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### The Importance of Biostatistical Methods in the "Evidence-Based Medicine"

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### Abstract

The levels of evidence were first described in a report by the Canadian Task Force on the Periodic Health Examination in 1979. Quantitative approaches has the strength of the evidence. Randomized controlled trials RCTs are considered the gold standard for determining evidence. The results of a quantitative study provide best evidence information by using statistical analyses. Statistics is a crucial process behind how we make discoveries in science, make decisions based on data, and make predictions.

Statistical thinking and methods are important guide for all scientists. The investigator should use powerful statistical methods to increase the strength of the evidence and to interpret the results with a higher sensitivity. Using multivariate statistical methods that do not divide the whole and evaluates all variables together, it is a fact that more powerful results and comprehensive description of the typical relationship between variables will be obtained. This gives more sensitive, more correct results and powerful evidence compared to univariate methods. The purpose of further evidence-based statistical research is to prove the hypothesis correctly.

In medical studies, statistical methods provide the best evidence. Since multivariate statistical methods are more powerful, they provide stronger evidence.

In fact, the development of multivariate statistical methods had hardly begun in 1898, when Bumpus was writing. The correlation coefficient as a measure of the relationship between two variables was devised by Francis Galton in 1877.

In short, all steps of the research should be based on evidence. In the first step of the research, the research design, sample size and power, sampling methods, statistical method, and interpretation of the results should have five evidence-based features.

Key words: Biostatistical Methods, Evidence-Based Medicine, Evidence, Multivariate Statistical Methods

#### Introduction

The levels of evidence were first described in a report by the Canadian Task Force on the Periodic Health Examination in 1979. The recommendation developed in the periodic health examination were

based on the evidence in the medical literature. Randomized controlled trials (RCT) were reported to be at the highest level, while case series or expert opinion





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was the lowest. RCTs are designed to choose the individuals randomly. Therefore the risk of systematic errors is low. According to the method, individuals are randomly assigned to two or more treatment groups and also randomize the confusing factors that will determine the outcomes. A case series or expert opinion is biased by the author's subjective views. There is therefore no control of confusing factors (1).

In the spring of 1990, the young McMasters University Internal Disease Life Coordinator, Dr. Gordon Guyatt introduced a new concept called "Scientific Medicine. Guyatt later used the term "Evidence-Based Medicine" (CPA). The written term was published in the next 1991 ACP Journal Club editor. At the same time, Alvan Feinstein. a physician who was a mathematician, was trying to solve the uncertainty that might arise in medical practice. The term "clinical epidemiology firstly used by Feinstain in his article published in Internal Medicine. The article was describing the details of a new discipline in medical education. This teaching would combine statistical methods of epidemiology with clinical reasoning to study clinical populations. Feinstein bridged the world of epidemiology and medical research, which had long been separated, hence propelling the utility of medical research beyond its traditional anecdotal works (2-4).Evidence-based policy used first in medicine after World War II, and has made tremendous contributions to human health. In social policy, randomized controlled trials (RCT) were conducted before 1980, but the number grew rapidly in U.S. welfare and

employment programs during the 1980s and 1990s and had an important impact on government policy. Since 2000, evidencebased policy has seen a major expansion in other social policy areas, including education and international development assistance. A recent milestone is the U.S. enactment of "tiered evidence" social programs in which rigorous evidence is the defining principle in awarding government funding for interventions (5).

Quantitative approaches has the strength of the evidence. For example randomized controlled trials RCTs are considered gold the standard for evidence. determining Ouantitative research methods used within different studies. The results of a quantitative study provide best evidence information by using statistical analyses. Quantitative methods have traditionally been considered more rigorous than qualitative methods, with randomized controlled trials (RCTs) and systematic reviews being the 'gold standard' for determining evidence (6).

The weak view of qualitative research is advocated by some researchers as follows: Qualitative research may seem unscientific by many medical scientists. However, scientific rules are important to evaluate the results but medicine is more than the application of scientific rules. Clinical experience, based on personal observation, reflection, and judgment, is also needed to translate scientific results into treatment of individual patients. Personal experience is often characterized as being ungeneralizable, and a poor basis for making scientific decisions (7-9).

