PUBLIC COMMENTS ON DRAFT VERSION OF GUIDELINE AND PANEL'S RESPONSES TO COMMENTS

Guideline Development Panel for Posttraumatic Stress Disorder

American Psychological Association

January 2017

(For final version of "Clinical Practice Guideline for the Treatment of Posttraumatic Stress Disorder (PTSD) in Adults," approved by APA Council of Representatives, see: http://www.apa.org/ptsd-guideline

PTSD Public Comments

Many comments received by the panel were points that were actually addressed in the draft document or the accompanying materials available for review during the comment process. However, given the frequency with which certain issues were raised, it seemed important to reiterate again several issues in these responses to comments. Additionally, since reviewers clearly did not find the information when they reviewed the guideline document, the panel specifically considered modifications to the document to make these points clearer in the final version. The majority of comments were about the specific treatment recommendations- and generally the comments focused on why a particular intervention should either be more strongly recommended or should be included with the recommended interventions. For each of these treatments, the panel summarized the process for arriving at recommendations and reviewed their original decisions as needed.

This document is a summary of selected comments organized by area of concern. Within any specific area of concern, representative comments are included as examples in this document. Interested parties may wish to review all comments that were received, as the panel members did, but for ease of understanding the panel process, only a selection of pertinent comments are included in this document.

Systematic review and selection of evidence

Several commenters expressed dissatisfaction with the panel's use of the systematic review produced by the RTI-UNC evidence based practice center. Some raised concerns about the review itself while others suggested other types of evidence that should have been considered in formulating the guideline recommendations. A selection of comments follows.

Commenter: Robert Whitney, PhD; robert.whitney@temple.edu

Comment: I consider the body of evidence to be the entire literature from which the subsets of psychotherapy studies were chosen. It is striking that the Jonas/Cusack analysis narrowed down the thousands of PTSD psychotherapy studies done since 1997 to just a handful, including 6 for CPT, 4 for EMDR, 11 for all exposure therapies combined (how can CPT be considered separate from cognitive therapy, while PE is seen as just a part of all exposure therapies?), and 3 for cognitive therapy. CBT had a larger final sample of 20- still not a lot to represent over 12 years of treatment research. The APA recommendations strive to minimize bias and maximize quality, which is admirable. Given the tiny final sample of acceptable studies out of thousands in the population, I can come to only two conclusions. Either the research done by thousands of mental health researchers in dozens of psychological and psychiatric journals over the last two decades is seriously inadequate, or the exclusion criteria used in the AHRQ analysis are excessive and impractical. If the former, this calls into question the meaningfulness of our body of psychotherapy research. Why were all these psychotherapy articles accepted if they are not sufficient to provide answers to our most important questions, such as does psychotherapy work for PTSD? Perhaps the latter conclusion, that the AHRQ analysis is just too exclusive, is a better explanation. I believe that APA, while being cognizant of the highest standards of research, should take a more conservative approach to something as important as the efficacy of our most widely disseminated psychotherapies. As in the IOM guidelines, perhaps the emphasis should be on the nature of research design more than on judged effectiveness.

The criteria have become so challenging, and the intricacies of research design so demanding, as to be impractical except for the most well-funded entities. Is it realistic to hold psychotherapy research to the same standards as we expect for pharmacological interventions, given their additional complexities?

Commenter: Peter Kotcher; pkotchermd@gmail.com

Comment: Following on this point, we believe that clinical practice guidelines should be designed to balance evidence derived from randomized trials and evidence derived from effectiveness studies, single case studies, case series and naturalistic studies. Without such contributions, we question if they are really clinical guidelines in any practical sense.

Even if there are no studies which meet the methodological standards applied in generating this CPG, it still seems unreasonable that there is literally no mention of psychodynamic therapy anywhere in the document. We have developed a spreadsheet of research which we believe supports the value of psychodynamic psychotherapy for your review (attached). While your team may argue that none of these studies meets the necessary level of current methodological rigor, we believe that they provide clear evidence that psychodynamic psychotherapy for PTSD is too important to be completely absent in the new APA CPG.

In their 2010 review, "A Guide to Guidelines for the Treatment of PTSD and Related Conditions"), (J. Traum. Stress, 23: 537–552. doi:10.1002/jts.20565), Forbes et al. endorse revision of the methodology by which guidelines are constructed to include: "… effectiveness research that explores the application of evidence-based treatments in routine clinical practice settings. … the data from those studies provide crucial information about the practical applicability of the intervention and could reasonably serve as a useful complement to RCT studies in establishing the evidence base for key clinical questions and Level I recommendations. This would require changes to the evidence rules governing virtually all existing trauma-related guidelines. Whereas this might be met with some opposition, most would agree that a compromise is required—the findings of RCTs and other carefully designed research are of vital importance in guiding clinical decision making, but they must be translated and applied with caution."

