

**Statistics is the Science that Provides Best Evidence Methods
for All Sciences**

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Abstract

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. This development has led to new approaches, methods, and training programs in clinical trials, and evidence-based medicine. Therefore Bio-statistician can play a vital role in educating the editors, reviewers and authors.

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 Randomised 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.

Key words: Best evidence, Statistics, Biostatistics, RCT method, Meta analysis

Introduction

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 (1).

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In recent decades, Statistics has come to play an increasingly important role in the methodology of the medical sciences.

Biostatistics is the study of statistics in medical areas and concerned with best evidence statistical methods for clinical decisions. Medical research (including clinical research), and health services research all use statistical methods. Many other biological disciplines rely on statistical methodology.

Evidence-based methods of practice are becoming widely used in many areas of healthcare. Electronic databases provide the technology which makes evidence-based practice feasible. The most wellknown are as follows (2): MEDLINE, EMBASE, Cochrane reviews, OSHROM, World wide web, Other sources: such as conference proceedings, theses and official reports.

Citations in articles found on databases and informal discussion may lead to these, Textbooks: these can reflect current practice but only a few so far adopt a rigorous evidence-based approach and Library Access.

According to Sackett DL et al (3), collection of evidence-based medicine databases are as follows:

- The Cochrane Database of Systematic Reviews (Cochrane Reviews)
- The Database of Abstracts of Reviews of Effects (DARE)
- The Cochrane Central Register of Controlled Trials (CENTRAL)
- The Cochrane Database of Methodology Reviews (Methodology Reviews)
- The Cochrane Methodology Register (Methodology Register)
- Health Technology Assessment Database (HTA)
- NHS Economic Evaluation Database (NHS EED)

Evidence Based Medicine (EBM) caused great interest among health professionals. According to definition Evidence Based Medicine represents integration of clinical expertise, patient's values and best available evidence in

process of decision making related to patients health care (4). Evidence-based medicine as “integrating individual clinical expertise with the best available external clinical evidence from systematic research” in making decisions about patient care. Evidence-based medicine is “a process of life-long, self-directed learning in which caring for our own patients creates the need for clinically important information about diagnosis, prognosis, therapy and other clinical and health care issues evaluate our performance” (5).

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Understanding Randomised Controlled Trials

It is well recognised that some research designs are more powerful than others in their ability to answer research questions on the effectiveness of interventions. This defined as “hierarchy of evidence”. Figure 1 illustrates such a hierarchy.

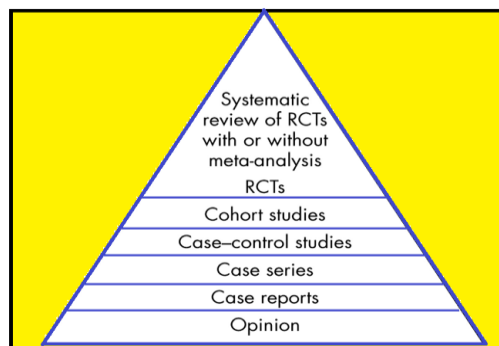


Figure 1. Hierarchy of evidence

The pyramid shape is used to illustrate the increasing risk of bias inherent in study designs as one goes down the pyramid. The randomised controlled trial (RCT) is considered to provide the most reliable evidence on the effectiveness of interventions because the processes used during the conduct of an RCT minimise the risk of confounding factors influencing the results (6).

The clinical trial is a relatively recent development in medical research. The randomized clinical trial (RCT) is the ultimate paradigm of clinical research. Many consider the RCT to be the most important medical development of the twentieth century, as their results are used to dictate clinical practice. A randomized clinical trial is an experiment. In an RCT, subjects are randomly assigned to one of two or more therapies. Subjects in an RCT are just as likely as unlikely to get the therapy of interest as they are to get the comparator therapy. Ideally the researchers are blinded to the group in which the subjects are allocated. The randomization

code is not broken until the study is finally completed (7).

The quality of a randomized controlled trial can be assessed by finding out the answers to the following questions (8):

1. Was the assignment to the treatment groups really random?
2. Was the treatment allocation concealed?
3. Were the groups similar at baseline in terms of prognostic factors?
4. Were the eligibility criteria specified?
5. Were the assessors, the care provider, and the patient blinded?
6. Were the point estimates and measure of variability presented for the primary outcome measure?
7. Did the analyses include intention-to-treat analysis?

The study of Randomised Clinical Trials is a member of Experimental study. Figure 2 illustrates the the study design scheme.

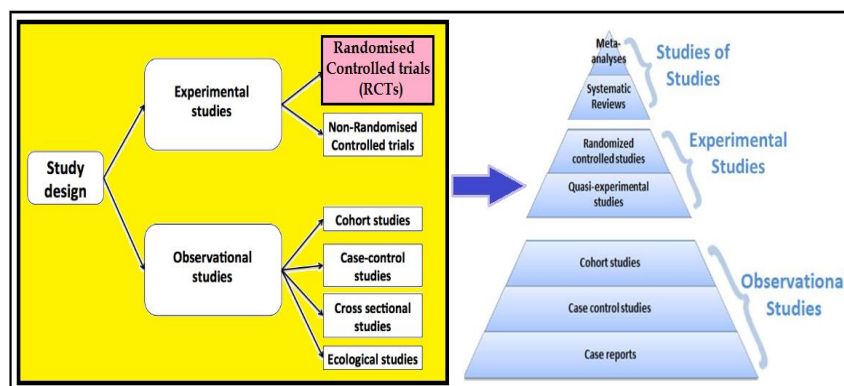


Figure 2 Study design of experimental and observational studies

Figure 3 shows the the structure of Randomized Clinical Trial (RCT).

