

DSM-5 TASK FORCE AND WORK GROUP UPDATE

APA Division of Research Report to the APA Board of Trustees

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Included in this report is an overview of the DSM-5 text development activities, the current progress and timeline for DSM field trials; the Scientific Oversight Committee's progress in reviewing proposed DSM-5 disorders; an overview of a Clinical and Public Health review process that will take place in conjunction with the SRC review; and plans for the remainder of 2011 and for 2012.

Progress in DSM Text Development

Susan Schultz, M.D., DSM-5 Text Editor, led a study group to create guidelines for the descriptive text that will accompany the diagnostic criteria to enable a streamlined approach for how the text is organized and used throughout the manual. A password protected SharePoint site was developed for collection, archival, and tracking of drafts. The site includes instructions and guidelines for various draft versions, and an overview of the phases of the revision process. A text coordinator has been assigned from each work group to be the point-of-contact for the work group's text. Monthly calls are being held with the text coordinators, Dr. Schultz, and relevant DSM staff to provide procedural guidance and answer any questions.

Text Coordinators are continually monitoring and updating documentation on the status of their work group's text that is still in preparation so as to keep the text study group and APA publishing apprised on chapter development across all of DSM-5. Finally, Text Coordinators are fulfilling a vital role in communicating to their work group various aspects of text development, such as providing guidelines to the respective work group chair about drafting introductory sections of his or her diagnostic chapter.

To date, draft text for 66 disorders has undergone an initial phase of editorial review. Draft text for all disorders will be available from the work groups for editorial review by December 15th. Below are the current number of text drafts received and pending:

Total drafts (mid- and full-length) to be submitted: 81

Total received as of November 15, 2011: 26 (32%)

Total of all drafts to be submitted (brief, mid-, and full-length): 199

Total of all received as of November 15, 2011: 67 (37%; with 68 in preparation = 68%)

Each of the DSM-5 work groups took part in two day in person meetings between October 11th and November 17th, with text creation as the primary meeting goal. All text will undergo editorial review during December and January, and an initial draft of the DSM-5 will be made available to the DSM-5 Task Force for review February 1st. The Task Force will meet February 27th-28th, and the major portion of the agenda will be dedicated to discussion and recommendations regarding the draft.

After draft chapters are received, they will be further reviewed for cross-cutting content by a select group of internal experts (e.g., Dr. Kim Yonkers for gender-related content). This is to ensure that all diagnostic chapters address, to the extent possible, diagnostic issues related to lifespan, gender, and culture in a thorough and consistent manner.

In the second half of December, and in January, the work groups will be able to incorporate findings from the field trial analyses relevant to their specific disorders into their edited drafts.

Field Trials:

The field trials were designed to examine whether the proposed DSM-5 criteria for disorders are reliable over time, to assess how useful these criteria are to clinicians, and to help determine how the proposed changes impact diagnosis as well as treatment planning. Proposed dimensional assessments (both those that cut across diagnoses and those used to help assess severity, disability, and impairment) are also being tested, to permit clinicians to rate the usefulness of such measures, and to better assess whether they should be used in DSM-5.

The primary disorders that were tested include those that are new, have major changes from DSM-IV, have the potential to strongly affect the way that patients are diagnosed and, thus, treated or where the proposals may result in changes in prevalence. Disorders we particularly wanted to assess include those such as autism spectrum disorder, major neurocognitive disorder (dementias), avoidant/restrictive food intake disorder, borderline personality disorder, and mixed anxiety/depression.

The field trials at the academic sites were extended to obtain the sample sizes needed to analyze the test-retest reliability of the criteria sets with sufficient statistical power to make confident conclusions. All first and second patient visits have now been completed. Nearly 2300 patients have taken part in the large academic site Field Trials to date. More than 600 patients were seen at pediatric sites, and over 1600 were seen at adult sites. Of these, nearly 600 pediatric patients and over 1500 adult patients took part in two visits to clinicians. All visits, (including visit 3) ended for all sites on October 31, though one site (Houston VA) will continue to see visit 3 patients to continue to evaluate the criteria for PTSD until November 30.

