

Evidence Based Medicine: Clinical Trials

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Abstract

Evidence based medicine is very important for success of modern medicine. It is the ongoing process of using the most reliable evidence from clinical studies, scientific understanding and medical practice to make the best possible medical choice for patients. Evidence based medicine is how medicine advances and how we get improvements in life expectancy and quality of life. It not only identifies which treatments are effective but also those which are ineffective and may do more harm than good, and identifies areas where more investigation is needed and where there may be gaps in knowledge. In this review we focus on clinical trials.

Keywords: Clinical trial; Clinical Research; Evidence based medicine



Evidence based medicine can be found as far back as the 1940s. However, it was in 1972 that the concept first came into play, originated by Professor Archie Cochrane, in his book, *Effectiveness & Efficiency: Random Reflections on Health Services*. This was the foundation for evidence based research, and in 1992 a facility was funded by the UK government, with the aim of performing randomly controlled tests on health services [1].

From those early days, when methodical and clinical testing was still growing in merit, the practice of evidence based medicine has expanded and developed into the leading body in the systematic testing of medical treatments. Without the critical appraisal and unbiased approach of such research, the medical practice would surely be a very different arena [2-5].

The care of the nation is top of the list when it comes to evidence based medicine. Whether it is an individual's mental state or their physical being, evidence based medicine is of utmost importance in ensuring people's future health. Through clinical research, conducted by both medical and scientific professionals, evidence based medicine is able to assess the effectiveness and non-effectiveness of treatments, as well as the cost of such treatments, and work to generally improve people's health. This is a discipline that requires those of utmost professionalism, as it is such an important process in the future health of the nation, and there is no doubt that the research conducted will make a real difference to the treatment processes used in the future [5-10].

What is evidence based medicine?

Evidence based medicine is a methodological and systematic approach, which is of immense importance to the treatment of patients. It involves treatment

processes being clinically tested, not only to discover what benefits such treatment has, but also to find what consequences there are of using such treatment. It is also the case that evidence based medicine should aim to discover what treatments are cost-effective, in order for medical physicians to offer the best treatment available, but at a good price [7-10].

This is all done in controlled settings and through unbiased procedures. Without such research, the medical arena would not contain treatments that have been clinically tested to their limits, and also, medical professionals would not be so trusting of the care they give to their patients.

Why is evidence based medicine so important?

Without the guidance of evidence based medicine the governing bodies of several countries would only have a limited understanding of the benefits and consequences of treatments, and would be just as unknowing of each treatment's cost-effectiveness. The national health services in the countries, private clinics and other medical institutions would not be able to offer such life changing treatments, which can help to battle medical conditions ranging from cancer, asthma and other serious illnesses [10-12].

However, the research conducted by evidence based medicine will not only play a major part in the treatment patients are given, but will also give physicians the chance to apply medical treatments for the individual, catering for their specific needs and requirements. There is also the small matter of evidence based medicine playing a part in the guiding principles and procedures that medical organizations use [1, 13].

The National Institutes of Health defines "clinical research" as research conducted with human subjects (or on material of human



origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Indeed, Clinical trials are important component of evidence based medicine. A clinical trial is a research study that finds new ways to prevent, diagnose or treat disease. Cancer clinical trials test new treatments in people with cancer. These treatments investigate promising new drugs, drug combinations, new approaches to surgery or radiation therapy, and advances in new areas such as gene therapy. Clinical trials are the final step in a long process [9-11].

Human subject research to develop or evaluate clinical laboratory tests (e.g. imaging or molecular diagnostic tests) might be considered to be a clinical trial if the test will be used for medical decision-making for the subject or the test itself imposes more than minimal risk for subjects.

Biomedical clinical trials of experimental drug, treatment, device or behavioral

intervention may proceed through four phases:

Phase I clinical trials test a new biomedical intervention in a small group of people (e.g., 20-80) for the first time to evaluate safety (e.g., to determine a safe dosage range, and to identify side effects).

Phase II clinical trials study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and to further evaluate its safety.

Phase III studies investigate the efficacy of the biomedical or behavioral intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.

Phase IV studies are conducted after the intervention has been marketed. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use [10-16].

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