

# Data Analytics for Bioequivalence



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## Abstract

We encourage the growth of data analytics and other computer methods including artificial intelligence and machine learning in the growth of procedure to diagnose and treat those inflicted with disease or indications of the spread of infectious diseases. With the rapid advances in machine intelligence, we have seen the development of the application of machine learning in business forecasting, analyzing treatment data and the results of analytic and diagnostic tests.

**Keywords:** Quality control and improvement; Diagnostic testing; Data analytics; Artificial intelligence; Machine learning; Autoregressive-integrated moving average (ARIMA); Multivariate methods

**Abbreviations:** AI: Artificial Intelligence; ML: Machine Learning; HTA: Health Technology Assessment; TQM: Total Quality Movement; ASQC: Automated Statistical Quality Control; ASPC: Automated Statistical Process Control; EWMA: Exponentially Weighted Moving Average; SPC: Statistical Process Control; SQC: Statistical Quality Control; MQC: Most Popular Multivariate; MEWMA: Multivariate Exponential Moving Average Method; ARIMA: Autoregressive-Integrated Moving Average

## Introduction

Modern methods of management enter the field of healthcare, diagnostics and bioequivalence in a variety of ways. Everywhere one looks from the production of medical and diagnostic equipment the use of such equipment in medical offices, hospital and other health care providers we observe the automation of procedures and the production of medicines which are similar to each other. We refer to this as automation, but it is the advances in computer technologies that drove this mechanization of seemingly simple but technological advanced tasks to streamline production and development methodologies. The growth of these technologies in the future will accelerated by breakthroughs in artificial intelligence (AI) and machine learning (ML) which will continue the mechanization of tasks improve the quality of output. To incorporate AI into health care procedures is not simple but it includes the methodology of statistical/ mathematical science as it applies the data-driven methodologies. In this study, we focus on one such plan that involves the analytics associated with a volume of diagnostic tests to produce plans to generate treatments.

Recently, Allen, Sudlow & Downey [1], in a large data prospective study of resources for the investigation of the genetic, environmental and lifestyle determinants of a many diseases of mid-life and older patients. The employed the notion that data analytics can yield great results and alter the methods by which health care solutions are determined. In addition, Abelson, Giacomini, Lehoux & Gauvin [2], indicated that health care coverage decisions utilize health technology assessment (HTA) for crucial information to provide for diagnostics and health

strategies. This indicates that health care policy and technology combined to improve the health of human populations and bring changes to those populations whose quality of care are equal to those who can afford the expenses associated with the better health programs. This is especially true to those populations who do not have the ability to acquire the best reproductive health programs. Jarrett [3], expanded the applications of using data analytics in managing health and medicine using new multivariate methods to suggest quality care solutions.

In another opinion article, Marcus and Davis [4], advance some new notions concerning the development of data analytics via AI and the new development of computer technology. Recent programs such as "Google Duplex" suggest that machine learning is on its way to solving ordinary problems in life and produce the hypothesis that machine will take over many tasks done by humans and lead to great strides in producing strategies now common to only humans. The great applications of this program is the notion that machines can learn, but in health care policy improvement through technology it is extremely far from aiding health practitioners in prescribing patient care strategies. Machine learning and AI must turn it focus on solving the difficult problems in patient care. In, addition, machine learning should also employ strategies utilize in other field that do lend themselves to the usefulness of computer technology.

## Quality Movement in Diagnostics

Improvements in diagnostic care whether in hospitals, treatment and diagnostic centers and other health care units are

a central function of quality health care. In many places, they are the principal methods by which patients can secure care. Planned Parenthood is one such example where patients can receive care and treatment in an affordable and often convenient manner. A client enters the clinic to possibly have diagnosed a severe set of symptoms for which scientific tests are given to determine a condition and the therapeutic plan to produce a treatment to successfully reduce the problem and achieve positive results. Earlier in industrial applications, this process was called “total quality movement (TQM)” which is a plan to achieve successful outcomes to the patient’s health problem. In the future we, expect AI and TQM to spread everywhere and become a central focus of machine outcomes. This is similar to the development of the laser industry and its applications in medical care. Examine the current research in automobiles and the relative changes made by the driverless vehicle. The purpose is to have cleaner exhausts from motor vehicle and greater safety. Humanity is not there as of now but encouragement by governments through proper regulations and other programs changed the motor vehicle industry greatly. Similarly, motor vehicle parts may change this product immensely in the future. Data analytics and ML are both components of the new frontier in the motor vehicle and motor vehicle parts industries as well as the health care industry.