Commenter: David Wade, Psy.D. dwade@gorge.net

While I subscribe to psychologists utilizing research that meet high standard with statistically significant reliability and validity, it is my understanding is the AHRQ review has strict criteria and arduous process resulting in the need for adequate funds, personnel and time to meet the criteria. As an unintended consequence, robust studies that provide useful clinical information will not be included in AHRQ findings, consequently potentially skewing the goal of determining the most efficacious treatment in the APA report. Again, I appreciate the time and energy by the committee constructing PTSD guidelines. What I'm suggesting involves more work. Including studies outside the AHRQ would provide more accurate information for the guidelines.

Commenter: Laurie Donovan, LMFT, LCSW *ldonovanlmft@gmail.com*

I am not a researcher. I am a clinician. I value research. I also know what cannot be translated into a research project that might be valuable to clients. To negate this, and to rule out more than half the research that was otherwise acceptable because it was deemed "highly biased" is I believe a disservice to the larger than academic professional community and the public.

Commenter: Shawn Brndiar, LSW, LAC *shawn.brndiar@uchealth.org*

A more exhaustive review of the literature would be the first step and then present data that has been peer reviewed and note your specific worries about bias (your entire document REEKS of bias and clearly had an agenda when examining CBT and CPT as interventions). There are numerous studies that look at exposure, CPT and CBT and note that initially it is effective but there are no long term studies that adequately support the data longitudinally. Many people have relapses of the PTSD when using any type of cognitive therapy. Whereas, EMDR has a number of longitudinal studies that show long term remission of PTSD symptoms.

Commenter: Lewis Aron PhD and Susan Warshaw, EdD; drswarshaw@gmail.com

Comment: The American Psychological Association should be leading the field in terms of determining the adequacy of evidence, as opposed to relying primarily on methodology derived from other fields and following the standards developed by Medicine and the Department of Health and Human Services. APA should be critiquing the sole use of the RCT standard, and expanding the horizons of those who seek to develop clinical guidelines to include knowledge derived from other evidentiary forms that have important relevance to the treatment of human conditions.

Commenter: Michael C. Freed, PhD, EMT-B; mfreed@cbhw.org

We suggest that these guidelines focus more on delineating strength and quality of evidence by nuancing clinical trial design. While clinical trials are considered the gold standard of evidence, not all clinical trials are alike.

Efficacy studies tend to have stricter inclusion/exclusion criteria and have high internal validity, and thus study sample sizes can be relatively small to detect an effect. Also, study interventionists - or their protégés - tend to be the treatment developers. Efficacy studies seek to answer this research question: "could" this treatment work under ideal circumstances? Efficacy studies set the stage for effectiveness/pragmatic trials.

Effectiveness/pragmatic trials include more generalizable ('real world') samples, are conducted in clinical practice settings (e.g., versus a university lab), have high external validity, and because of the heterogeneity of samples, often require a larger sample size (relative to efficacy studies) and more resources to conduct. Effectiveness/pragmatic studies seek to answer this research question: "does" the intervention work in real-world settings?

Implementation studies (to include hybrid effectiveness-implementation studies) go beyond effectiveness/pragmatic studies by examining factors (e.g., intervention reach, adoptability, and sustainability) necessary for the intervention to be effectively delivered outside of the research context.

Comparative effectiveness studies offer the benefit of head-to-head comparisons of active treatments. These studies require relatively large samples and relatively high resources to conduct. This is because effect sizes between active treatments are likely to be small, and thus, the studies need to be powered appropriately to show a priori-determined non-inferiority or superiority. There is an inherent assumption in these studies that the treatments being compared are a) fully available to patients or b) are on the cusp of being fully available in the near future. These studies seek to answer this question: "which treatment should be used, when all alternatives are available to the patient?" If treatment alternatives are not available, these resource intensive studies offer little practical solutions to most providers and patients.

We make these suggestions not to devalue the existing evidence base, but as a means to encourage providers to be mindful of possible limits to the citied evidence and leverage important knowledge about how to make these treatments adaptable to their own clinical practice setting, scalable to people with PTSD who are not in treatment, and to encourage more effectiveness and implementation research going forward.

