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APA Announces Start of Field Trials for *DSM-5*
Sites to Test Proposed Diagnostic Criteria in Real-World Clinical Settings

ARLINGTON, Va. (Oct. 5, 2010) – The American Psychiatric Association today announced the start of field trials to test proposed diagnostic criteria for the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders (DSM)*. Field trials will help assess the practical use of proposed *DSM-5* criteria in real-world clinical settings.

The field trials follow a public comment period in which more than 8,000 written comments on the draft diagnostic criteria were submitted to the *DSM-5* website by clinicians, researchers and family and patient advocates. Submitted comments were reviewed by *DSM-5* Work Groups and resulted in further refinement of the criteria.

Evaluation measures

For the diagnostic criteria that are being evaluated, the results of the field trials will address:

- Feasibility: are the proposed criteria easy for clinicians to understand and to use?
- Clinical Utility: do the proposed criteria do a good job in describing patients' psychiatric problems and help clinicians make decisions about treatment plans?
- Reliability: are the same conclusions reached consistently when the criteria are used by different clinicians?
- Validity: how accurately do the diagnostic criteria reflect the mental disorders they are designed to describe?

In addition, the field trials will help assess severity measures and cross-cutting dimensional measures. Severity measures are questionnaires and other tools intended to help clinicians evaluate how severe the symptoms of an individual are on a rating scale. Cross-cutting dimensional measures are tools for assessing symptoms that occur across a wide range of diagnoses, such as anxiety or sleep problems. Field trials will help determine whether these proposed tools provide useful information for clinicians and their patients, and whether they capture changes in symptoms over time to evaluate progress in treatment.

Two rigorous study designs

Since the *DSM* is used in many care settings, two standardized and methodologically rigorous study designs were developed by the *DSM-5* Research Group to gather data from a wide range of clinicians and settings.

"It is important that the proposed diagnostic criteria are subjected to rigorous and empirically sound field trials before *DSM-5* is published in 2013," said David Kupfer, M.D., chair of the *DSM-5* Task Force. "The two field trial designs will allow us to better understand how the proposed revisions affect clinicians' practices and, most importantly, patient care."

One study design was developed for use in academic or other large clinical settings, and will be employed at 11 sites, chosen from among 65 centers that responded to APA's call for proposals. Another study design was developed for use by individual practitioners and smaller clinical practices. These field trials

will be conducted in diverse care settings by 3,900 mental health professionals: 1,400 psychiatrists selected from a randomly selected sample, as well as an additional 2,500 volunteer clinicians, including psychiatrists, psychologists, social workers, and advanced practice psychiatric-mental health nurses. Participating clinicians must meet eligibility criteria and complete a web-based training seminar.

Clinicians in the field trials will evaluate new and existing patients at different stages of treatment using the proposed *DSM-5* diagnostic criteria and measures. All patients considered for participation in the field trial will receive information about the trial and must give their consent. None of the patients will have their identities revealed in the results of the studies.

In the field trials conducted in the academic and large medical centers, patient evaluations will begin with an initial baseline assessment by a clinician. A different clinician will conduct a second assessment 4 hours to 2 weeks later, to help determine reliability of the diagnostic criteria. This assessment will be repeated in a follow-up visit (4 to 12 weeks after the second evaluation) to test whether the severity and cross-cutting measures are sensitive to changes in treatment progression.

Academic and Large Medical Centers

The 11 large academic medical settings participating in field trials are:

Pediatric Sites

- Baystate Medical Center, Springfield, Mass.
- Columbia University/New York State Psychiatric Institute, Child Psychiatry Division, in collaboration with colleagues at New York Presbyterian Hospital/Weill Cornell Medical Center, New York Presbyterian Hospital/Westchester Division, and the North Shore Child and Family Guidance Center, Roslyn Heights, New York
- Stanford University, Lucile Packard Children's Hospital, Palo Alto, Calif.
- The Children's Hospital, Aurora, Colo.

Adult Sites

- Centre for Addiction and Mental Health, Toronto
- Dallas Veterans Affairs Medical Center
- DeBakey Veterans Affairs Medical Center and Menninger Clinic, Baylor College of Medicine, Houston
- Mayo Clinic, Rochester, Minn.
- University of California, Los Angeles
- University of Pennsylvania, Philadelphia
- University of Texas Health Science Center, San Antonio

More information on the participating academic large medical centers and the specific disorders being tested in field trials is available on www.dsm5.org.

Disseminating the Field Trial Findings

The DSM-5 Field Trials team will disseminate the results of these initial field trials through presentations at scientific meetings, with professional and consumer groups and in articles published in peer-reviewed scientific journals and DSM-5 source books.

After completion of the first phase of field trials and another period of public comment via the DSM5.org web site, work group members will make any necessary revisions to their draft criteria. This will be followed by a second phase of field trials for further examination of selected criteria, scheduled to take place in 2011 and 2012.

“The process for developing DSM-5 continues to be deliberative, thoughtful and inclusive,” said Darrel Regier, M.D., M.P.H., vice-chair of the DSM-5 Task Force, and APA research director. “Large-scale field trials are the next critical phase in this important process and will give us the information we need to ensure the diagnostic criteria are both useful and accurate in real-world clinical settings.”

The American Psychiatric Association is a national medical specialty society whose physician members specialize in the diagnosis, treatment, prevention and research of mental illnesses, including substance use disorders. Visit the APA at www.psych.org and www.healthyminds.org.

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