The ethical approach to evidence-based medicine

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Abstract

This paper will explore the role of evidence-based medicine in ethical practice of health care professionals. It will also address some of its limitations and potential for negative impact on health care.

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Evidence-based medicine has had a major impact on health care in the last 30 years. This approach has lead to the critical appraisal of therapeutic knowledge. Archie Cochrane, an epidemiologist, gave a series of lectures in 1972 regarding his reflections on the effectiveness and efficiency of health services.[1] He introduced the scientific and practical evaluation of treatment modalities and drew attention to the possible harm and even iatrogenic injury, as well as waste, that can occur if systematic review of interventions is not done.

The concept of evidence-based medicine is defined as "the process of systematically finding, appraising, and using contemporaneous research findings as the basis for clinical decisions".[2] The practice of evidence-based medicine implies the use of individual clinical expertise, in combination with a systematic review of the best available clinical evidence, which is derived from the relevant research.[2] The aim is to use the most efficacious interventions in the pursuit of quality and quantity of life. This approach is especially useful in medical education to teach best clinical practice.

Evidence-based medicine relies on a hierarchy of evidence, which is ranked from absolute proven interventions to the least reliable knowledge.[3] The process of examining evidence involves multiple steps, where the first involves using the available information to formulate answerable questions.[4] The next step is to search for the evidence that can best answer these questions. The third step involves the evaluation of the evidence for its importance and validity. The clinician thereafter has to integrate these findings with her/his clinical expertise and apply it in clinical practice in combination with patient values. Continuous evaluation of clinical practice is the last ongoing step. There are at present several evidence-based resources to assist health care professionals, which provide peer reviewed critical appraisal of the best evidence for intervention or treatment, of which the Cochrane database is probably the best known.

The practice of evidence-based medicine usually assists in answering two questions, namely what is in the best interest of the patient and how should we allocate of health care resources fairly.[5] Evidence-based medicine enables the health care practitioner to strive for a clinical ideal, which addresses our ethical responsibility towards the best interest of our patient. For this purpose health care professionals should pursue health.[5] This should be done through the pursuit of the most effective ways of achieving health, which is a generally acceptable value shared by most people. As professionals it is through the pursuit of truth, that we will find most effective means to health.[5] The premise is in general valid, and most health care professionals and researchers will be in agreement with this premise. A second premise is that if we pursue evidence-based medicine, we shall increase the likelihood of finding truth, which shall ensure the provision of the effective means to achieve health.[5] This is not necessarily valid, since the assumptions are that there is no bias and that inferences made are not influenced by subjective interpretation.

This necessitates an investigation into the potential limitations of evidence-based medicine. The first is that there may be the potential for bias.[5] Funding of health care research is conducted where there is commercial value involved for the intervention tested and can in this way create bias towards research that will generate good return on investment. Furthermore, there can be a technical bias, since we may conduct only research where we know how to do it, leaving other fields of health care with inadequate or no research. Another potential bias is a publication bias, since only positive results are published, leaving huge gaps in knowledge regarding interventions that did not whave a positive effect on health or, indeed, did harm.

Evidence-based medicine is, furthermore, better suited to secondary and tertiary health care, since it deals with a single disease with well-defined symptoms and clinical signs. However, in primary health care it is not always that easy, since the symptoms are

often non-specific, are still evolving and may be related to complex psychosocial problems.[6] Evidence-based medicine is also not very helpful in, especially, rare diseases. At the same time, evidence may also be supported poorly by relevant research, since studies may contradict each other or may be inconclusive. The application of the evidence may also be problematic due to the individual patient with confounding health care problems or due to patient value systems.

The gold standard for evidence-based clinical information is the randomised controlled trial (RCT), which is a valuable approach to limit the use of worthless treatments and promote effective treatments.[6,7] Unfortunately RCT is limited to only a section of health care management, where interventions are involved in a single entity under investigation, leaving other health care sections not being examined.[6,7] Furthermore, there should be genuine "therapeutic equipoise" which implies that the there is a valid doubt about the value of the treatment modalities under investigation, which can only be answered by the RCT. Again this is difficult to achieve when there is great benefit to be obtained if an intervention will have great commercial value. Another important factor is that RCT only produces the average effect, while some patients may experience harm crudely applied. RCT can therefore generate valuable evidence for efficacy in the context of a single disease with measurement between interventions, but there is a paucity of RCT in primary care and other fields of health care.[6] This is especially true also for rare disease where it is not possible to conduct RCT or where other ethical issues are involved, such as lack of informed consent as illustrated by GSSI-2 trial, which is widely quoted as evidence due to its outcome.[8,9]

As already referred to above, the information generated by the RCT does not take into account non-quantifiable factors and does not provide a framework to integrate such knowledge, such as differences in social and cultural backgrounds that may impact on health.[6,7] RCT also relies on the classical theories of statistical inference, requiring large sets of data.[7] An important argument regarding the use of statistical inference is whether this truly provides measures of objective probability versus rational subjective interpretation.

Another limitation of evidence-based medicine relying on RCT is that new skills and interventions, which should be developed to ensure that there is continuous health care improvement, may be difficult to initiate. These very necessary novel interventions will initially not be supported by evidence and a good example is pain management in neonatology. Pain management per se is difficult to assess, and even more so in newborn babies. At the same time the majority of therapies are being used off label for these infants, and therefore there is no evidence to be derived from the appropriate RCT. This leads to the situation that there is little active research into this field, which is potentially harmful to neonates. We can conclude that there are competing claims that cannot all be resolved by evidence-based medicine, i.e. relying on RCT for the evidence.

Another important negative impact of evidence-based medicine is that it may create a barrier to quality health care in the context of high demand versus scarce resources. The different stakeholders may interpret the evidence differently and their conclusions will not be congruent with each other.[10] Problematic values in this context are justice and quality of life, which are often replaced by more easily measured values such as cost and mortality respectively. Resource allocation on the basis of evidence-based medicine involves value judgements and often a lack of evidence means a lack of value.[10] Government and service providers may use evidence-based medicine to the disadvantage of patients when they agree to only fund what has been proven by evidence-based medicine, which usually implies RCT. This again implies that only conditions that are well researched will get access to resources, while other areas where there is little or no evidence, will receive no resource allocation.[10] If evidence-based medicine is used for "evidence-based purchasing", it will create a tension between the best interest of the individual versus the population .[10]

A further problem with evidence-based medicine is that it is doctor-driven and patients have little influence on the subject matter. Another concern is that it only focuses on the evidence for efficacy and not on the way the information was obtained. Again the GISSI-2 trial is often quoted for proof of efficacy, while the study did not obtain informed consent from participants and therefore was conducted not respecting patient autonomy.[8]

In conclusion evidence-based medicine is probably a simplistic solution to inherent complex problems. However, even if there are limitations, it is a shared value in the sense that we all want to be treated with the best proven intervention and therefore we do expect health care professionals to practice their profession by combining their individual clinical skill with evidence-based medicine.

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