To consider the depth of management science, data analytics, AI and machine learning topics in health care include the following manuscripts by Jarrett [5]; Jarrett & Pan [6], In addition, others including Patel et al. [7], Machado and Costa [8], Khoo and Quah [9], and more recently, Acampora et al. [10], added specific illustrations of new computer-based methods. Technology firms such as Google, Amazon, Microsoft, and Apple in recent years made huge investments in AI to deliver tailored search results and build items called personal virtual assistants. The technology is seeping down to hospital care and other forms of diagnostic and treatment methodology in health care in general. With reforms in health care, health care reform law will enable physicians and other health care personnel to be assisted in choosing medicines and treatments for patients in both an efficient and timely manner. For example, a physician will be able to choose the best medicine to counter the effect of a patient’s severe diagnosis quickly. With the huge number of medications available much of a physician’s decision making will be automated thanks in part to the push for computer systems to prescribe the best treatment available. No longer will a physician need to observe volumes of data bases to find the optimal treatment. The computer will perform the search and inform health care personnel to act quickly and optimally. Health policy makers must encourage the greater development of these methods.

Today, data collection by health statisticians include volumes of patient demographics, clinical data and billing data that are available in an electronic format for analysis by intelligent software. For these difficult tasks AI software can analyze quickly to perform the tasks of recommending medicines, treatment protocols and general advice to assist physicians in attacking

the problems associated with difficult diagnoses. For example, applications of AI have been utilized in intensive care for nearly a generation; Hanson & Marshall [11], and Liu & Salinas [12]. Digital devices and home tests are allowing a more thorough patient examination from remote places, which addresses some of the previous setbacks of telemedicine. Remote diagnostic tools such as Tyto, Scanadu and Med Wand are expanding the perception of telemedicine. Heartbeat and respiration rate can now be checked remotely. The same is true for blood pressure, blood glucose, body temperature, and oxygen levels. A device may contain a high-definition camera that can look down throats and ear canals. Cameras can also provide high-resolution images of skin to examine lesions, suspicious skin changes and other dermatological issues. Urine-testing kits may also be employed in the home or specific diagnostic centers to provide information to medical personnel to suggest a treatment without the patient being at the same physical location as the medical personnel.

At this point, we should consider automated statistical quality control or (ASQC) or automated statistical process control (ASPC) as it applies in the quality movement. These terms are no longer new in diagnosis and treatment. however, they are based on previous applications in industry, in banking and everywhere one seeks assistance in the analysis of data where the timing of decisions is very important. The quality movement is the field that ensures that management maintains a set of standards set and continually improves the process to achieve successful goals. Instead of final, end-of-service inspection (whether the patient is found healthy or not after the treatment ends). The quality movement according to Lee & Wang [13], and Weihs & Jessenberger [14], provides guidelines for this. Otherwise, instead of end-of-service inspection and decision-making TQM emphasizes prevention, integrated source inspection, process control and continuous improvement [15-17]. The mitigating of risks of type I and type II errors are the prime purpose of these methods. In addition, AI will provide software, services, and analytics solutions to the ambulatory care market. Also, Health care information technology and services companies that deliver the foundational capabilities to organizations will aid the promotion of healthy communities. Technology provides a customizable platform that empowers physician success, enriches the patient care experience and lowers the cost of health care and, in turn, health insurance. Stated simply, AI statistical quality control monitors the incidence characterized by the results of multiple tests on a similar fluid per period of a short interval over a lengthy period (10 - 20 weeks). The monitoring requires an intelligent system analyzing items (control charts, for example) and seeking whether there are common causes of variation or special causes of variation. In industrial applications, these were called Shewhart charts. Later, others suggested additional methods including the use of exponentially weighted moving average (EWMA) control charts [17].

The great rise of health information systems enables AI and machine learning in the very early stages of its development to match one’s own intelligence. Computers certainly cannot

physicians, however, machine learning software and computer technology contain the capability of processing vast amounts of data and identifying patterns that humans cannot. Machine learning solves the complex algorithms that analyze this data and is a useful tool to take full advantage of electronic medical records, transforming them from mere e-filing cabinets into full-fledged physician analysts' who can deliver clinically relevant, high-quality data in real time to allow doctors to use the technology in prescribing treatment.

### AISPC and AISQC

SPC (statistical process control) and SQC (statistical quality control) environments usually assume a steady process behavior where the influence of dynamic behavior does not exist or is ignored. The focus of control there is only one variable (i.e., medical test) over a lengthy interval of time. SPC controls for the changes in either the measure of location or dispersion or both. These procedures as practiced in each phase may disturb the flow of the service production process and operations. We note that in recent years the use of SPC to address processes characterized by more than one test or treatment emerged. First, we review the basic univariate procedures to improve the process of SPC and allow machine learning to enter the process.

Shewhart control charts were the central foundation of univariate (one variable) SPC has a major flaw. The process considers only one piece of data, the last data point, and does not carry the memory of the previous data collected. Often, a small change in the mean of a random variable is not likely to be detected quickly. Griggs & Spiegelhalter [18], EWMA control charts improved upon the detection process of small process shifts. Rapid detection of relatively small changes in the characteristic of interest and ease of computations through recursive equations are some of the important properties of the EWMA control chart that makes the process attractive and easy to use the intelligent software to detect changes.

