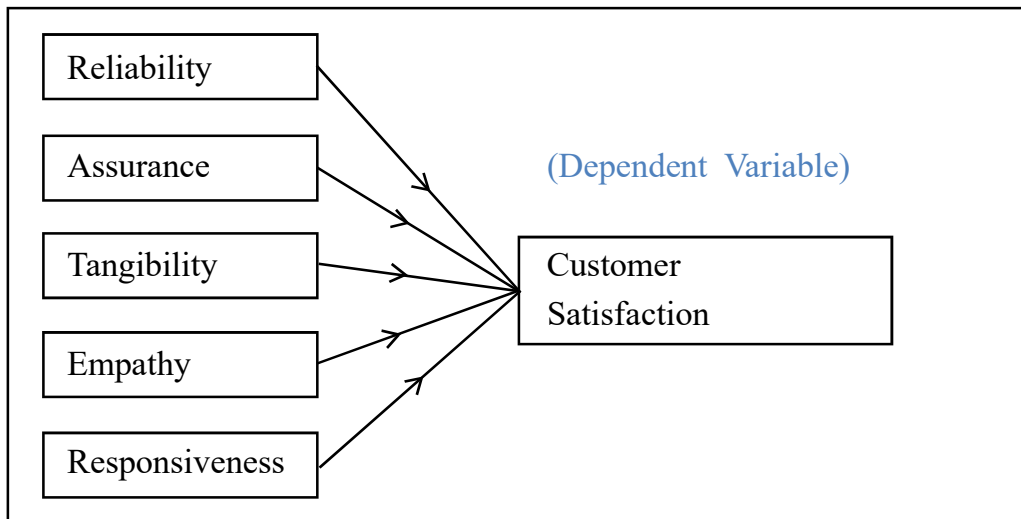


Figure-1

5.2 Research Hypothesis:

From the review and research objective, hypothesis can be formulated as follows:

Hypothesis-1: There is no significant relationship between dimensions of service quality of CRM practices and Customer Satisfaction in private banks in Gujarat.

This hypothesis bring to develop following sub-hypotheses

- H_{01} : There is no significant relationship between Reliability and customer satisfaction in private sector banks of Gujarat.
- H_{02} : There is no significant relationship between Assurance and customer satisfaction in private sector banks of Gujarat.
- H_{03} : There is no significant relationship between Tangibility and customer satisfaction in private sector banks of Gujarat.
- H_{04} : There is no significant relationship between Empathy and customer satisfaction in private sector banks of Gujarat.
- H_{05} : There is no significant relationship between Responsiveness and customer satisfaction in private sector banks of Gujarat.

Hypothesis-2: CRM service dimensions do not significantly explain Customer

Satisfaction in private sector banks of Gujarat.

6. DATA ANALYSIS AND INTERPRETATIONS:

6.1 Demographic Characteristics:

The demographic characteristics of the 285 customers of three private sector banks are included in the study. Among the total respondents; 34% from ICICI bank, 32% from AXIS bank and 34% from HDFC bank gave their perceptions about the service quality of their respective bank. From the total respondents 57.3% are males and 42.7% are females. The customers are mostly between the ages 30 to 60 years which represent 62.5% of the total respondents. In qualification variable 22.6% are Graduate and 37.3% are Post Graduate. 43% of the respondents are service people and 23.3% are business people. Eventually the percentage of customers who have been associated with these banks for more than 11 years is 78.9%.

6.2 Reliability Scale:

Cronbach's alpha is a Statistic which tests the internal consistency of items in a dimension or constructs. Among the 6 items of dimension Reliability, two items are inconsistent, so these two items are removed from the data. Alpha values of all dimensions are more than 0.700; hence questionnaire items are reliable and fit for the purpose.

Table-1 Reliability Statistic

Dimensions	No. of Items	Cronbach's alpha
Reliability	4	0.700
Assurance	5	0.753
Tangibility	8	0.822
Empathy	7	0.826
Responsiveness	6	0.850
Satisfaction	5	0.830

6.3 Karl Pearson Correlations and t Test:

The following table represents the correlation coefficients between Customer Satisfaction and various dimensions of service quality of CRM practices; it also represents the significant value of t-statistic.

Table- 2 Correlation Coefficient and Student t- Statistic

	N	Reliability	Assurance	Tangible	Empathy	Responsiveness
Customers Satisfaction	Correlation Coefficient	0.604	0.682	0.659	0.752	0.754
	Sig. Value p	0.001	0.001	0.001	0.001	0.001

Table-2 revealed that on the basis of customer's responses of public sector banks, there is a significant relationship between all the variables of service quality of CRM practices and Customer Satisfaction. It has been found that **Responsiveness** has the highest Pearson Correlation Coefficient r (0.754) and the p -value is 0.001 which is less than 0.05 therefore H_{01} is rejected, hence there exists the strong positive relationship between Responsiveness and Customer Satisfaction.

In case of **Empathy**, the Pearson correlation r is 0.752 and p -value is 0.001 which is less than the α level of significance of 0.05 therefore H_{02} rejected; it implies that there is a statistically significant strong positive relationship between Empathy and Customer satisfaction.

Tangibility has Pearson correlation coefficient $r = 0.659$ and the p -value = 0.001, H_{03} is rejected hence there is a statistically significant positive relationship between Tangibility and Customer Satisfaction.

Assurance has Pearson correlation $r = 0.682$ and the p -value = 0.001 thus H_{04} is rejected which indicates that there is a statistically significant positive correlation between Assurance and Customer Satisfaction.

Reliability has Pearson correlation r value is 0.604 and p -value is 0.001 hence H_{05} is rejected which indicates that there is a statistically significant positive correlation between Reliability and Customer Satisfaction.

6.4 Regression Analysis:

Table-3 Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Durbin-Watson
1	.803 ^a	.645	.638	.40266	1.225

a. Predictors: (Constant), Empathy, Reliability, Tangible, Assurance, Responsiveness

b. Dependent Variable: Customer Satisfaction

In Table-3; R value represents the multiple correlation coefficients. R can be taken as a measure of the predictive degree of the dependent variable. The column “R squared” indicates the square of R value, which is the amount of fluctuation in the dependent variable that can be explained by the independent variables. Table-3 shows that adjusted R Square is 0.638, which means that 63.8% of the variation is explained by the service quality dimensions of CRM on customer satisfaction. The value of Durbin - Watson statistic d is 1.225, which lies between two critical values 1.5 and 2.5 that is $1.5 < d < 2.5$. Therefore, we can conclude that there is no first-order linear autocorrelation in our multiple linear regression data.