Commenter: Brian Mahon, PhD; drbmahon@aol.com

Comment: No The guidelines are issued with caveats, but there is insufficient attention to "anecdotal evidence," i.e., non randomized reports and insufficient attention to "common factors" research. I understand the desire to to follow AHQR and IOM and Cochrane Collaborative protocols for assessing validity, but these omissions in an area in which it is much easier to assess cognitive and behavioral approaches systematically lead to an unavoidable bias in the review and limits on its suggestions for further research. You could have reviewed both the non randomized literature and alternative treatments for what they suggest for further research or for various issues that have real-world importance and may affect generalizability (what exactly might be included in "brief eclectic therapy" for example; what about "complex trauma;" what about the clear preference noted by community members for attention to self-soothing and self-regulation techniques, and what about the importance of the common factor of therapeutic relationship to the community members [suggesting the integration of relaxation and hypnotic approaches for self-regulation into eclectic trauma-focused treatment; did anybody remember or reference all of the relevant data on individualized desensitization versus prolonged exposure?]). The appendix definitions of the various treatments are too brief, and there was no mention of psychodynamic factors that might need to be addressed in treatment and for which there is a large body of evidence, whether or not it is in the form of randomized trials (this could be included appropriately in "cognitive processing therapy" but this would not fit with implicit treatment biases. No empiricist worth the name would only attend to randomized trials--a parallel would be the tendency to ignore global epidemiological evidence and only look at randomized trials regarding dietary guidelines and their effects on longevity. The end result of these omissions is that the outside world will receive this review and these tentative guidelines as gospel to determine insurance reimbursement and availability of treatment. This is a profound disservice, and your caveats will ring hollow vis-a-vis the seeming definitiveness of the guideline's tables.

Commenter: Suzette Doescher, LCSW-S; practicalwisdom.suzette@gmail.com

Comment: Sounds like someone is afraid and jealous, or sour grapes; like you are jockeying for positioning in the mental health field.

It is not an "either/or". It is a "both/and". Your organization is not the be all/end all of all therapeutic approaches. The "one size fits all" attitude does not demonstrate the open mindedness is essential to our profession.

We still utilize Freudian approaches when it applies, as well as Jung and all the great innovators that have come before us. What's the difference now?

They did not fall out of favor because something new and better came along. And they didn't have any scientific evidence to support them.

The therapeutic process is dynamic, not static. It will never totally fit the scientific model. There will always be as much room for growth as there are people.

Don't worry, you won't lose your positioning in the mental health field because a new idea comes along. Stop competing and start expanding and embracing.

Commenter: Zona Scheiner; zonags@comcast.net

Comment: I do not believe it honors the purposes. It was stated The GDP endorses the following statement from the British National Institute for Health and Care Excellence (NICE, 2016) "When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The application of the recommendations in this guideline is not mandatory and the guideline does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian,"

However, what it does in fact is ignore the incredible amount of data and reviews that have been done to date by many credentialing organizations and spend a huge amount of time, effort and money, endorsing what seems to be preconceived notions.

In addition, it is the height of naivete to publish a document such as this and not be aware of the impact on people's ability to access treatment not recommended as Insurers find even more reasons to deny coverage.

Commenter: Charles W. Hoge, MD; Charles.w.hoge.civ@mail.mil

Comment: There is a fundamental problem with the APA draft CPG that leads to recommendations that are not sufficiently evidence-based. The core problem stems from the APA's decision to rely almost exclusively on the AHRQ PTSD systematic review, Comparative Effectiveness Review #92 by Jonas, et. al, as the core evidence synthesis for this CPG. This means that all of APA's recommendations are dependent on the quality of the methodology used by the AHRQ. Although the APA considered the Jonas, et. al. AHRQ report to represent a gold-standard review (citing IOM), this is incorrect when one looks at the methodology of this review. Because of the methodological flaws in the AHRQ methodology, the APA needs to reconsider its recommendations, particularly those concerning topiramate and exposure (or exposure plus cognitive restructuring) therapies, including its decision to

rate the quality of evidence for EMDR, brief eclectic psychotherapy, and NET lower than exposure or cognitively based therapies.

The APA recommendations do not reflect the evidence, due to serious flaws in the evidence synthesis that relied largely on the RTI Jonas, et. al. AHRQ systematic review.

Key problems with Jonas, et. al. AHRQ systematic review include:

1) Lack of adequate peer-review

Although the AHRQ report stated that it underwent peer-review, and invited public commentary, the report did not actually appear to have been subjected to a peer-review process consistent with standards. Key informants consulted during the study design phase, technical expert panel members responsible for establishing study questions, and "independent" peer-reviewers all overlapped with each other. Four of the five peer-reviewers listed in the report also served as key informants and/or technical expert panel members, or in one case was a close associate of a prominent member of all three panels. One member, with strong ties to industry-sponsored trials, served as both a key informant and technical expert. Due to the inadequate peer-review, numerous methodological problems with the AHRQ report were missed (see below).