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# Statistical evidence has a high power for complementary role

Statistical thinking and methods are important guide for all scientists. The investigator should use powerful statistical methods to increase the strength of the evidence and to interpret the results with a higher sensitivity. Using multivariate statistical methods that do not divide the whole and evaluates all variables together, it is a fact that more powerful results and comprehensive description of the typical relationship between variables will be obtained. This gives more sensitive, more correct results and powerful evidence compared to univariate methods. The purpose of further evidence-based statistical research is to prove the hypothesis correctly.

Evidence-based medicine based on from data arising convincing, methodologically sound studies, and no longer simply on individual clinicians' experience and preferences. Clinical guidelines are based on this type of evidence, and include the declaration of levels of evidence. The highest levels of evidence are attained by meta-analyses of published data from controlled trials, followed by published results from multicenter. randomized, individual controlled studies. In order to make a judgment about the relevance of research results for patients, clinicians need to understand the design and analysis of a study, as well as its strengths and limitations (10). Although statisticians are convinced of the importance of unbiased, wellthought-out study designs and evidencebased approaches in the context of clinical research, these principles have being ignore when designing the studies for evaluating statistical methods in the context of methodological research (11).

The field of statistics is the science of learning from data. Statistical knowledge helps you use the proper methods to collect the data, employ the correct analyses, and effectively present the results. Statistics is a crucial process behind how we make discoveries in science, make decisions based on data, and make predictions. Statistics allows you to understand a subject much more deeply (12).

When doing hypothesis tests, the loss of information when dividing continuous variables into categories. For example five separate t-tests would affect the stated or desired level of significance. You would increase the risk of committing a Type 1 error. Therefor it needs to use ANOVA that analyze all groups together and does not increase the Type I error.

Most research design with multiple variables is tries to answer complex These questions questions. are best by multivariate addressed statistical methods. Each method tests the theoretical models of a research question about associations against the observed data. They can control association between variables by using cross tabulation, partial correlation and multiple regressions, and introduce other variables to determine the links between the independent and dependent variables or to specify the conditions under which the association takes place. This gives a much richer and realistic picture





than looking at a univariate analysis. They also provide a powerful test of significance compared to univariate methods (13).

In multivariate analysis we use the information many sources from simultaneously to get a better picture of our surroundings. Essentially, multivariate analysis is a tool to find patterns and relationships between several variables simultaneously. It lets us predict the effect a change in one variable will have on other variables. Therefore the methods are powerful and strong and their predictions are high. Again using the example of our senses, while taste and smell are two separate measures, they are not independent of each other. For example, if it smells bad, it often tastes bad. This gives multivariate analysis a decisive advantage over other forms of analysis. Multivariate analysis is also highly graphical in its approach. This allows an analyst to examine the inner or hidden structure of large data sets, and to visually identify the factors which influence the results. The expression 'a picture is worth a thousand words' is particularly relevant when trying to interpret large, complex data sets! (14).

The five steps of evidence-based statistics include the: Validity, Reliability, Generalizability, Unbiased and Completeness.

Evidence-based methods of practice are becoming widely used in many areas of healthcare. In recent decades, Statistics has come to play an increasingly important role in the methodology of the medical sciences. In recent years, clinical research has been redefined by the application of biostatistical methods. Statistics is a science that produces the best evidence methods. As it is known, science is developed by best evidence methods not by materials. Statistics is the main inferential tool used in science and medicine. Therefore it defines that is the center of all sciences and is the grammar of science. It provides a process for drawing valid conclusions and making reasonable decisions on the basis of such analysis. It has been reported that like as Randomized Clinical Trials and Meta-Analysis are the best evidence methods of Biostatistics that make reasonable decision in clinical research. Medicine must be building as a central part of its scientific base a solid underpinning of biostatistical knowledge (15,16).

The five steps of evidence-based medicine include the 5 A's: ask, acquire, appraise, apply, and assess were presented by Haughom J (17).

The five steps of evidence-based statistics include the: Validity, Reliability, Generalizability, Unbiased and Completeness presented by Figure 1.