Table-4 ANOVA and F test

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	82.107	5	16.421	101.284	.001 ^b
	Residual	45.235	279	.162		
	Total	127.342	284			

a. Dependent Variable: Customer Satisfaction

b. Predictors: (Constant), Empathy, Reliability, Tangible, Assurance, Responsiveness

In Table-4, p-value of F statistic is 0.001 which is less than 0.05 therefore; the regression model is fit for the data. This shows that different dimensions of CRM

collectively explain the customer satisfaction significantly. The F test is significant thus we can say that model explains a significant amount of variation on customer satisfaction.

Table 5: Regression Coefficients

Model 1	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	Co-linearity Statistics	
	B	Std. Error	Beta			Tolerance	VIF
(Constant)	.159	.177		.902	.368		
Reliability	.085	.066	.073	1.281	.201	.387	2.583
Assurance	.265	.062	.250	4.276	.000	.372	2.690
Tangibility	.118	.064	.107	1.834	.068	.374	2.677
Empathy	.289	.085	.264	3.398	.001	.211	4.729
Responsiveness	.356	.079	.329	4.513	.000	.240	4.169

a. Dependent Variable: Customer Satisfaction

From Table-5, all VIF values are less than 5, which indicate that there is moderate multi co-linearity between independent variables. It is found that CRM dimensions overall has positive relationship with customer satisfaction (R=0.803). However adjusted R² is 0.638 thus CRM variables explain 63.8% variation in dependent variables customer satisfaction. However among CRM dimensions, only Assurance, Empathy and Responsiveness give significant impact on customer satisfaction as their p-values are less than 0.05 while Reliability and Tangibility are not significantly influenced to customer satisfaction as their p-values are greater than 0.05.

7. FINDINGS AND CONCLUSIONS:

The analysis output found that overall quality of CRM practices is likely to improve satisfaction. This output also made it clear that there is a strong positive correlation between customer satisfaction and CRM dimensions Reliability, Assurance, Tangibility, Empathy and Responsiveness. Three dimensions; Assurance, Empathy and

Responsiveness are significantly explaining customer satisfaction. Moreover, it turned out that two dimensions Reliability and Tangibility are significantly related with customer satisfaction but they are not influencing customer satisfaction significantly therefore to improve the satisfaction level of customers, bank organisation should keep more interest to perform the pre-decided service regularly and accurately and improve physical facilities, equipment and machines used to provide the service etc. CRM training programs are crucial for employees, especially sales and front desk employees. These training programs are essential as customers expectations change with time.

8. LIMITATIONS OF THE STUDY:

The parameters of the research show that customer satisfaction can be enhanced by the variety of CRM dimensions. But customer satisfaction can also be influenced by other factors such as cost of services, gender, age, occupation, etc. Therefore other independent variables can be added to the study to get better results. In addition, more accurate results can be obtained by increasing the size of the sample.

9. ACKNOWLEDGEMENT:

We thank the referee for reviewing our paper which has helped us in its revision.

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RESEARCH ARTICLE

OVERVIEW OF MASTER PROTOCOL IN CLINICAL TRIALS

Pinakin R. Jani⁽¹⁾ and Manish B. Thaker ⁽²⁾

ABSTRACT

There is increased interest in expediting late-stage drug development through developing trial designs that test multiple drugs and/or multiple cancer subpopulations in parallel under single protocol, without a need to develop new protocol for every clinical trial. The term “*master protocol*” often used to describe the designs of such trials, with variable terms such as “*umbrella, basket, or platform*” describing specific designs. In traditional trial design single drug is tested in a single disease population in the one clinical trial, master protocols use a single infrastructure, trial design, and protocol to simultaneously evaluate multiple drugs and/or disease population in multiple sub trials, allowing for efficient and accelerated drug development.

KEYWORDS:

Master Protocol, FDA, Umbrella trials, Basket trials, Platform trials, FDA.

1. INTRODUCTION

A clinical trial has several complexities evaluating multiple drugs and/or disease populations and the potential regulatory impact, it is important that such trials are well designed and well conducted to ensure the patient safety and to obtain the quality data that supports the drug approval. Master protocols, classified as basket trials, umbrella trials and platform trials are novel designs that investigate the multiple hypothesis through concurrent sub trials (e.g. multiple treatments or population or that allow adding/removing

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treatment arms during the trial), offering enhanced efficiency and a more ethical approach to the trial evaluation. Despite of many advantages of these designs, they are infrequently used. Advancement in genomics, particularly in tumor sequencing, have improved our ability to differentiate cancers by their genetic mutation. This has fueled the efforts towards “*precision oncology*”, in which therapies are selected to specifically target cancers on basis of their genetic mutations. These are commonly referred to as targeted therapies. However, it is unrealistic to investigate the broad spectrum of genetic sub-populations by conventional trial designs. Thus “master protocol” framework have been proposed to provide a means of comprehensively and adaptively evaluating treatments from the field of oncology. A master protocol may be used to conduct the clinical trial(s) for exploratory purpose or to support marketing application and can be structured to evaluate, in parallel, different drugs compared to their respective controls or to a single common control. The sponsor can design the mater protocol with a fixed or adaptive designs with the intent to modify the protocol to incorporate or terminate the individual sub trials within the master protocol.

2. MASTER PROTOCOL DEFINITION AND POTENTIAL OPPORTUNITIES AND CHALLENGES

The term “master protocol” refers to single design developed to evaluate multiple hypotheses and the general goals are improving efficiency and establishing uniformity through standardization of procedures in the development and evaluation of different interventions. Under a common infrastructure, the master protocol may be differentiated into multiple parallel sub-studies to include standardized trial operational structures, patient recruitment and section, data collection, analysis and management. Master protocols are often classified in to “basket trials”, “umbrella trials”, and “platform trials”. Basket trials refer to designs in which targeted therapy is evaluated on multiple diseases that have common molecular alternations. Umbrella trials, on the other hand, evaluate multiple targeted therapies for a single disease that is stratified in to subgroups by molecular alternations. Basket and Umbrella trials employ a molecular screening protocol that allows either recruitment of different disease with common molecular alteration(s) or that differentiates the single disease in to different

molecular subtypes. Platform trials, also referred to as multi-arm, multi-stage design trials, which evaluates several interventions against a common control group and can be perpetual. This design has pre-specified adaptation rules to allow dropping of ineffective intervention(s) and flexibility of adding new intervention(s) during the trial. Master protocol can be tailored and adapted to suit the research objective of multiple clinical indications, but master protocols have not been well established outside of oncology.