2) Serious Methodological Problems with AHRQ report

Outcomes and Strength of Evidence. Research questions did not include clear definitions or prioritization of outcome measures. Outcomes encompassed PTSD symptom reduction or remission, quality of life, disability or functional impairment, return to work or to active duty, and adverse events. PTSD symptom reduction could be measured with virtually any clinician-administered or self-reported (non-blinded) measure, and there did not appear to be any clear prioritization of one over the other. Although certain meta-analyses limited studies to CAPS and PSS-I outcomes, it was unclear how these were weighted in final recommendations in relation to other data based on non-blinded self-report measures. Strength of evidence (SOE) was subjectively graded for outcomes that were not well defined, and there appeared to be many inconsistencies in how SOE (low, medium, or high) was determined (as noted below, for example, with psychotherapy trials).

Bias Assessment and Analytic Strategies. Bias assessment was based on a set of mostly yes/no questions that appeared on the surface to be generally consistent with other measures, such as the Cochrane bias assessment tool, but ended up being scored in a highly subjective manner (low, medium, high risk) inconsistent with Cochrane. For example, the only topiramate trial to show a statistically significant benefit on CAPS outcomes compared with placebo was a study incorrectly classified at medium bias risk that met virtually all criteria for very high bias risk, and would have been excluded from any other meta-analysis. Trials conducted by Dr. Davidson, who served as both a key informant and technical expert on the AHRQ report, were noted to have "unclear" randomization and allocation concealment, two key criteria for bias risk under Cochrane, and would have met criteria for high risk for other reasons, but were generally scored as "medium" risk in this report. The issue of assigning LOCF essentially equal consideration for bias assessment, in addition to intent-to-treat itself, is highly problematic. What this means is that if a study completed an ITT analysis but used the LOCF method to conduct the ITT, it was considered essentially on par with studies that used no ITT analysis at all. In other words, an acceptable method of addressing missing data, albeit not the current state of the science, was considered equivalent with studies that relied only on completer analyses and did not factor in missing data at all. Furthermore, there was lack of definition or clarity for how evaluators rated outcome measures as "equal, valid, and reliable." For example, it appeared that various self-report scales were given similar consideration as structured interviews. There was also no mention of how often evaluators disagreed.

Most importantly, there was no assessment of reporting bias (e.g. selective reporting of data), which is a major problem especially with industry sponsored trials. Numerous industry-sponsored trials that clearly meet Cochrane's criteria for high or very high risk of bias were deemed moderate risk in this analysis.

There was inconsistent handling of studies deemed high risk of bias. Studies rated as high risk were selectively excluded from certain analyses but included in others, and there did not appear to be consistency in how this was done. In addition, studies were only included in quantitative analysis if they were deemed to be sufficiently "homogeneous." The authors stated that "when quantitative synthesis was not appropriate (e.g., due to clinical heterogeneity, insufficient numbers of similar studies, or insufficiency or variation in outcome reporting), we synthesized data qualitatively." This resulted in 92 studies included in the qualitative review and 77 for the quantitative analysis. This indicates lack of systematic or a-priori decisions on which studies were included in which types of analyses. Heterogeneity measures clearly showed that many of the core analyses had high heterogeneity, and thus it was not clear what the criteria were for including studies that were sufficiently "homogeneous" in these analyses. It was also unclear exactly how qualitative synthesis was used or how this informed the quantitative approach. There was no clarity on which conclusions were based on qualitative versus quantitative data synthesis.

The conduct of sensitivity analyses throughout the report was also inconsistent. For some treatments studies were added back in one at a time, for other treatments studies with high risk of bias were added back in, and for other treatments that excluded studies with high risk of bias, no sensitivity analysis was conducted at all. Most experts in the field agree that all qualifying studies that meet inclusion criteria should be included up front, and that approaches need to be consistent. If the I2 is high, which is virtually a given for PTSD studies, then that is taken into consideration as a limitation in considering the overall strength of evidence. In some cases researchers may opt to permanently remove certain outlier studies, but whatever is done with exclusions or adding studies back in for sensitivity analyses, the approach must be consistent, which was not the case in the AHRQ report.

Problems with Analysis of Psychotherapy Trials. For psychotherapy studies, the principal meta-analyses prioritized comparisons involving inactive controls (e.g., wait-list, usual care, no intervention, sham) over active control conditions (e.g., PCT, supportive psychotherapy, IPT). This is highly problematic, as the active control conditions reflect stronger studies. Furthermore, when answering the question of comparative effectiveness, it was not clear that studies involving direct head-to-head comparisons of two active treatments were prioritized over inactive controls. Meta-analyses stratified results to see if there were differences when wait-list studies were analyzed separately from studies that relied on TAU controls, although the limitations of TAU is usually very similar to wait-list. Sensitivity analyses added in studies that included PCT, supportive therapy, or supportive counseling as controls along with the wait-list/TAU conditions in certain analyses but not others, and further sensitivity analyses added in studies with high risk of bias. However, these sensitivity analyses were handled differently for different trauma-focused treatments, and it was unclear how these analyses changed the overall conclusions reached by relying largely on TAU and wait-list studies.

