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Evidence-based medicine — is psychiatry ready?

Evidence-based medicine is a phenomenon that is sweeping across medicine. There are a number of reasons for this. Firstly, it is a response to an earlier period when treatments were anecdotal and poorly supported by empirical data. Treatments were often based on an extrapolation of pathophysiological principles and logic. Other treatments developed on the basis of endorsement by authoritative proponents. Nowhere was this more apparent than in psychiatry, where treatment schools evolved on the charisma of a few leaders (e.g. Jungian psychotherapy, Freeman and frontal lobotomy). This has increasingly made way for a research-based approach to medical care, in which only those interventions validated by methodologically rigorous study are regarded as acceptable. Lastly, external influences such as managed care are embracing the evidence-based approach. Having started as a cost-containment exercise aimed at eliminating unnecessary investigations and treatments, managed care organisations are increasingly defining treatment algorithms for many conditions based on the available evidence of efficacy.

Clearly it would be ideal if treatment guidelines could be drawn up solely on the basis of data validated by replicated, large, well-controlled, multicentre trials. There could be no losers in this scenario; patients would have access to optimal care, practitioners could sleep at night knowing that the treatment algorithms they used were based on the best available knowledge, and third-party reimbursers could be assured that their finances were appropriately allocated. Under such circumstances, it would be ethically untenable to expose patients to treatments the efficacy and tolerability of which is not adequately established. Similarly, from a medicolegal perspective, the evidence-based approach is undeniable solid ground.

How close are we to this ideal state? One of the problems of this approach is that the standards that define a study as adequate have become markedly more rigorous with time. Multicentre international trials with sample sizes of thousands of patients are now commonplace. The resources available to do this quality of trial are restricted to the large multinational pharmaceutical companies for purposes of new drug development. This is a substantial problem for many older treatments, which were accepted into clinical practice on the basis of clinical trial data that are suboptimal by today's standards. Lithium is such a casualty; and the absence of any financial incentive implies that large, controlled and long-term studies are unlikely to be done.

Other research ‘orphans’ include treatments for conditions which are rare (e.g. autism), or, because they are endemic in areas outside the First World, elude First-World interest and finance (e.g. malaria), or for which little new drug development is underway (e.g. mania). Indeed, even some important and common clinical areas are profoundly deficient in controlled data. Decisions nevertheless have to be made. An example is the issue of the length of maintenance antidepressant therapy; very few good data are available to guide in this area.

Clinical trials currently have extensive exclusion criteria: medically ill patients, patients on concomitant medical or psychiatric drugs, substance abusers, patients with comorbid psychiatric illnesses, and patients with personality disorders are typically excluded. It is therefore debatable whether findings of these trials can be applied to the large group of patients who would not have met the entrance criteria.

So where does this leave evidence-based practice? It remains the ideal state, where ample data would exist to validate each treatment choice. Certainly there are areas where this is the case, such as the utility of neuroleptics in schizophrenia. In areas where data are clear, deviation from accepted practice is becoming increasingly difficult to justify. At the same time, psychiatry is littered with treatments for which little or no data exist; it is becoming difficult to justify use of these modalities, particularly if substantiated alternatives exist. However, decisions frequently need to be made where there is a relative paucity of methodologically rigorous data. A common example is where first-line and well-established therapies have failed.

The validation by methodologically rigorous trials of treatments that have eluded such scrutiny must become a priority. In situations where a clear body of quality data exists, there can be little justification for deviation from guidelines based on that evidence. However, flexibility is essential in situations removed from the optimal. Evidence-based care should be embraced with caution. Psychiatry remains an immature discipline with a significant art to science ratio, the body of available knowledge is incomplete, and rigidity in areas of uncertainty may stifle innovation.

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