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Implementing Treatment Guidelines

In his important article in this issue of *Clinical Schizophrenia & Related Psychoses*, my colleague Troy Moore, PharmD, first reviews a number of key issues in guideline development, applications, and implementation in clinical settings, with a focus on schizophrenia treatment guidelines in the United States. In the second part of the article he compares and contrasts some widely cited schizophrenia guidelines. This editorial will raise two related questions: 1) what are the essentials of guideline implementation; and, 2) how do we evaluate the impact of guideline implementation?

The goal of treatment guideline implementation is improved clinical care. When it comes to treatment interventions, good clinical care requires provider knowledge of available interventions *and* provider knowledge of the history and characteristics of the individual patient being seen. That is to say, treatment guidelines presume that the provider will gather all relevant information about the patient in making decisions about interventions, though extant guidelines differ in the degree to which they explicitly define "relevant information" and in the degree to which they provide mechanisms for gathering and recording "relevant information" about patients. In the world of clinical treatment of schizophrenia, almost all patients come to us having received some prior treatment for their psychotic disorder. Under these circumstances, it is meaningless to talk about guideline implementation in the absence of detailed and accurate patient treatment histories. Moreover, one may reasonably ask what is the point of implementing treatment guidelines without concurrently measuring the outcomes that the treatments are intended to affect? The current catch phrases are "management by measurement" or "measurement-based care," but it is not new to the practice of medicine that quantifying treatment effects with objective measures is almost always preferable to subjective, qualitative judgments that are often inconsistent across observers.

Thus, effective implementation of treatment guidelines under real world clinical conditions rests on three legs: 1) a set of recommendations that is feasible and based on available evidence; 2) a patient recordkeeping system that contains the information needed to match patient with recommendation choices; and, 3) outcome measures that tell the clinician how well the treatment(s) is/are working. The task of putting together these three elements and making clinical judgments ultimately falls to the treating clinician, but there are many ways to support the process, and it is incumbent on provider organizations to use their resources to foster systemic measures that help achieve implementation goals. An obvious example is the electronic medical record, which, when properly constructed, can make information storage and retrieval enormously more efficient. Additionally, provider organizations can ensure that providers are given sufficient time and training to perform quantitative evaluation measures. Finally, guideline recommendation cues, prompts, and options can be programmed into clinical recordkeeping processes (1-3), in the same ways that many electronic systems alert clinicians to possible drug interactions, to allergies, etc. The abundant evidence of lack of adherence to guideline recommendations cited by Moore in his article underscores the need for systemic approaches that weave guideline implementation steps into normal workflow. Simply telling clinicians to follow a guideline, without attending to how the guideline can be implemented in their setting, is clearly ineffective.

Research to evaluate the effects of guideline implementation in psychiatry is methodologically challenging to do. The impact of guideline implementation on outcomes is presumably mediated through changes in care received by patients, though it is difficult to exclude the role of nonspecific factors that may accompany guideline implementation, such as increased attention, use of novel treatments, provider enthusiasm, etc. The

randomized, controlled trial (RCT), in which patients are randomly assigned to different treatment arms and evaluated by independent raters, is considered the "gold standard" for measuring effects of new interventions. The traditional RCT model, however, is not so easily applied to testing impact of guideline implementation. How does one randomly assign patients within a clinic setting to different treatments, when one of the treatments, guideline implementation, involves changing the entire clinic milieu? Moreover, clinicians could not conceivably be blinded to patient condition and yet would be expected to use two very different approaches in treating the same population of patients. Randomization by clinicians also has major feasibility problems, in that clinicians working side by side would have to practice very differently, within a single practice setting. Randomization by clinic is a more viable option, so long as the clinics do not overlap in the clinicians they employ or the patients they serve. The major drawback is that one needs a large number of participating clinics to mitigate site effects. This makes such studies very expensive to do.

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An alternative is to use the "mirror image" study design, which compares the period before beginning an intervention with the period after it begins. The appeal of this design is that the same groups of patients and clinicians can be compared under two different conditions. However, many studies using this design have arrived at erroneous conclusions because they have not included matching groups of clinicians and patients from within the same system who continue "treatment as usual." Apparent changes in the patient group receiving the new intervention may simply reflect regression to the mean, or be due to systemic changes unrelated to guideline implementation. For example, there may be major changes in budget and resources that have profound effects on quality of patient care.

The conclusion that research on effects of treatment guideline implementation in psychiatry is difficult does not mean it should not be done, but does mean that definitive results will be slow to emerge in the literature. To abandon guideline implementation until research on its effects is conclusive would, however, be unwise. Rather, clinical care systems should proceed with the elements of guideline implementation that everyone agrees make good clinical sense, such as improving medical recordkeeping and using objective patient assessment instruments. Within the context of the recordkeeping system, there should be clinical prompts and recommendations that are clearly evidence-based. In the realm of schizophrenia, for example, creating systemic approaches to identifying treatment-resistant patients and offering them trials of clozapine is quite feasible and strongly clinically warranted. The complete Moore paper can be found on page 00.

References

1. Trivedi MH, Kern, JK, Grannemann, BD, Altshuler KZ, Sunderajan P. A computerized clinical decision support system as a means of implementing depression guidelines. Psychiatr Serv 2004;55(8):879-885.
2. Garg AX, Adhikari NK, McDonald H, Rosas-Areliano MP, Devereaux PJ, Beyene J, et al. Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: a systematic review. JAMA 2005;293(10):1223-1238.
3. Kurian BT, Trivedi MH, Grannemann BD, Claasen CA, Daly EJ, Sunderajan P. A computerized decision support system for depression in primary care. Prim Care Companion J Clin Psychiatry 2009;11(4):140-146.

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