Most problematic was the report's conclusions highlight exposure-based treatments (PE) as the one with the highest level of evidence among all treatments (repeated in the APA recommendation to offer either exposure or exposure plus cognitive restructuring). There were marked differences in the way in which study data were handled for the different active treatments. Sensitivity analyses for PE presented in the report clearly showed much lower effect sizes and high heterogeneity when PCT control studies were added to wait-list and TAU studies, yet this did not change how PE was given emphasis in the

conclusions. For CPT, three of Dr. Resick's RCTs were listed as high risk of bias but no sensitivity analyses including these studies were conducted, as was done with exposure treatments. A separate meta-analysis for studies that compared CPT with PE concluded that there was insufficient evidence for one being more efficacious than the other, yet this is not factored in to how the report's conclusion reads, which prioritized PE. For EMDR the data on efficacy in reducing PTSD symptoms or loss of diagnosis showed that the heterogeneity of studies were highly comparable to the heterogeneity in CPT or PE trials (when PCT controls were included), effect sizes were similar, and sensitivity analyses resulted in minimal changes compared with included studies. For loss of diagnosis, the NNT of 2 was identical for PE, CPT, and EMDR. However, based on all these data, the authors of the AHRQ report chose to rate the overall strength of evidence as low for EMDR, moderate for CPT, and high for PE, which is similar to how the APA CPG recommendations also reads. These distinctions appear to be arbitrary and unsubstantiated, based on the data and limitations actually presented in the AHRQ report. In conclusion, there is strong evidence that these treatments produce comparable results, and it is a mistake to draw strong distinctions between these treatments, as was done in the AHRQ report and mirrored in the APA CPG draft.

Network Mata-Analysis. Network meta-analysis was used to compare pharmaceutical interventions with one another, and results, for example involving topiramate, were highlighted in the abstract and conclusions of the AHRQ report. However, this is a controversial approach, and slope of change was the only outcome used, which is not a clinically meaningful outcome, particularly for short term (up to 12 week) trials.

Treatment Follow-Up Duration. Another problem in the report is that it makes no effort to distinguish between outcome data obtained at 4-12 weeks and longer-term follow-up, despite considerable data on longer term outcomes for some treatments. For the forest chart data, short term efficacy was essentially lumped together with longer-term outcomes in supporting the conclusions reached. This is particularly problematic for psychopharmacology trials.

3) Many of the key conclusions in the AHRQ report (and hence the APA CPG draft recommendations) are incorrect:

a. The emphasis on exposure therapies having greater strength of evidence compared with CPT, and lower strength of evidence for EMDR, and other TF-CBTs is mistaken based on the many methodological problems noted above, such as prioritizing wait-list and TAU studies over much better controlled studies that involved active control conditions or direct head-to-head comparisons, inconsistency in sensitivity analyses, inconsistent approaches in qualitative synthesis, and subjective determinations of strength of evidence. The conclusions contradict virtually every other well-conducted review/meta-analysis, including Cochrane, and should be reconsidered.

b. The AHRQ's highlighting of paroxetine's efficacy in remission and recovery from PTSD is incorrect because the authors failed to check the Cochrane Registry of Controlled Trials (which includes clinicaltrials.gov), and missed one of the largest paroxetine trials (GalaxoSmithKline) that was a negative study for both primary and secondary outcomes, and had longer term follow-up. Had they included this, paroxetine would not have received the level of endorsement it did in the abstract and conclusions.

c. The highlighting of venlafaxine efficacy stems solely from two Davidson trials that are rated as moderate risk of bias by AHRQ, but at very high risk of bias in other assessments that have reached entirely different conclusions. Davidson's own data showed that the efficacy of venlafaxine drops off at 24 weeks, but this was missed because all outcome time points were combined.

