Evolution of Clinical Practice Guidelines for Psychiatric Disorders; Why, What and How?

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Introduction

The Indian Psychiatric Society has embarked upon the task of developing clinical practice guidelines (2003) which culminated in the development of draft proposals following a workshop (2004) at Jaipur which has already been published as a supplement for extensive interaction and review (2004). As a prelude to final acceptance and publication, it is pertinent to look back at the history, its current status and the future directions.

The beginning

The history of systematic efforts to identify empirically validated treatments for mental disorder is only a few decades old. Eysenck’s influential article on “The Effects of Psychotherapy, An Evaluation”, is the first study to look into methodological issues to distinguish effective from ineffective mental health treatments. (Nathan & Gorman, 1998) This initial emphasis validating psychotherapy research was important because “psychosocial researchers” have had to deal with unavailability of a true placebo control and the impossible nature of getting a relevant double blind. This lacuna has been source of debate whether and how to examine Psychotherapy outcomes which are fundamentally different and they are good deal more extensive than those in the history of psychopharmacology outcome studies which dates back to approximately 50 or so years. As it is, the failure of many clinicians to attend to the research evidence on many validated treatments is common to both psychosocial and pharmacological treatments (Wilson, 1996). However, research designs increasingly capable of discriminating efficacious psychosocial and pharmacological treatments have been developed. Assembling diagnostically homogeneous patient groups became easy with the appearance of diagnostic systems. Further to this, practice guidelines, reflecting more potent outcome methodology and more effective treatments have come into being. There are differences in the standards of proof, methodological criteria used for outcome studies and the degree to which importance is accorded to clinical experience and judgement by different practice guidelines.

Why are clinical practice guidelines necessary?

The primary reason is to ensure that patients with psychiatric illness receive the highest possible quality of care. Thus, the guidelines specify the special training, knowledge, and skills required to provide psychiatric treatment. Special emphasis is placed on fundamental components of psychiatric assessment (history taking; physical, neurological, and mental status examination; laboratory and neuroradiographic tests) as well as the process of consultation systems analysis. Treatment issues receive special attention as well and emphasize treatment intervention based on a biopsychosocial model. The importance of family and social assessment and intervention in the treatment plan is also outlined. The last part of the guidelines discuss special issues such as supervision standards, ethical standards and research issues (Hayward et al, 1995).

These guidelines outline the knowledge base and clinical skills necessary to render quality care; and sets the basic standards for the diagnostic evaluation, psychotherapeutic, and pharmacologic treatment of this patient population. These guidelines are not meant as a mandatory set of imposed standards that the psychiatrist must follow. The uniqueness and necessities of each individual clinical situation is paramount. Ideally, guidelines should be based on well-developed scientific evidence such as controlled clinical studies. Because medicine is a continuously evolving field, guidelines by their nature are a hybrid construction from evidence based on scientific investigation and evidence based on consensus opinions from clinicians. The Institute of Medicine (IOM) has outlined the process of developing guidelines that incorporates these principles. As the primary goals of medicine are the prevention of disease and the promotion of the health and well-being of the patient, these guidelines will help meeting the ends by ensuring excellence in the clinical care of patients with combined medical and psychiatric illness (Gitlin et al, 1998).

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What constitutes a good clinical guideline?

First, they define practice questions and explicitly identify all their decision options and outcomes. Second, they explicitly identify, appraise and summarize, in ways that are most relevant to decision-makers, the best evidence about prevention, diagnosis, prognosis, therapy, harm, and cost-effectiveness. Third, they explicitly identify the decision points at which this valid evidence needs to be integrated with individual clinical experience in deciding on a course of action (Sackett et al., 1997). Thus, the good ones don’t tell you which decision to make, but identify the range of potential decisions and provide you with the evidence which, when added to your individual clinical judgment and your patient’s values and expectations, will help to make our own decision in the best interest of our patient.” There are three questions that must be answered before integrating “a guideline into the care of your patients,...for that implementation requires changes in your behavior...” “Are the recommendations in this guideline valid? Is this valid guideline or strategy potentially useful (or important)? And Should this guideline or strategy be applied in your practice?” A Good guidelines come from evidence-based medicine (EBM), which is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients (Stoudemire et al., 1998).