The potential advantage of a master protocol is flexibility and efficiency in drug development, consistent with FDA's goal of helping to make safe and effective drugs and drug combination treatments available to the public. A master protocol provides an opportunity to incorporate efficient approaches, such as shared control arm and/or the use of centralized data capturing systems to enhance the efficiency. However, master protocol can also create challenges in the conduct and analysis of the trial that, if not properly addressed, can increase the risk to patients or delay the development of the drug.

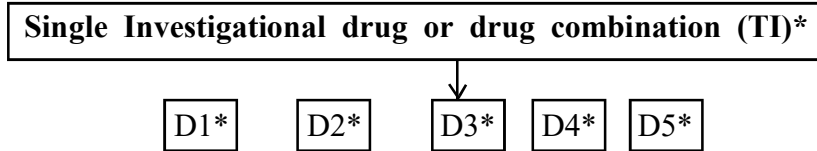
Example of potential challenges includes following:

- ✚ Difficulty in attributing of adverse event to one or more investigational drugs can occur when multiple drug are administered within various arms and the trial lacks a single internal control for those drugs
- ✚ With multiple drug being studies across multiple protocols and investigational new drug applications (INDs), assessing the safety profile of any given investigational drug is difficult.
- ✚ The presence of multiple study groups allows potential *over interpretation* of findings, resulting in delays in drug development. For example, a biomarker-defined subpopulation could be identified, because of multiple comparisons, as a responder population based on ad hoc between-arm comparison that proves to be false.

3. TYPES of MASTER PROTOCOLS

Single Investigational Drug or Investigational Drug Combination Across Multiple Cancer Populations

A master protocol designed to test a single investigational drug or drug combinations in different populations defined by disease stage, histology, and number of prior therapies, genetic or other biomarkers, or demographic characteristics is commonly referred to as a basket trial. (Shown in figure below)



*T – Investigational drug, D-protocol defined sub population in multiple disease subtypes.

The sub studies within basket trials are usually designed as single arm activity estimating trials with overall response rate (ORR) as primary end point. A strong response signal seen in a sub study may allow for expansion of the sub study to generate data that could potentially support a marketing approval. Each sub study should include specific objectives, the scientific rationale for inclusion of each population, and a detailed statistical analysis plan (SAP) that includes sample size justification and stopping rules for futility.

Single Investigational Drug or Investigational Drug Combination in Single Cancer Type

A master protocol designed to evaluate multiple investigational drugs administered as single drugs or as drug combinations in a single disease population are commonly referred to as “*umbrella trials*”, sub studies within umbrella trails can include dose finding components to identify safe doses of an investigational drug combinations before proceeding with an activity estimating component.

	Control
	T1*
Single tumor type or	T2
historical sub-type (D1)* ———>	T3
	TX

*T = investigational drug, D=Protocol defined subpopulation in single disease subtypes;





TX=highlighted in bold depicts future treatment arm.

Umbrella trials can employ randomized control designs to compare the activity of the investigational drug(s) with a common control arm. The drug chosen as the control arm for the randomized sub study or sub studies should be the standard of care (SOC) for the target population, and this may change over time if newer drugs replace the SOC.

Master Protocol design may also incorporate design features common to both basket and umbrella trials and may evaluate multiple investigational drugs and/or drug combinations regimens across multiple tumor types.





4. SPECIFIC DESIGN CONSIDERATIONS IN MASTER PROTOCOLS

The different considerations in the master protocols are highlighted as below:

-  Use of Single Common Control Arm
-  Novel Combination of Two or More Investigational Drugs
-  Studies with Drug Targeting Multiple Biomarkers
-  Adding and Stopping Treatment Arms

5. STATISTICAL CONSIDERATIONS

The different statistical considerations in the master protocol as highlighted below:

-  Non-Randomized, Activity Estimating Design
-  Randomized Designs
-  Master Protocols Employing Adaptive/Bayesian Design
-  Master Protocols with Biomarker-Defined subgroups

6. SUMMARY

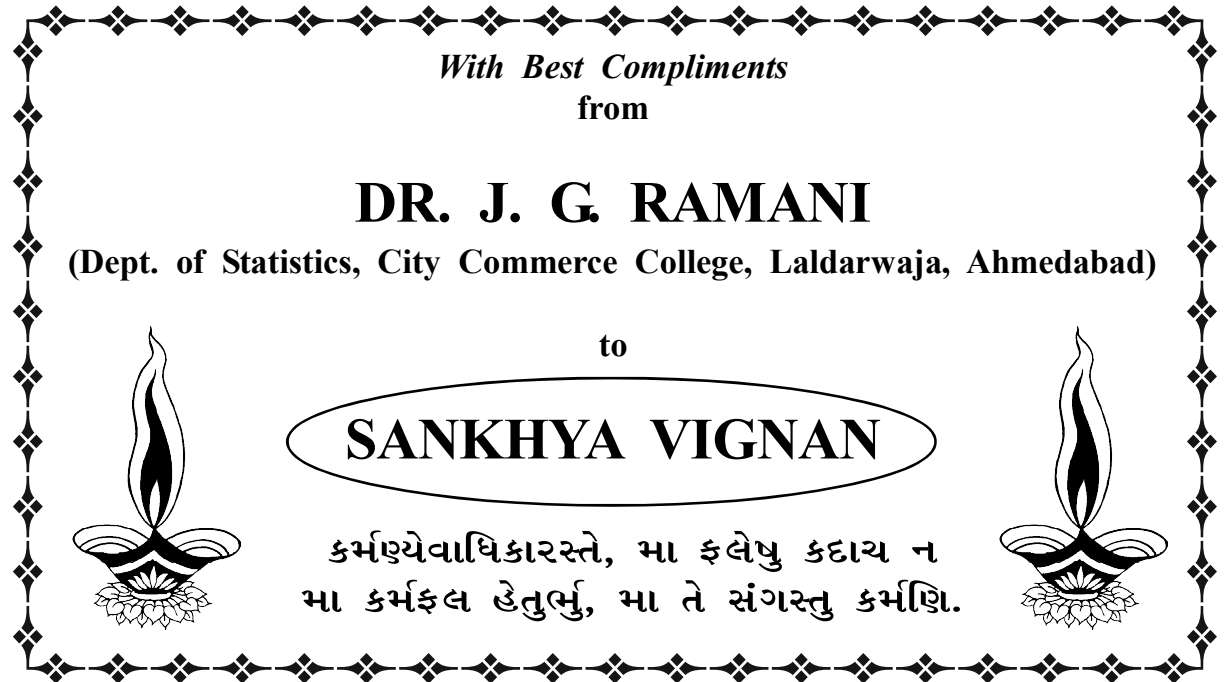
It is anticipated that the number of master protocols will continue to increase at a rapid pace over the upcoming decades. More efforts to improve the awareness and trainings are needed to apply these innovation trial designs methods outside of oncology. Recently during COVID-19 pandemic industry has witnessed the high use of Master Protocols to conduct the vaccine trials and different targeted symptomatic therapies.