d. The support for topiramate, highlighted prominently in the AHRQ report and included as a suggestion in the APA CPG draft appear to be driven largely from a single 12-week study (Akuchekian, et. al.) that found a statistically significant difference between topiramate, used adjunctively with other psychotropics(including neuroleptics and mood stabilizers), versus placebo that was inappropriately determined to be at medium risk of bias. Of the three very small pilot studies included in the main quantitative analysis, the Akuchekian study was the largest and the only one to reach significance. This study was incorrectly categorized by AHRQ as being at "medium" risk of bias, although it met virtually every criteria for high risk of bias using both the Cochrane tool and AHRQ's own criteria. There was no indication of how participants were randomized or whether allocation concealment was adequate. There was inadequate comparison of groups at baseline, and unclear indication of how patients or providers were masked. Placebos were produced by the institution's own pharmacy, increasing risk to allocation concealment. Although the authors reported using CAPS for DSM-IV, it was unclear if they used it for diagnosis and they did not report what scoring process they used. CAPS scores at the beginning of the trial were reportedly moderate (48-50). The only results presented in the only two data tables in the paper were for 12-week frequency and intensity mean scores of 11 of the 17 individual PTSD symptoms (the other symptoms were missing), and a t-test for difference in total CAPS scores at this single time point, which is inconsistent with any other clinical trial in this field. There were no change scores or data for any of the other study time-points during treatment, and no ITT analysis. The likelihood of reporting bias is extremely high. Furthermore, the chronically ill participants had to have been on a variety of other psychotropic medications for at least six months in order to meet inclusion criteria, which included neuroleptics, valproate, and carbamazepine, medications usually reserved for severe mental illness (psychosis, bipolar), not PTSD. The data clearly do not support any suggestion or recommendation regarding the use of topiramate in PTSD.

e. The AHRQ decision to highlight risperidone as possibly being effective is inconsistent with other interpretations of the evidence, including the VA/DoD CPG committee that downgraded risperidone to "D" after the largest multicenter trial by Krystal. The AHRQ included one study in its main analysis that involved veterans with active psychosis, and the search strategy completely missed another study (2006, Padala, et. al.).

Panel Response:

The panel followed the practices for guideline development as described in the IOM report and as endorsed by the Guidelines International Network (GIN). To that end, the panel relied on an independent systematic review conducted by an external entity that followed methodology similarly described and endorsed by IOM and GIN.

The APA has determined that high quality clinical practice guidelines are an important investment for the field of psychology and more importantly for the care of those with mental and behavioral disorders. The development of CPGs has been occurring for over 20 years and international processes for creating such guidelines have been identified and agreed to by entities around the world These processes serve to first identify the highest quality of evidence that will allow guideline developers to determine whether interventions are efficacious and then following that determination, to make further assessments about their effectiveness with different populations or to compare treatments. While certainly these processes can be improved and inclusion of other evidentiary forms could be useful, this initial CPG reflects a close adherence to international development standards.

One important outcome is that high quality guidelines be accepted into the National Guideline Clearinghouse which requires a development process consistent with the IOM standards. The IOM report, Clinical practice guidelines we can trust, is widely recognized among groups that generate guidelines as

the most rigorous exposition of standards required for development of high-quality guidelines. Based on the recognition that the rigorous standards promulgated by the IOM may not always be feasible, the Guidelines International Network (G-I-N) (which represents 104 organizations in 51 countries) has been developing minimal standards for clinical practice guidelines. Although there are some differences in approaches to guideline implementation, the standards recommended by the IOM and by G-I-N are very similar and include the same components, such as use of a systematic review as the evidence base, transparency of methodology, inclusion of a diverse panel membership, disclosure and management of conflict of interest, and others.

The National Institute for Health and Care Excellence in the United Kingdom has also developed standards for guideline development and has developed a large number of clinical practice guidelines using those standards (NICE, 2016). Those standards are very similar to the IOM guidelines. The NICE standards were developed explicitly for "health and care in England" and include items pertinent specifically to English law, such as the 2010 Equality Act.

Concern: Stringency of criteria to select studies

The panel acknowledges that the inclusion and exclusion criteria for studies evaluated for the RTI-UNC systematic review were quite stringent, comparably stringent to other high quality systematic reviews. The point of the systematic review was to make determinations about the efficacy of various treatments and the panel believes that utilizing the criteria that are used by most other systematic review teams is valuable.

Concern: Lack of other evidence informing clinical practice guidelines

The panel relied on a high quality systematic review to make recommendations about interventions based on efficacy. The panel recognizes that other kinds of evidence, such as effectiveness studies, single case studies, implementation studies and naturalistic studies, provide important information however have less relevance to the question of whether a treatment produces effective outcomes. The panel did include evidence from non-randomized studies regarding harms and burdens of treatments and for patient preferences and values and that evidence played a role in decision-making when relevant.

To the extent possible, these other types of evidence can inform the individual clinician regarding selection of interventions, use of interventions under different circumstances or with different patient populations. The panel acknowledges that in keeping with standard practices in guideline development, it utilized an approach that focused on evidence regarding "what works" and provided less context regarding the provision of psychotherapy.

