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Biostatistics in Medical Laboratory Science: Implications

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Abstract

It is well acknowledged that biostatistics is a crucial tool in medical, clinical, and health research. The application of statistics to biological fields, medical fields, or medical studies is known as biostatistics. It covers a wide range of topics, including agriculture, genetics, biology, biochemistry, demography, epidemiology, ethnography, and many more, in addition to health, medicine, and nutrition. The medical laboratory scientist uses biostatistics to assess a variety of issues including life and death. The purpose of this article is to inform the general public about the uses of biostatistics in the field of medical laboratory science.

Keywords: Biostatistics; Medical Laboratory Science; Research; Medicine

Introduction

The use of statistical methods on biological data gathered prospectively or retrospectively is known as biostatistics. It is also known as the area of statistics concerned with information pertaining to biological processes. Statistical science has come a long way from the origins of number crunching; this is particularly true for the field of medical biostatistics. Biostatistics typically deals with biological data, such as those related to agriculture, veterinary medicine, and fisheries. However, the majority of people regard biostatistics as a discipline that studies information pertaining to human life and health. It seems preferable to categorize this as "medical" biostatistics when applied to humans only. Additionally, this qualification elevates the "medical" and "bio" components above the "statistics" component, making it more medical than statistical [1].

This topic's fundamental contribution to the management of data-based medical uncertainties is another underappreciated aspect of the field. As a result, the science of controlling empirical uncertainty relating to human health is referred to as medical biostatistics. This definition gives the topic a completely new perspective, thoroughly integrates it with medical disciplines, and eliminates its estrangement from medical experts. It may also set a higher standard and introduce a fresh mandate for this area. Without statistics, it would be difficult to declare the results of any clinical or laboratory investigation. Statistics is the foundation for drawing meaningful conclusions from the data gathered in a biological examination [2,3].

In addition, a number of researchers have gradually drawn attention to the numerous statistical flaws and errors found in a large number of biomedical publications, specifically noting that these observations affect "every stage of a medical research related to data analysis; design of the experiment, data collection and pre-processing, analysis method and implementation, and interpretation" [1].

Biostatistics in medical laboratory science: A Perspective

Medical laboratory science involves the examination of human and animal tissues, bodily fluids, excretions, and the creation of biological products for the purposes of diagnosis, treatment, monitoring, and research, to the extent that these activities are related to the health of the subject(s) or subject(s) of interest(s). In several fields of laboratory medicine, statistics is essential. Medical laboratory scientists can deal with data variance, organize and synthesize information, draw conclusions, and communicate meaningful experimental results when they have the understanding and proper application of statistical procedures. Furthermore, regular results and experimental data from validation study designs or verification protocols are typically subjected to certain statistical approaches [4].

Medical laboratory scientists can provide accurate, dependable, and exact results by using biostatistics during the pre-analytical, analytic, and post-analytic phases of their work in private and public health laboratories. Additionally, it supports biomedical research from the planning stage to monitoring, data gathering, analysis, and result interpretation. In situations involving medical uncertainties and in the management of these uncertainties, for instance, biostatistics plays a significant role in medical laboratory science [5].

Medical uncertainties

Uncertainties in medicine are well recognized, yet it is simple to understand them when their existence is acknowledged on two levels. It is the potential for decisions about the diagnosis, treatment, and prognosis of medical problems to be flawed at the level of the individual patient. Medical uncertainty at the group or community level refers to a lack of certainty on the involvement of primary and secondary risk factors for various illnesses as well as the precise impact of various promotion, prevention, and treatment strategies. Uncertainty about the current situation and its trajectory, with or without intervention, is a key element in each of these scenarios [6].

Management of Medical Uncertainties

The data are the fundamental inputs for managing empirical medical uncertainties. These demand skilled treatment because they are almost always plagued by aleatory variances and epistemic bottlenecks.

Example: Plasma replacement therapy for patients with COVID-19.

Consider the coronavirus disease (COVID) epidemic that is currently spreading (August 2020). Due to the fact that this condition is new, not much is known about it. Let's look at how medical biostatistics can help with some of the medical uncertainties around this condition. Since there is no recognized cure for COVID, it falls under the area of epistemology. No sensitivity analysis can be performed in this situation, however clinical trials on many potential treatment modalities are being carried out all over the world to address the treatment modality uncertainty. The most notable of these is convalescent plasma therapy, which in the past with other major infectious infections had shown positive outcomes [7].

Regarding the real effectiveness of plasma therapy in comparison to the standard of care for sick and critical patients, there is a great deal of ambiguity. If it works, how much and what types of patients are helped; young or old, with comorbidities or without comorbidities, serious or critical; patients going to the intensive care unit (ICU) or those not going to the ICU; how the length of hospital stay is affected; what kinds of side effects does it express; for how long does it protect; and so on and so forth. Thus, the difference in mortality between this treatment and normal care for serious and critical patients would be the impact. To begin with, this necessitates the identification of a medically important consequence. This is a clinical issue, but statistical calculations are needed to determine the sample size needed to detect that kind of effect with a certain power when it is there. This resolves the ambiguity about the size of a trial [8].

The strongest level of evidence for all such novel regimens is a randomized control trial; but, in this instance, obtaining informed consent may be challenging, and other ethical concerns can surface if essential patients do not receive plasma. A significant portion of individuals believe that this therapy will cure their condition. The results' application would therefore continue to be a mystery. By guaranteeing baseline equality between the cases and controls using the statistical approach of randomization if the sample size is high or by matching if the number is small, aleatory uncertainty regarding the effect of moderator (preexisting) variables on the outcome can be handled [9].

As was previously discussed, matching is possible in a record-based study whereas randomization can lead to ethical issues when assigning a patient to the control group. Age, gender, and the number of co-morbidities are the moderator factors in this situation, and they must all match. If they do not match, it may be necessary to use methods like logistic regression or the standardized mortality ratio to help determine the adjusted effect. These statistical approaches significantly lessen the doubts about the actual impact and produce a reliable conclusion [10].

A biostatistician who specializes in medicine would be aware of the disruptive nature of mediator variables. In this instance, the use of a ventilator and admittance to the intensive care unit can both significantly change the result. Either post-stratification or the determination of adjusted rates are necessary for the management of uncertainty regarding the impact of these mediators. Fundamentally, both are statistical solutions [11].

However, some unexplained variation may still exist as a result of unidentified or unexpected circumstances. They are regarded by statisticians as random error. A reliable conclusion about efficacy can be reached if this error is significantly lower than the factor variation. For this, statistical tests of significance are employed. Instead of testing for a null impact, the significance should look for a medically significant effect [12].

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