7. ACKNOWLEDGEMENT

I thank the referee for his comments for reviewing this article which has helped its revision.

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ABSTRACT

This paper is in continuation to Sankhya Vignan (NSV16) June 2020, pg76-88, STATISTICAL METHODS IN CLINICAL TRIALS – (II), introduction and basics on statistical methods applied in clinical trials. I have made an effort to highlight topics related to one-way ANOVA, two-way ANOVA, Repeated Measures ANOVA and Cross over designs in clinical trial.

KEYWORDS: Two way ANOVA, Repeated Measures, Cross Over Designs.

1. INTRODUCTION

The paper highlights the application of the above methods in the clinical trial data.

2. ONE-WAY ANOVA

One-way ANOVA (analysis of variance) is used to compare two or more groups means based on independent samples from each group, this method is appropriate for comparing mean response among number of parallel dose groups or among various strata based on patients background information, such as race, age group, or disease severity. We assume all samples are from normally distributed populations, samples are independent from each group and variance homogeneity among the groups (i.e. with the same variance σ^2). In general, there are k ($k \geq 2$) level of the factor group. From each independently sample a number of observations, letting y_{ij} represents the

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(rcd. Sep. 2020 / rvd. Oct. 2020)

j_{th} measurement from the i_{th} group and n_i represent the number of measurements within Group i ($i=1, 2, \dots, k$).

Lay out for the One-way ANOVA

GROUP			
Group 1	Group 2	Group k
Y_{11}	Y_{21}	Y_{k1}
Y_{12}	Y_{22}	Y_{k2}
.....
Y_{1n_1}	Y_{2n_2}	Y_{kn_k}

The null hypothesis is that of “no Group effect” (i.e. no difference in the mean response among the groups), the alternative hypothesis is that “the Group effect is important” (i.e. at least one pair of the Group means differs).

When H_0 is true, the variation among the groups and the variation within the groups are independent estimates of the same measurement σ^2 , and their ratio should be closer to 1. This ratio is used as test statistics F , which has the F -distribution with $k-1$ upper and $N-k$ lower degrees of freedom ($N=n_1+n_2+n_3+\dots+n_k$).

The test summary is given as below:

Null hypothesis: $H_0: \mu_1=\mu_2=\mu_3 =\dots= \mu_k$

Alt. hypothesis: $H_A: \text{not } H_0$

Test statistics: $F = \text{MSG}/\text{MSE}$

Decision rule: reject H_0 if $F > F_{\alpha, k-1, N-k}$ (α)

MSG is an estimate of variability among the groups and MSE is an estimate of the variability within group. The parameters associated with the F -distribution are the upper and lower degrees of freedom.

Clinical Example: HAM – A Scores in GAD

A new serotonin-uptake inhibiting agent, is being studied in the subjects with general anxiety disorder (GAD). Sixty patients diagnosed with GAD of the moderate or greater severity consistent with the “diagnostic and statistical manual, 3rd edition”

(DSMIIR) were enrolled and randomly assigned to one of the three treatment groups: 25mg, 50 mg, 100 mg or placebo. After 12 weeks of once-daily oral dosing in double blind fashion, a test based on the Hamilton Rating Scale of Anxiety (HAM-A) was administered. The test consists of different anxiety related question items (e.g. anxious mood, tension, insomnia, fears etc.) each rated by the subject as “not present”, “mild”, “moderate”, “severe” or “very severe”. HAM-A test scores were found by summing the coded values of all the question items, where 0 for “not present”, 1 for mild, 2 for “moderate”, 3 for “severe” and 4 for “very severe”. The data are presented as below:

Low Dose (25 mg)		Medium dose (50 mg)		Hi dose (100 mg)		Placebo	
Patient Number	HAM-A	Patient Number	HAM-A	Patient Number	HAM-A	Patient Number	HAM-A
101	21	102	16	103	17	104	22
105	18	106	21	107	22	108	26
109	19	110	31	111	18	112	29
113	n/a	114	25	115	25	116	19
117	28	118	23	119	18	120	n/a
121	22	122	25	123	18	124	33
125	30	126	18	127	22	128	37
129	27	130	20	131	19	132	25
133	28	134	18	135	n/a	136	28
137	19	138	18	139	23	140	26
141	23	142	24	143	16	144	n/a
145	22	146	22	147	19	148	31
149	20	150	16	151	18	152	2
153	19	154	33	155	17	156	30
157	26	158	21	159	16	160	25
161	35	162	17	163	n/a	164	22
165	n/a	166	n/a	167	22	168	36

SAS Code for reading and executing the example:

/******
/*****

Data Gad1;

Input PATNO DOSEGRP \$ HAMA @@;

Datalines;

101 LO 21 105 LO 18

109 LO 19 113 LO .

..... so on

102 ME 16 106 ME 21

..... so on

103 HI 17 107 HI 22

.....so on

104 PB 22 108 PB 26

.....so on

164 PB 22 168 PB 36

;

Proc sort data =GAD1, by dosegrp;

Proc Means Mean STD N data=GAD1;

by dosegrp;

var HMAA;

Title1 "One-way ANOVA"

Title 2 "HAM-A Score in GAD"

Run;

Proc GLM data =GAD1;

Class dosegrp;

Model HMA=dosegrp

Means dosegrp/t dunnett ("PB");

Contrast "ACTIVE vs. PLACEBO" dosegrp (1, 1, 1, -1);

Run;

/******
/*****

The parameters associated with the F-distribution are the upper and lower degrees of freedom. Many elementary statistical texts provide tables of critical F-values associated with a fixed significance level (usually 0.10, 0.05 and 0.01) for various combinations of values for the upper and lower degrees of freedom. F-values or associated probabilities for known degrees of freedom can be also found by using most statistical programs. In SAS, the FINV function ($1-\alpha$, udf, ldf), where udf and ldf represent the upper and lower degrees of freedom respectively, is used to obtain the critical F-values for significance level of α .