The EWMA chart is used extensively in time series modeling where the data contains a gradual drift [19], EWMA provides for identifying gradual shifts in medical tests by predicting where the observation will be in the next period of time. Hence, the EWMA process improves decision support in future time periods and is therefore dynamic [20]. The EWMA statistic is useful for monitoring the results of lengthy periods of tests having short intervals when the actual tests are performed. Furthermore, the method gives less and less weight to data as they become more remote in time. Montgomery [21], contains the development of models for finding control limits in this univariate process, but appears to be another example of where intelligent software applies.

### Univariate Models and Its Obsolescence

Alwan [22], found that the great majority of SPC applications studied results in control charts with misplaced control limits and essentially false signals to the care providers. The misplacement results from auto correlated process observation.

The auto correlated time series observations violate an assumption associated with Shewhart control charts [14]. Autocorrelation of process observations is common in many applications. For example, cast steel [22], wastewater treatment plants [23], chemical processes [24], and many other processes in the health care industry, especially diagnostic care and similar applications. In addition, Alwan and Roberts [25], suggested using an autoregressive integrated moving average (ARIMA) charts for decision analysis. Continuous intelligent software can be of particular aid to identification of the appropriate methods for decision analysis if one follows the works of Atienza, Tang and Ang [26], Box, Jenkins and Reinsel [27], West, Dellana and Jarrett [28], who employed ARIMA modeling with Intervention; and, in addition, Jarrett [29,30], summarized many of these methods in SPC. All these models are in the process of being computerized to develop intelligent systems that will enable computers intelligently point to optimal patient treatments and diagnoses. The notion of physicians having patient-centered diagnostic programs using AI will be of immense aid.

### Multivariate Quality Controls (MQC) and ML

Multivariate methods utilize additional analyses due to having two or more variables that are the results of several diagnostic procedures to determine specific plan of care (treatment). The use of univariate analysis can lead to incorrect interpretation of data due to the co-integration of the tests performed. The most popular multivariate (MQC) methods are those based on the Hotelling T<sup>2</sup> distribution [15,28,31], and multivariate exponential moving average method (MEWMA). Other MQC methods include those developed by Kalagonda and Kulkarni [32,33]; Jarrett and Pan [34-37]; Vanhatalo and Kulachi [38], and Billen et al. [39]. All the above MQC modelers produced results that achieve superiority to SQC analysis because of one or more of the following factors:

- a. The control region of variables is represented by an ellipse rather than parallel lines.
- b. The Intelligent software is programmed to maintain a specific probability of a type I error in the analysis.
- c. The determination of whether the process is out of control is a single control limit (ARL).
- d. Correcting T<sup>2</sup> based MQC analysis where autocorrelation is present.
- e. Use of MEWMA, when time series methods have unique schemes.

As a result, the above methodology indicate that intelligent software cannot ignore the various possibilities to lead to non-optimal decisions. However, proper machine learning methods will adjust to new research and patient assisted analytical software will be of great use to find diagnoses that enable one to use AI to solve difficulties with patient care. A recent study by Makridakis [40], indicated the possibilities of machine learning in prediction which give evidence that data analytics can produce

the best results many situations. Hence, medical diagnostic tests may then be couple with newer programs in machine learning [41-42].

### Summary and Conclusion

The purpose of this review and study is encourage development in a very important and growing industry called AI as it applies in the technology of health care. AI based platforms for digital transformation will play an increasing role in patient diagnoses health programs. The growth will occur in treatment and emergency care centers as well as intensive care units. Intelligent software is being developed which will suggest to physicians and other health care workers the meaning of studying data bases of information data analytics. In turn, intelligent software will prescribe and set protocols for treatments of difficult prognoses and intensive care. Intelligent programs are AI-based platform for digital transformation. They are modular and an interconnected mixture of flexible digital technologies that span from robotic automation to ML. The programs learn over time and produce new ways to arrive at results. The study indicates that new ways to get results and in timely fashion. The blending of intelligent software and comprehensive data analytics will eventually move health care analysts from the task of interpreting results to have protocols produced for them. Intelligent software will blend seamlessly with a decision maker's operations insights and produce a unique domain expertise to create better analytical conclusions in the real world. By examining quality operations, we observe how AI shares the burdens of care and assists health care personnel in achieving their goals. As stated earlier, AI in health care incorporates AI into many health care procedures that are not simple but includes the methodology of statistical/ mathematical science as it applies the data driven methodologies. The notions of bioequivalence will become clairvoyant as one becomes more knowledgeable in modern healthcare and diagnostic innovations.

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