Data analyses for the clinical utility and cross-cutting assessment began on September 12th, 2011. Analyses of the clinical utility questionnaire are mostly descriptive and include a range of comparative analyses. Analyses of the cross-cutting assessment will be more complex involving test-retest reliability, specifically intraclass correlation analyses. Reliability analyses for the diagnostic criteria began September 30th. Clinician comments on the clinical utility of the disorders that have been tested have been made available to each of the work groups, and some groups have received preliminary data. The work groups are able to use these clinician comments to better assess the

usefulness of the criteria and accompanying measures and make any changes to ensure ease of use and understandability by clinicians.

DSM research staff is working around the clock to conduct data analyses and provide these to the work groups. We have obtained two additional temporary staff members experienced with SAS, SUDAAN, and SPSS statistical software output to assist in extracting the results from the analyses and transferring them to the templates to provide these to the work groups.

The DSM-5 Field Trials in Routine Clinical Practice Settings (RCP) are being conducted to involve specialty psychiatrists and other mental health professionals who work in small or independent practices. Volunteer recruitment for the RCP trials involved psychiatrists, advanced practice psychiatric-mental health nurses, clinical psychologists, clinical social workers, licensed counselors, and licensed marriage and family therapists. An additional representative sample of psychiatrists, randomly selected from the AMA Physician Masterfile, has been invited to participate in the RCP field trials.

Training for eligible clinicians in the main RCP study began July 12th. Clinicians will be able to recruit patients as soon as they complete training. The RCP trials will continue until February 29, 2012. The feedback we obtain from these clinical practitioners will provide us with additional information as to how useful the criteria are to clinicians who work in routine patient settings.

DSM Review Process

The DSM review process has involved a scientific review committee (SRC) appointed by the APA President to provide an independent scientific review similar to that which is conducted by the NIH Study Sections, or by peer reviewers for scientific journals. An additional review committee, the Clinical and Public Health Review (CPH), is now being formed to serve the same function, with the explicit goal of assessing clinical and public health impact of the changes. Results from all of these reviews are being made available to the workgroups for potential revisions and will be considered by the Task Force in making its final recommendations to the Board of Trustees (BOT), and available for the final BOT review process.

To date, 47 proposals have been submitted to the SRC for review and 35 have been reviewed. Feedback from these reviews has been provided to the work groups, which has been the basis for some revisions and resubmissions in several cases. Drs. Kupfer and Regier continue to hold monthly calls with Drs. Kendler and Freedman to discuss the findings and to improve the efficiency of the SRC review process. They have been utilizing these calls to ensure that the process is appropriately implemented, that submissions are adequately addressing the requirements, and that the needs of both parties are addressed. The SRC plans to continue to review proposals through the Spring of 2012.

The SRC reviews have focused on antecedent, concurrent or predictive validity studies that could be found to support revision proposals. In the case of disorders without a history of alternative criteria formulations, where clear deficiencies in DSM-IV criteria remained that were producing significant public health and clinical practice difficulties, revision proposals have been developed to address logical inconsistencies and conceptual errors based on available scientific studies and clinical experience. Such rationales for change will be reviewed by a Clinical and Public Health (CPH) review process that is currently being established. Although these reviews are proceeding as expeditiously as possible, we recognize that some decisions about the evidence base for revisions of criteria and text will be dependent on results from the field trials. There is already preliminary evidence from the academic field trials that will have a substantial impact on the revision proposals.

Plans for 2012:

Our primary focus for 2012 will be on completion of initial draft text for all proposed DSM-5 disorders, and data analysis of information gathered from the Large Academic Site and the Routine Clinical Practice (RCP) Field Trials. All of the text will receive editorial review throughout December and January, and a penultimate draft of DSM-5 will be presented to the DSM-5 Task Force for their recommendations by February 1st (though portions will be provided beginning in December, as these become available). The SRC and CPH will continue to conduct reviews through Spring of 2012. DSM criteria and text will continue to undergo changes based on reviews and recommendations of these various parties, as well on comments received from a 3rd public posting of the DSM-5 criteria on the DSM5.org Web site, slated for May, 2012. The final draft of DSM-5 will be submitted to the APA Assembly and to the BOT in Fall of 2012, and will be submitted to APPI press for publication by December 31st.