The Shapiro Wilk test or Kolmogorov Smirnov test for normality and Bartlett's test for variance homogeneity are some of the many formal tests available for determining whether sample data are consistent with the required assumptions. These test can be conducted in SAS using the options available in PROC UNIVARIATE and PROC GLM. Graphics of the data, such as histogram plots of the residuals, often provide an informal but convenient means of identifying departures from the ANOVA assumptions.

In the event of significance preliminary tests that identify departure from the assumption, a data transformation might be appropriate. Logarithmic and rank transformation are popular transformations used in the clinical data analysis. The Kruskal-Wallis test is an analogue of one-way ANOVA when normality can't be assumed.

When comparing more than two means, a significant F-test indicates that at least one pair of means differs, but which pair (or pairs) is not identified by ANOVA. If the null hypothesis of equal means is rejected, further analysis must be undertaken to investigate where the differences lie, numerous multiple comparison procedures are available for conducting such investigations.

2. TWO-WAY ANOVA

The two-way ANOVA method is for simultaneously analyzing two factors that affect a response. As in the one-way ANOVA, there is a group effect, such as treatment

group or dose level. The two-way ANOVA also includes another identifiable source of variation call a blocking factor, whose variation can be separated from the error variation to give more precise group comparisons. For this reason, the two-way ANOVA layout is some time called a “randomized block design”.

Clinical studies uses factors such as center, gender, diagnostic group, disease severity etc. as stratification of blocking factors, the two-way ANOVA is one of the most common ANOVA methods used in clinical analysis.

In general, the randomized block design has g ($g \geq 2$), level of a ‘group’ factor and b ($b \geq 2$) levels of a ‘block’ factor. An independent sample of measurements is taken from each of the $g \times b$ cells formed by the group-block combinations. Let n_{ij} represent the number of measurements taken in Group i and Block j (cell i - j), and let N represent the number of measurements overall $g \times b$ cells. Let y_{ijk} denote the k_{th} response in the cell i - j ($k=1, 2, \dots, n_{ij}$), the general layout of the randomized block design is as below:

	Group 1	Group 2	Group g
Block 1	$Y_{111}, Y_{112}, \dots, Y_{11n_{11}}$	$Y_{211}, Y_{212}, \dots, Y_{21n_{21}}$	$Y_{g11}, Y_{g12}, \dots, Y_{g1n_{g1}}$
Block 2	$Y_{121}, Y_{122}, \dots, Y_{12n_{12}}$	$Y_{221}, Y_{222}, \dots, Y_{22n_{22}}$	$Y_{g21}, Y_{g22}, \dots, Y_{g2n_{g2}}$
.....
Block b	$Y_{1b1}, Y_{1b2}, \dots, Y_{1bn_{1b}}$	$Y_{2b1}, Y_{2b2}, \dots, Y_{2bn_{2b}}$	$Y_{gb1}, Y_{gb2}, \dots, Y_{gbn_{gb}}$

ANOVA Summary Table for the Two-Way ANOVA

Source	Degrees of freedom	SS	MS	F-Statistics
Group (G)	$g-1$	SSG	MSG	$F_G = MSG/MSE$
Block	$b-1$	SSB	MSB	$F_B = MSB/MSE$
G x B (Interaction)	$(g-1)(b-1)$	SSGB	MSGB	$F_{GB} = MSGB/MSE$
Error	$N-gb$	SSE	MSE	
Total	$N-1$	TOT (SS)		

SS represents the sum of squared deviations associated with the factor, the mean square (MS) is founded by dividing the SS by degrees of freedom. The MS represents a measure of variability associated with the factor listed under the source. When there

is no effect due to the specified factor, this variability reflects measurement error variability, σ^2 , which is also estimated by MSE.

The F-values are ratios of the effect mean square to the mean square error (MSE). Under the null hypothesis of no effect, the F-ratio should be close to 1. These F values are used to test statistics for testing the null hypothesis of no mean difference among the level of factors.

The F-test of the group F_G tests the primary hypothesis of the no group effect. Denoting the mean for the i^{th} group by μ_i , the test summary is as below:

Null hypothesis: $H_0: \mu_1 = \mu_2 = \mu_3 = \dots = \mu_g$

Alt. hypothesis: $H_A: \text{not } H_0$

Test statistics: $F_G = \text{MSG}/\text{MSE}$

Decision Rule: reject H_0 if $F_G > F_{g-1, N-g}(\alpha)$

The F-test for the block effect (F_n) provides second test, which is used in a similar way to determine if the mean response differ among the blocking levels. A significant block effect often results in a smaller error variance (MSE) and greater precision for testing the primary hypothesis of “no group effect” than if the block effect were ignored.

The GroupxBLOCK factor (GxB) represents the statistical interaction between the two main effects. If the F-test for interaction is significant, this results indicates that trends across the groups differ among the levels of blocking factor. This is usually the first test of interest in two way *ANOVA*, because the test for the group effects might not be meaningful in presence of a significant interaction. If the interaction is significant, further analysis might be required, such as to compare the groups within each level of the blocking factor.

3. REPEATED MEASURES ANOVA

Repeated measures refer to multiple measurements taken from the same experimental unit, such as serial evaluations over time on the same patient and they cannot be considered independent, so analysis must make provision for the correlation

structure. Most clinical studies require outpatients to return to the clinic for multiple visits during the trial with response measurements made at each, this is most common example of repeated measures, sometimes called “longitudinal” data. These repeated response measurements can be used to characterize a response profile over time period. One of the main question the researcher asks is whether the mean response profile for one treatment group is the same as for another treatment group or a placebo group. This situation might arise, for example, when trying to determine onset of effect or rate of improvement due to a new treatment is faster than an existing treatment. Comparison of the response profiles can be tested with a single F-test from a repeated measure analysis.