Concern: Risk of bias assessment was subjective and was not similar to the Cochrane approach

Dr. Hoge states that the risk of bias assessment used by the RTI-UNC Evidence-based Practice Center (RTI-UNC EPC) in conducting the systematic review of treatments for adult PTSD (Jonas et al., 2013) was "scored in a highly subjective manner (low, medium, high risk) inconsistent with Cochrane."

The panel asserts that the risk of bias assessment utilized by RTI-UNC was no more subjective than any other system used to assess risk of bias and was very similar to the Cochrane Collaboration assessment of risk of bias.

The RTI-UNC EPC used a method for assessing risk of bias that was based on methodological principles used by all thirteen AHRQ-funded Evidence-based Practice Centers (Viswanathan et al., 2013).

That approach is highly similar to the Cochrane approach (Higgins & Green, 2011) and is also similar to the GRADE consortium approach (Guyatt et al., 2011).

For each trial, two reviewers (one of whom was an experienced researcher) independently evaluated 12 methodological features of the trial, designed to address specific domains including "selection bias, confounding, performance bias, detection bias, and attrition bias (i.e., those about adequacy of randomization, allocation concealment, similarity of groups at baseline, masking, attrition, whether intention-to-treat analysis was used, method of handling dropouts and missing data, validity and reliability of outcome measures, and treatment fidelity" (Jonas et al., 2013, p14). Based on the answers to those questions, trials were rated as low, medium or high risk of bias, based on the following criteria:

Low risk of bias: Few flaws in the design, conduct or analysis and no serious flaws. Results are likely to be internally valid. A low risk of bias rating required favorable responses to at least 10 of the 12 questions "with any unfavorable responses being of relatively minor concern (e.g., lack of provider masking in studies of psychological interventions, which is generally not considered possible)" (Jonas et al., 2013, p 14).

Medium risk of bias: Some flaws in the design, conduct or analysis but none are serious enough to invalidate the results.

High risk of bias: Flaws in the design, conduct or analysis that may invalidate the results, typically at least one or more fatal flaws. The following criteria were used for assignment of high risk of bias (Jonas et al., 2013, p 14):

a. Selection bias due to inadequate method of randomization (e.g., alternating) and resulting baseline differences between groups with no subsequent approach to handle potential confounders
b. Attrition ≥40 percent or differential attrition ≥30 percent
c. Risk of attrition bias (attrition over 20% or differential attrition over 15%) and inadequate handling of missing data (e.g., completers analysis with nothing done to address missing data)
d. Other combinations of multiple serious risk of bias concerns

The Cochrane Collaboration uses a very similar method for assessing risk of bias. First, the Cochrane Collaboration uses the same classification scheme for assessing biases that threaten internal validity (Higgins & Green, 2011; Table 8.4.a). Second, like the AHRQ Evidence-based Practice Center approach, the Cochrane Collaboration encourages the use of domain-specific assessment items and discourages adding items to create an overall risk of bias score (as had been done in earlier approaches to assessment of risk of bias (Jadad & McQuay, 1996)). Third, the criteria for determining the answer to each domain-specific methodological item is operationalized to increase inter-rater reliability. Fourth, the EPC approach to categorizing a study's overall risk of bias is generally similar to the Cochrane approach, with some differences. Cochrane's categorization of risk of bias is shown below:

Low risk of bias: Plausible bias unlikely to seriously alter the results. Low risk of bias for all key domains.

Unclear risk of bias: Plausible bias that raises some doubt about the results. Unclear risk of bias for one or more domains.

High risk of bias: Plausible bias that seriously weakens the confidence in the results. High risk of bias for one or more key domains.

There are two small differences between the Cochrane approach and the EPC approach to overall categorization of risk of bias. First, while both use the terms low and high risk of bias, the EPC approach uses the term "medium" risk of bias for the middle category while the Cochrane approach uses the term "unclear". The description of those categories is, however, similar. Second, the EPC approach categorizes a study as being low, medium or high risk of bias while the most recent iteration of the Cochrane Methods Handbook recommends categorizing each outcome, within a study, as low, unclear or high risk of bias, based on the idea that various biases might have different effects on different outcomes. For instance, lack of blinding of outcome assessors might have a substantial potential for producing bias in outcomes that are measured by self-report and less potential for bias for "harder" outcomes, like death.

Finally, the Cochrane approach to incorporating risk of bias ratings into the analysis is similar to the approach that was used in the PTSD treatment systematic review. The Cochrane Methods Handbook (Section 8.8.3.1, Possible Analysis Strategies) lists as the first option inclusion of low (or low and unclear) risk of bias trials in the analyses and performance of sensitivity analyses to determine if the conclusions change when high risk of bias studies are included. That is exactly what was done in the PTSD treatment systematic review.