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Figure 1. The five steps of evidence-based statistics include the: Validity, Reliability, Generalizability, Unbiased and Completeness

Research in clinical study must also base on evidence. The pyramid of Clinical Evidence and the level of evidence presented by Figure 2, Figure 3 respectively (17,18).



Figure 2. The pyramid of Clinical Evidence adopted from <u>https://www.tcd.ie/medicine/psychiatry/\_research/\_depression\_/evidence/, (17).</u>







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fact. the development of In multivariate statistical methods had hardly begun in 1898, when Bumpus was writing. The correlation coefficient as a measure of the relationship between two variables was devised by Francis Galton in 1877. However, it was another 56 years before Harold Hotelling described a practical method for carrying out a principal components analysis, which is one of the simplest multivariate analyses that can usefully be applied to Bumpus' data. Bumpus did not even calculate standard deviations. Nevertheless, his methods of analysis were sensible. Many authors have reanalyzed his data and, in general, have confirmed his conclusions. The development of biostatistics with multivariate methods has been interesting (19,20).

In short, all steps of the research should be based on evidence. In the first step of the research, the research design, sample size and power, sampling methods, statistical method, and interpretation of the results should have five evidence-based features.

### References

1. Burns PB, Rohrich RJ and Chung KC. The Levels of Evidence and their role in Evidence-Based Medicine. Plast Reconstr Surg. 128(1): 305–310, 2011

2. <u>Sur</u> RL and <u>Dahm</u> P. History of evidencebased medicine. <u>Indian J Urolv. 27(4)</u>; 2011

3. Feinstein AR. Clinical epidemiology. 3. The clinical design of statistics in therapy. Ann Intern Med. 69:1287–312, 1968;

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4. Feinstein AR. Clinical epidemiology: II. The identification rates of disease. Ann Intern Med. 69:1037–61, 1968.

5. <u>Baron</u> J. A Brief History of Evidence-Based Policy, Volume: 678 issue: 1, page(s): 40-50, 2018.

6. Hoe J, Hoare Z. Understanding quantitative research: part 1. Nursing Standard. 27, 15-17, 52-57, 2012.

7. Green J, Britten N. Qualitative research and evidence based medicine. BMJ 316:1230–2, 1998.

8. Naylor CD. Grey zones of clinical practice: some limits to evidence-based medicine. Lancet 1995;345:840-2.

9. Freidson E. Profession of medicine: a study of the sociology of applied knowledge. New York: Dodd, Mead and Company, 1970.

10. Prel JB, Röhrig B and Blettner M. Statistical Methods in Medical Research. Dtsch Arztebl Int 106(7): 99, 2009.

11. Anne-Laure Boulesteix1\*, Rory Wilson1 and Alexander Hapfelmeier2. Towards evidence-based computational statistics: lessons from clinical research on the role and design of real-data benchmark studies. BMC Medical Research Methodology 17:138, 2017.

12. Jim M. The Importance of Statistics. <u>https://statisticsbyjim.com/basics/importan</u> ce-statistics/ December, 2019.

13. Mushtak A.K. ShikerMAK., Multivariate Statistical Analysis, British Journal of Science 55 July Vol. 6 (1), 2012.
14. What is Multivariate Analysis? Bring data to life, CAMO Software. All rights reserved., 2011 15. Celik Y., Five Criteria for Evaluating a Scientific Manuscript, International Journal of Basic and Clinical Studies (IJBCS) 6(2): 1-4, 2017.

16. Celik Y., Statistics is the Science that Provides Best Evidence Methods for All Sciences, International Journal of Basic and Clinical Studies (IJBCS) 7(1): 1-6, 2018.

17. Evidence-Based Medicine, https://www.tcd.ie/medicine/psychiatry/

research/ depression /evidence/, December 2019

18. García G. Scientific evidence in surgery for the treatment of temporomandibular joint internal derangement, Stomatological Dis Sci;3:5, 2019.

19. Manly BFJ and Alberto JAN. Multivariate Statistical Methods, by Taylor & Francis Group, LLC, 2017.

20. Celik MY. The Miracle of Biostatistics in Medical Research International Journal of Basic and Clinical Studies (IJBCS), 2(2): 1-6, 2013.