In general, you have “g” independent groups of patients each of whom are subjected to repeated measurements of the same response variable, “y” at “t” equally spaced time period. Letting n_i represents number of patients in the group i , ($i=1, 2, \dots, g$), the layout for $g=3$ groups is shown as below, in the comparative trials, the group often represents different parallel treatment groups of dose level of a drug.

Group	Patient	Time			
		1	2	t
1	1	Y_{111}	Y_{112}	Y_{11t}
	2	Y_{121}	Y_{122}	Y_{12t}

	n_1	Y_{1n11}	Y_{1n12}	Y_{1n1t}
2	1	Y_{211}	Y_{212}	Y_{21t}
	2	Y_{221}	Y_{222}	Y_{22t}

	n_2	Y_{2n21}	Y_{2n22}	Y_{2n2t}
3	1	Y_{311}	Y_{312}	Y_{31t}
	2	Y_{321}	Y_{322}	Y_{32t}

	n_3	Y_{3n31}	Y_{3n32}	Y_{3n3t}

There are number of analytic approaches for handling repeated measures. For example, ‘univariate’ method that uses the ANOVA concepts, ‘multivariate’ method which treats the repeated measurements as a multivariate response vector. Modeling techniques use the MIXED and GENMOD procedures in SAS, which are often

preferable when clinical trial has missing data.

The ‘Univariate’ Approach

As shown in the above table, we have group, patient and time effects as three factors in the ANOVA. We can examine the variability within and among these factors noting the Time effect represents correlated measurements. The response might vary among the groups, among patients within groups, and among the different measurement times. Therefore, we include a Group effect, a Patient (within-Group) effect, and a Time effect as source of variation in the ANOVA. *In addition, the repeated measure analysis using a univariate approach includes Group-by-Time interaction.*

ANOVA methods, we assume normality of the response measurements and variance homogeneity among the groups. In addition, the univariate ANOVA requires that each pair of repeated measures has the same correlation, a feature known as ‘compound symmetry’

A significant interaction means that changes in response over time differ among groups, i.e. a significant difference in response profiles, when profiles are similar among groups (i.e. no Group-by-Time interaction), test for the Group effect measure the deviation from the hypothesis of equality of mean responses among the groups ‘averaged’ over time. This test using the repeated measures analysis method might be more sensitive to detecting group differences than using one-way ANOVA to compare group at single time point. However, the group effect might not be meaningful if there is significant Time effect. The Time effect is a measure of deviation from the hypothesis of equality of mean response among the measurement times for all groups combined.

The simplest case of *repeated measures of ANOVA*, which is shown here, the Group and the evaluation Time are cross-classified main effects. However, the samples are not independent among the Group-Time since measurement taken over time are taken from the same patient are correlated. To account for this correlation patient effect must be included as source of variation in the ANOVA.

ANOVA summary for Repeated Measures Design

Source	df	SS	MS	F
GROUP	g-1	SSG	MSG	$F_G = \text{MSG}/\text{MSP}(G)$
PATIENT (within GROUP)	N-g	SSP(G)	MSP(G)	—
TIME	t-1	SST	MST	$F_T = \text{MST}/\text{MSE}$
Group-by-TIME	(g-1) (t-1)	SSGT	MSGT	$F_{GT} = \text{MSGT}/\text{MSE}$
Error	(N-g) (t-1)	SSSE	MSE	—
Total	Nt-1	TOT(SS)		

$N = n_1 + n_2 + \dots + n_g$, for balanced layout ($n_1 = n_2 = \dots = n_g$). Variation from patient-to-patient is one type of random error, as estimated by the mean square for Patient (within Group). If there is no difference among groups, the between-group variation merely reflects patient-to-patient variation. Therefore under the null hypothesis of no Group effect, MSG and MSP(G) are independent estimates of the among-patient variability, so that F_G has F-distribution with g-1 upper and N-g lower degrees of freedom.

If there is no time effect, the mean square for the Time (MST) is an estimate of within-patient variability, as is the error variation MSE. The ratio of these independent estimates is the F-statistics used to test the hypothesis of no Time effect. Similarly, the interaction mean square, which is also a measure of within patient variation under H_0 , is compound to the MSE to test of a significant Group-by-Time interaction.

The ‘Multivariate’ approach to repeated measures analysis using SAS makes the within-patient test using 4 criteria: *Wilk’s Lambda*, *Pillai’s Trace*, *Hotelling-Lawley Trace* and *Roy’s Greatest Root*. Each of these statistics is based on multivariate statistical analysis methods to obtain an F-test of significance for the given factor based on the complex function of the sums of squares. The difference among these tests depend on the alternative hypothesis. ‘Wilk’s’ Lambda, for example might be more powerful test to use under some alternatives. Research suggests that Pillai’s Trace might be most appropriate one for use under wider range of applications. When

there are only two groups ($g=2$), all four test yields the same results.

4. CROSSOVER DESIGNS

The cross over design is used to compare the man responses of two or more treatments when each patient receives each treatment over successive time periods. Typically, patients are randomized to treatment sequence groups which determine the order of treatment administration. The response among treatments in a parallel study are considered independent, response among the treatment in a crossover study are correlated because they are measure on the same patient, much likely the repeated measure set-up. In fact, the cross over is special case of repeated measure design for treatment comparison and must consider this correlation when analyzing data from a crossover design. In addition to treatment comparisons, the crossover analysis also investigates period effects, sequence effects and carryover effect.

The cross over study features within patient control among the treatment group, fewer patients are generally required as compared to parallel study. This advantage is often offset, however, by an increase in the length of the study. For example, when there are two treatments, the study will be at least twice as long its parallel-design counterpart because treatments are studies in each of the two successive periods. The addition of a wash-out period between treatments, which is usually required in a crossover study, tends to further lengthen the trial duration.

The crossover design is normally used in the studies with short treatment periods, most frequently in pre-clinical and early-phase clinical studies, such as bioavailability, dose ranging, bio-equivalence, and pharmacokinetic trials. If it's thought that all the patient's condition will not be the same at the beginning of each treatment period, the cross over design should be avoided. Longer treatment period provide increased opportunities for changing clinical conditions and premature termination. For the same reasons, cross over design should limit the number of study periods as much as possible. For 2 period cross over designs the responses are assumed to be normally distributed.