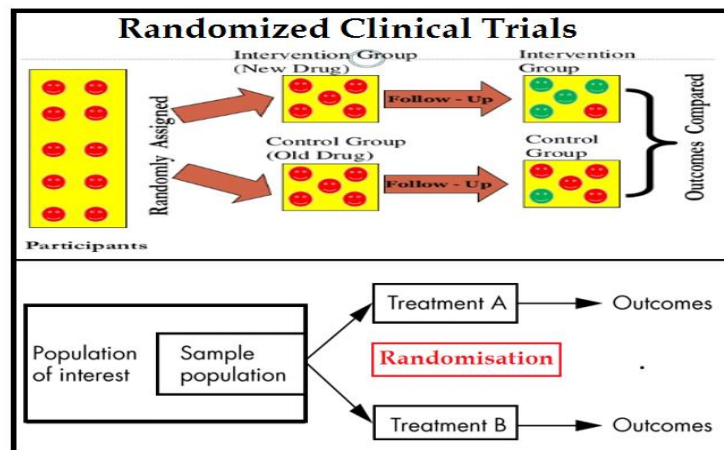


Figure 3. Randomized Clinical Trial (RCT).

Understanding Meta Analysis

The majority of meta-analyses combine data from randomised controlled trials (RCTs), which compare the outcomes between an intervention group and a control group. While outcomes for binary variables are expressed as ratios, continuous outcomes measures are usually expressed as 'weighted mean difference (WMD)' in metaanalyses (9).

Meta analysis is only one of many ways to summarize, integrate, and interpret selected sets of scholarly works in the various disciplines. First, metaanalysis applies only to empirical research studies; it cannot be used to summarize theoretical papers, conventional research reviews, policy proposals, and the like. Second, it applies only to research studies that produce quantitative findings, that is, studies using quantitative measurement of variables and reporting descriptive or inferential statistics to summarize the resulting data. This rules out qualitative forms of research such as case studies, ethnography, and

"naturalistic" inquiry. Third, metaanalysis is a method for encoding and analyzing the statistics that summarize research findings as they are typically presented in research reports (10).

The first formal attempt to combine information from multiple sources was made in 1904 by K. Pearson with the aim of ascertaining the effectiveness of vaccination in preventing soldiers from contracting typhoid. R. A. Fisher, another important figure in the development of modern statistical science, subsequently introduced a method for combining probabilities from different studies. In the late 1930s, W. Cochran and F. Yates described approaches that were essentially the same as modern fixed-effect and random-effects models⁸⁵, which were later formalized and generalized by Cochran. However, it was not until the insight of psychologists G. Glass and M. Smith in 1977—that outcome measures from different experiments could be standardized and put on the same scale—that meta-

analysis began to affect scientific research to a large extent. Meta-analysis was initiated almost simultaneously in medicine and the social sciences and was initially met in all fields with a combination of enthusiasm and condemnation. Methodology was formalized and developed in the two decades following 1977 in multiple fields^{16,89–91}, with influential studies spreading from medical and social sciences to EEC in the early 1990 (11).

The term “meta-analysis” was introduced by Glass (1976), who differentiated between primary analysis, secondary analysis, and meta-analysis. In the terminology of Glass, primary analysis involves analyzing the data of a study for the first time. Secondary analysis involves the analysis of data that have been analyzed before, for example to check the results of previous analyses or to test new hypotheses. Meta-analysis then involves integration of the findings from several independent studies, by statistically combining the results of the separate studies. Meta-analysis is used to integrate findings in many fields, such as psychology, economy, education, medicine, and criminology (12).

Statistics help us turn quantitative data into useful information to help with decision making. We can use statistics to summarise our data, describing patterns, relationships and connections (13).

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Bio-statistician can play a vital role in educating the editors, reviewers and authors. Bio-statistics is one such specialty subject which is taught minimally at graduate and postgraduate levels, and majority of the researchers are unaware of its significance either. To put an end to scientific errors is the employment of a biostatistician for every journal and editor should ensure that highest quality of statistical reporting is carried out. These steps and checking can be done during the peer review stage of the article where one can add statistical review stage. This allows the biostatistician to have a deeper look at the various mathematical observations. The ideal situation is to involve the biostatistician at the planning stage of the study itself (14,15).

According to Thomas; from here on, as far ahead as one can see, medicine must be building as a central part of its scientific base a solid underpinning of biostatistical knowledge. Hunches and intuitive impressions are essential for getting the work started, but it is only through the quality of numbers at the end that the truth can be told (16). In recent years, clinical research has been redefined by the application of biostatistical methods. This development has led to new approaches, methods, and training programs in clinical trials, and evidence-based medicine (17).

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