Priorities for Agenda Building: Mental Health and Primary Care

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Why do treatments rarely work as well in practice as they do in clinical trials? Why do we study approaches to treatment that are rarely used in practice? Does early treatment lead to a more favorable response?

These are the kinds of questions raised within the context of a public health model of treatment.[1] We cannot yet answer them as well as we would like, because the direction and culture of treatment research has been determined by a more narrowly defined regulatory model.[2]

In a treatment study driven by a regulatory model of investigation, there is no minimum effect size for the treatment, no minimum proportion of responders necessary, and no requirement for subject representativeness. Traditionally, the inclusions and exclusions have been so limiting, the conditions of treatment delivery so optimized, and the outcomes so narrowly defined, that widespread application is virtually impossible.

This regulatory model evolved in response to the legal requirements of drug approval and registration that made it essential to isolate pure disease entities. Patients are rigorously assessed, and virtually all of those with coexisting medical conditions are excluded. Outcomes are limited to the direct symptomatic measures of the disease in question. Observation periods are, typically, very short. To prevent administrative or delivery problems from masking the effect of the treatment, clinicians are usually specially selected and trained. Intrusions such as the administrative requirements of a health care plan or a third-party payer are minimized, and the treatment is provided in optimal form, often in an academic health center. Specific measures are taken to assure the clinician's compliance with the protocol and the patient's adherence to the procedures and treatments under study. The conclusion of such a study becomes the gold standard for what is possible under closely controlled or ideal situations.

As shown in the article by Klinkman and Okkes[3] in this month's *Journal*, regulatory styles of thinking have pervaded even those studies carried out in the primary care setting. The authors' solution—as part of their comprehensive view of mental health in primary care—is to begin with descriptive and clinical epidemiology, then perform sociological studies of the clinical encounter and characterization of the dimensions of clinical decision-making, and ultimately develop models of collaborative care.

There is now an opportunity in the field to adopt a clinically relevant public health model of treatment studies. In a public health model, exclusion criteria are minimal (and based only on concerns for safety). Age, sex, and comorbidity should no longer be the basis for exclusion, but rather be included as important dimensions to assure sample representativeness and clinical generalizability. Outcomes should be broadly construed to include performance, interpersonal relationships, function, disability, quality of life, morbidity, mortality, institutionalization, and health care resource use. Settings should be widely selected from a full range of academic and nonacademic institutions, specialty and primary care, and public and private facilities. Sample sizes should be large enough to assure adequate power.

The 1997 reorganization of the National Institute of Mental Health (NIMH) provides the opportunity to address the public health needs of our field. A top priority of the new structure of the Institute is to use a public health model to accelerate the development and widespread application of treatments for major mental disorders. Small, tightly controlled studies will be the beginning of the treatment research process, not the end. In this approach, the concept of treatment response is broadened from the simple dichotomy of responder/nonresponder to include speed, completeness, and durability of response. Moreover, this inclusive concept of treatment studies extends to research on interventions for rehabilitation and prevention, including the prevention of relapse and recurrence.

At the NIMH, we recognize that investment in infrastructure is necessary to fulfill the mandate of this new program. We are strongly committed to future growth and development and will launch significant efforts in the areas of training and research career development. Most research will be supported through the investigator-initiated project grant mechanisms (R01), but we will use contracts and collaborative agreements (U01) when appropriate. Supplemental funding of existing treatment grants will facilitate the evolution of their focus from efficacy to the effectiveness of interventions. Changes to existing studies may include the addition of comorbidly ill subjects and the expansion of outcome assessments to incorporate functional measures.

Approaches to dissemination need to be tackled head-on. Our collective goal should be to place the most powerful tools available into the hands of those who need them. As a field, we do not do a very good job of this, and research is needed to identify optimal strategies for dissemination.

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REFERENCES

1. Lebowitz BD, Rudorfer MV. Treatment research at the millenium: from efficacy to effectiveness. J Clin Psychopharmacol 1998; 18:1.
2. Leber PD, Davis CS. Threats to the validity of clinical trials employing enrichment strategies for sample selection. Controlled Clin Trials 1998; 19:178-87.
3. Klinkman MS, Okkes I. Mental health problems in primary care: a research agenda. J Fam Prac 1998; 47:379-84.