For the two-way cross over design, each patient received two treatments, T and

R, in one of the two sequences, that is, T followed R (T-R) or R followed by T (R-T). Samples of n_1 and n_2 patients are randomly assigned to each of the two sequence groups. T-R and R-T respectively (usually $n_1=n_2$). Response measurement (y_{ijk}) are taken for each patient following each treatment for a total of $N=2n_1+2n_2$ measurements, where y_{ijk} is the measurement for the k^{th} patient in the sequence group for which Treatment i , ($i=1$ for Treatment T, $i=2$ for treatment R) is given in period ($j=1,2$).

Cross over Layout

Sequence	Patient Number	Period 1	Period 2
		Treatment T	Treatment R
T-R	1	Y_{111}	Y_{221}
	3	Y_{112}	Y_{222}
	6	Y_{113}	Y_{223}
	7	Y_{114}	Y_{224}

		Treatment R	Treatment T
R-T	2	Y_{211}	Y_{121}
	4	Y_{212}	Y_{122}
	5	Y_{213}	Y_{123}
	8	Y_{214}	Y_{124}

ANOVA Summary table for 2-Period Crossover

Source	df	SS	MS	F
Treatment (T)	1	SST	MST	$F_T = MST/MSE$
Period (P)	1	SSP	MSP	$F_P = MSP/MSE$
Sequence (S)	1	SSS	MSS	$F_S = MSS/MSP(S)$
Patient-within-Sequence (P(S))	n_1+n_2-2	SSP(S)	MSP(S)	
Error	n_1+n_2-2	SSE	MSE	
Total	N-1	TOT(SS)		

The treatment sum of squares, SST, is proportional to the sum of squared deviations of each Treatment mean from the overall mean. Likewise, SSP is computed from the sum of squared deviation of each Period mean from the overall mean etc. The mean squares (MS) are found by dividing the sum of squares (SS) by their respective degrees of freedom (df). The hypothesis of equal treatment means is tested at two tailed significance level, α , by comparing the F-test statistics, F_T with the critical F-value based on 1 upper and n_1+n_2-2 lower degrees of freedom. The test summary for no treatment effect is as below:

Null hypothesis: $H_0: \mu_T = \mu_R$

Alt. hypothesis: $H_A: \mu_T \neq \mu_R$

Test statistics: $F_T = MST/MSE$

Decision Rule: reject H_0 if $F_T > F_{1, n_1+n_2-2}(\alpha)$

Reject H_0 if F_T is significant.

The Period and Sequence effects can also be tested in similar manner. As in the repeated measure ANOVA, the test of Sequence effect uses the mean square for Patient-within-Sequence in denominator because patients are nested within sequence groups. When the hypothesis of no Sequence Group effect is true, the variation between sequence groups simply reflects the patient-to-patient variation. In the crossover analysis the presence of a Treatment-by-Period interaction generally requires separate analysis within each period.

The cross over designs can also be performed with the non-normal response, which include categorical and rank data. Using binary responses and non-parametric approaches to the analysis of non-normal response in crossover designs.

5 SUMMARY

Many of the statistical terms used in this paper are generally used by clinical researchers, both statisticians and non-statisticians. The concepts presented in this paper form a basis for general overview of statistical methods and applications for the clinical study data analysis. The overall approach needs to be planned as per

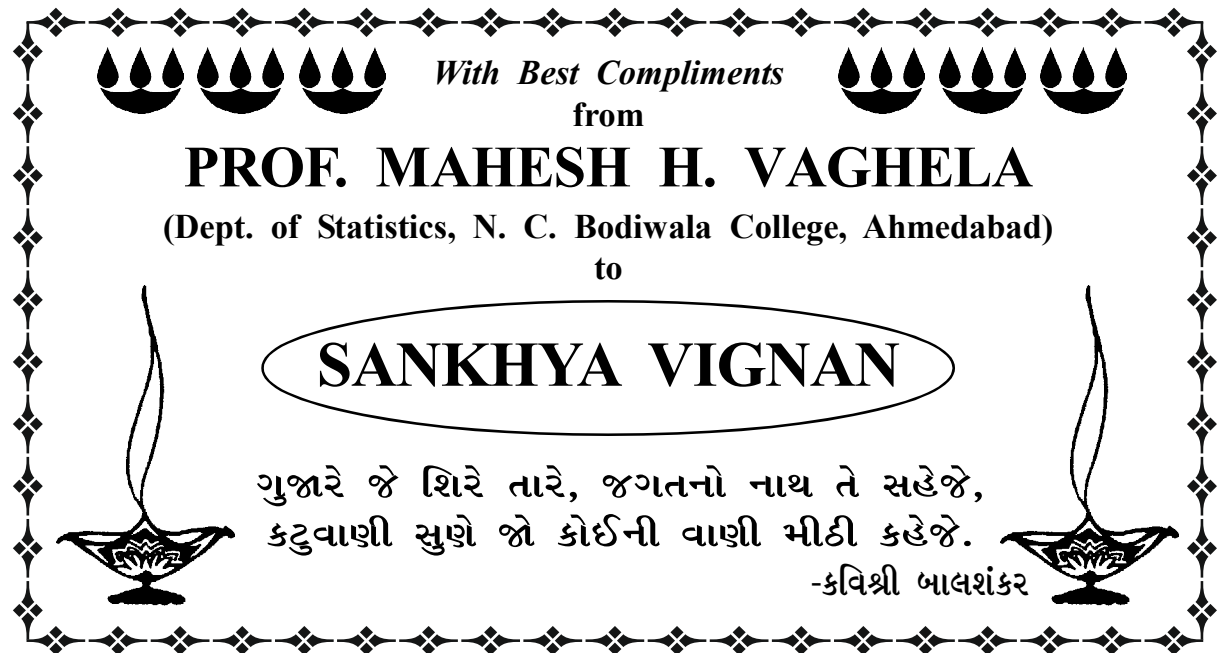
the clinical trial requirements, considering the trial objectives and adhering to the regulatory submission guidelines.

6. ACKNOWLEDGEMENT

I thank the referee for the comments after reviewing this article which has helped in its revision.