The five steps of EBM are: 1) convert clinical information needs into answerable questions. 2) track down the best evidence with which to answer them. 3) critically appraise that evidence for its validity (closeness to the truth) and usefulness (clinical applicability). 4) apply the results of this appraisal in clinical practice and 5) evaluate your clinical performance.

EBM can address each of the five clinical objectives of: achieving a diagnosis, estimating a prognosis, deciding on the best therapy, determining harm, and providing care of the highest quality.

Guideline Development

There are three main methods of developing guidelines (Woolf, 1990). Evidence Based Guidelines also describe the strength of the evidence and try to separate opinion from evidence. Consensus Guidelines is the most common method of guideline development. Also known as global subjective agreement of experts. Persons and Beck (1998) believe that consensus guidelines are a bad idea: according to them, The consensus guideline is founded on expert opinion and the experts can be wrong. The expert opinion guideline methodology teaches clinicians to rely on experts, not empirical findings and The expert opinion guideline does not distinguish between clinical questions for which data are available and clinical questions for which no data are available.

The American Medical Association (AMA) attributes apply to the development process, stating that practice parameters/guidelines should 1) be developed by or in conjunction with physician organizations, 2) explicitly describe the methodology and process used in their development, 3) assist practitioner and patient decisions about appropriate health care for specific clinical circumstances, 4) be based on current professional knowledge and reviewed and revised at regular intervals, and 5) be widely disseminated. The IOM’s attributes are criteria for evaluating the finished product; these criteria include 1) validity, based on the strength of the evidence, expert judgment, and estimates of health and cost outcomes compared with alternative practices; 2) reliability and reproducibility; 3) clinical applicability and flexibility; 4) clarity; 5) attention to multidisciplinary concerns; 6) timely updates; and 7) documentation. Taken together, the IOM and AMA prescriptive have essentially set international standards for guideline efforts (American Psychiatric Association(APA), 2001).

How practice guidelines are conceived?

They are part of a movement toward evidence-based treatment, not as a treatment protocol demanding rigid application. There are many limitations in all evidence-based approaches-an insufficiency of evidence in many disorders; the evidence is not equally relevant to clinicians, staffs, and researchers; the techniques for integrating evidence are often in an experimental stage; the evidence proffered evade the issue of how to incorporate both social values and individual preferences within an ongoing patient-therapist relationship; and potential for misuse (there are many procedures in medicine for which there is simply no evidence, nor is there ever likely to be, that they work). In choosing between Treatment A and Treatment B, for instance, how does one balance (1) the proportion of responders to each possible treatment, (2) the degree of beneficial response, (3) the length of response, (4) the likelihood of adverse effects with each treatment, (5) other nonclinical costs, and (6) individual (or societal) preferences?

Summary & Future Directions

The efforts to develop practice guidelines draw on a lengthy
history of efforts to develop methodological guidelines for outcome studies. Nathan & Gorman (1998) have analyzed the outcome research of their day to identify strengths and weaknesses and propose additional design features to make future studies more sensitive and selective. In the Indian context, as in the West, “What has been well known to clinical scientists has been largely unknown” (Nathan & Gorman, 1998) to practitioners and the public. As a consequence, the best available data on the efficacy of treatments have been neither widely taught nor widely applied. With the availability of the draft proposals, this situation seems destined to change. The growing interest in the effectiveness and clinical utility of treatments, not simply their efficacy represents an additional impetus for wider dissemination of these treatments beyond the clinical research community to that of the practice community.

In this direction, the involvement and interaction of each and every member of our society by sharing their experience and findings can enrich the proposals made in the guidelines. The empirical data used at present been borrowed heavily from Western studies and experience, much hard work remains to develop more effective intervention and outcome methodologies sensitive to our people, land and culture. The draft proposals cover 5 common categories – Schizophrenia, Depression, Bipolar Disorder, OCD and Anxiety & Panic disorders. Efforts to increase the range and to have guidelines on other categories in the coming days are welcome developments. Once approved, it is hoped that these guidelines would pave the way for reasonable ‘standards of care’ in mental health practice in varied settings and contexts. All said and done, being a broad based democratic exercise, it is hoped that it will stand the test of time.

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