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BIOGRAPHY

GERTRUDE MARY COX*

H. D. Budhbhatti**



Gertrude Cox was born in Dayton, Iowa on January 13, 1900. She studied at Perry High School in Perry, Iowa, graduating in 1918. At this time she decided to become a deaconess in the Methodist Church and worked towards that end.^[2] However, in 1925, she decided to continue her education at Iowa State College (which was renamed Iowa State University in 1959) in Ames where she studied mathematics and statistics and was awarded a B.S. in 1929 and a Master's degree in statistics in 1931.

From 1931 to 1933 Cox undertook graduate studies in psychological statistics at the University of California at Berkeley, then returned to Iowa State College to assist in establishing the new Statistical Laboratory.^[3] Here she worked on the design of experiments.

Academic career

In 1939 Cox was appointed assistant professor of statistics at Iowa State College.^[4] In 1940 Cox was appointed professor of statistics at North Carolina State College (now North Carolina State University) at Raleigh. There she headed the new department of Experimental Statistics, the first female head of any department at this institution.^[3] In 1945 she became director of the Institute of Statistics of the Consolidated University of North Carolina, and the Statistics Research Division of the North Carolina State College which was run by William Gemmell Cochran. In the same year of 1945 Cox became the editor of *Biometrics Bulletin* and of *Biometrics* and she held this editorship for 10 years. When prolific statistician and eugenicist Ronald Fisher founded the International Biometric Society in 1947, Cox was one of the

* Adapted from wikipedia (the free encyclopedia) and other related resources.
(We express our sincere thanks and gratitude for this assistance)

** Ex. CSO, Head , Statistics Dept. , GSRTC, Ahmedabad
(Thanks to the referee for reviewing this article)
(rcd May 2020 / rvd June 2020)

founding members.

In 1960 she took up her final post as Director of Statistics at the Research Triangle Institute in Durham, North Carolina. She held this post until she retired in 1965.^[4] After retirement, then worked as a consultant to promote the development of statistical programs in Egypt and Thailand.

Book

In 1950 she published a joint work with William Cochran, *Experimental Designs*,^[6] which became the major reference work on the design of experiments for statisticians for years afterwards.

Recognition

Cox received many honors. In 1949 she became the first woman elected into the International Statistical Institute. In 1956 she was elected President of the American Statistical Association while in 1975 she was elected to the National Academy of Sciences. She was also a Fellow of the Institute of Mathematical Statistics.

The University of North Carolina system named her an O. Max Gardner Award recipient in 1959. North Carolina State University honored Cox by naming Cox Hall in her honor in 1970, and awarding her a Watauga Medal in 1977. The Caucus of Women in Statistics also established a Gertrude M. Cox Scholarship fund in recognition of her work in 1986.

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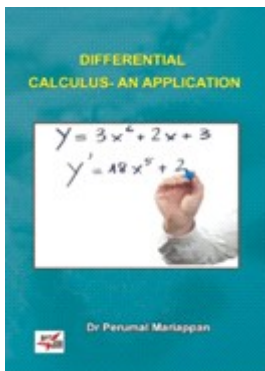
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Pages: 160



This book is highly readable and recommendable for the under graduates and post graduate students who want to learn Differential Calculus as it has an extensive knowledge in the area of engineering, mathematical sciences, and computer sciences. Thus, this book is the highly recommendable for learning the Differential Calculus.

This book has six important chapters that are in proper sequential orders that would help the readers to read this book interestingly. The book also has plenty of exercise problems together with the past year university questions. The author has done a good job by considering the novice who would find it easier to understand Differential Calculus even for self-study. The presentation of the content in this book is extremely captivating and satisfactory for the immense audience of all disciplines to learn Differential Equation. Evidently, this book would be the best choice to guide the undergraduate and graduate students, as the readers would quickly learn to solve an extensive range of current problems in engineering and science that can only be solved with differential calculus through applications. The exercises are well explained step-by-step through practical guidance which could inspire innumerable calculus skills.

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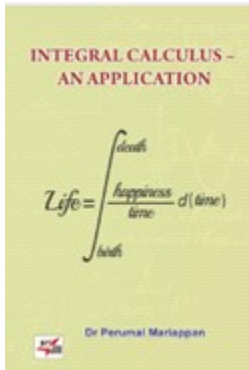
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Integral Calculus - An Application - Dr Perumal Mariappan

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This book caters nine chapters that are well-structured with its essential sub-topics. The author in this book provides various methodologies of integral calculus and applications of integration. The author then connects the application of integral calculus to business with innumerable real-world examples to ease readers to understand the application of integral calculus thoroughly by intriguing problem-solving skills. Evidently, this book would be the best choice to guide the undergraduate and graduate students, as the readers would quickly learn to solve. Book an extensive range of current problems in engineering and science that can only be solved with integral calculus and its applications. The exercises are well explained step-by-step through practical guidance which could inspire innumerable calculus skills.

Integral Calculus-An Application is an excellent book for Under Graduate and Post Graduate students in both Engineering and Science disciplines and even could contribute an ultimate reference for any students as well as professionals from any disciplines to obtain a better understanding of the use of calculus at its simplest form.

- Dr. Kavikumar Jacob

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GERTRUDE MARY COX*



Gertrude Mary Cox was born in Dayton, Iowa on Jan. 13, 1900. She was graduated in Maths from Iowa State University in 1929 and then earned Master's degree in 1931. Later on she received D.Sc. in Statistics in 1958. She had worked with North Carolina State University as **Professor of Statistics** and later on also as **Director of Statistics at Research Triangle Institute**. Her most important and influential research deals with experimental designs. In 1950, she published the book **Experimental Design, jointly with W. G. Cochran** which became the major reference work for statistician for years afterwards.

Gertrude expired at the age of 78 years on October 17, 1978, from Durham, North Carolina. She had recognition with **George Snedecore, Cochran, Yates, A.M.Mood, Anderjon etc.**

Awards

- **Fellow of American Statistical Association (1944)**
- **Fellow of IMS (1944)**
- **Members of International Statistical Institute (1949)**
- **Hon. Fellow of Royal Statistical Society (1959)**
- **Oliver Max Gardner Awards (1959)**
- **International Award for Distinguished Service to Agriculture (1960)**
- **Hon. Life Membership of the Biometric Society (1964)**
- **Member of the National Academy of Sciences (1975)**

*(Brief Biographical sketch is given inside the journal)

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