Overall, the method that was used to assess risk of bias in the PTSD treatment systematic review, based on the approach used by all AHRQ-funded EPCs, was similar to the Cochrane approach and no more subjective than Cochrane in categorizing the risk of bias as low, medium or high. The recommended method for incorporating risk of bias ratings into the analyses is also the same for Cochrane and the PTSD treatment systematic review.

<u>Concern: Impact of methods for handling dropouts and missing data on risk of bias</u>

One commenter raised a concern that the effect of ratings on two domains (handling of dropouts and handling of missing data) on overall risk of bias was different in the PTSD treatment systematic review and in the Cochrane approach. Specifically, the commenter stated that if a study is noted to have "unclear" randomization or allocation concealment, it would have met criteria for high risk of bias in the Cochrane approach but was rated as medium risk of bias in the PTSD treatment systematic review.

According to the Cochrane Methods Handbook, section 8.5.d (Criteria for judging risk of bias in the 'Risk of bias' assessment tool) indicates that if there is "Insufficient information about the sequence generation process to permit judgement of Low risk or High risk", the rating of unclear risk of bias (which corresponds to the category of medium risk of bias in the PTSD treatment systematic review) should be assigned. Similarly, if there is "Insufficient information to permit judgement of Low risk or High risk" when the "method of concealment is not described or not described in sufficient detail to allow a definite judgement" the rating of unclear risk of bias (which corresponds to the category of medium risk of bias in the PTSD treatment systematic review) should be assigned (Higgins & Green, 2011). The RTI-UNC EBPC and Cochrane approaches are parallel in this practice.

The commenter also raised concern that use of an intention to treat analysis was considered equivalent to use of last observation carried forward (LOCF) on risk of bias rating. Specifically, the commenter wrote, "an acceptable method of addressing missing data, albeit not the current state of the science, was considered equivalent with studies that relied only on completer analyses and did not factor in missing data at all." (The acceptable method being referred to was LOCF.)

First, it is important to note that the RTI-UNC reviewers, like Cochrane, considered the amount of attrition in determining whether lack of an intention to treat analysis would be likely to cause bias. If attrition were minimal, then a study that did not use intention to treat could at least theoretically be rated medium risk of bias rather than high risk of bias. We believe that is appropriate because the findings in studies with very low attrition that use a completer analysis are unlikely to be biased as a result of the completer analysis. Second, lack of intention to treat analysis coupled with completer analysis was indeed sufficient to trigger a rating of high risk of bias while use of intention to treat coupled with last observation carried forward resulted in a rating of medium risk of bias in all of the trials assessed in the PTSD treatment systematic review. It is therefore not accurate to say that intention to treat with LOCF was given the same risk of bias rating as lack of intention to treat with a completer analysis.

<u>Concern: Lack of clarity for evaluation of outcome measures</u>

One commenter raised concerns about how evaluators assessed whether outcome measures were "equal, valid and reliable" (one of the items on the risk of bias assessment). Specifically, the commenter was concerned that self-report instruments were rated similarly to structured interviews.

The following scales and structured interviews were considered valid and reliable measures of PTSD symptoms: Clinician-Administered PTSD Scale (CAPS), the Clinician-Administered PTSD Scale Part 2 (CAPS-2), the Impact of Events Scale (IES), the Impact of Events Scale–Revised (IES-R), the Modified PTSD Symptom Scale (MPSS-SR), the self-rated PTSD symptoms Checklist (PCL), the PTSD Symptom Scale–Interview (PSS-I), the PTSD Symptom Scale–Self-report Version (PSS-SR), or the Structured Interview for PTSD (SI-PTSD).

It is true that diagnostic interviews like the CAPS are likely to have greater reliability, sensitivity and specificity than self-report scales like the PCL. However, this distinction would have no practical impact on the findings in the systematic review because it would not change which studies would be included or excluded. The distinction between an excellent structured interview like the CAPS and a self-report instrument with good psychometric properties like the PCL is likely the difference between low risk of bias and medium risk of bias on the measurement dimension. In other words, we do not believe it would be reasonable to assign a high risk of bias rating to a study simply on the basis of measuring the outcome with a good self-report scale rather than a diagnostic interview. In the PTSD treatment systematic review, all trials that rated low or medium risk of bias were included in the meta-analysis and trials that were rated high risk of bias were only included in sensitivity analyses. Thus, if one accepts the proposition that a study should not be rated high risk of bias solely on the basis of use of a self-report instrument to measure the outcome, the distinction between studies that used a diagnostic interview to measure the outcome and those that used one of the self-report scales cited above with good psychometric properties had no impact at all on the findings in the systematic review.

If only low risk of bias studies were to be included in the systematic review and if studies that used self-report scales were to be rated medium risk of bias (if they did not meet other criteria for high risk of bias) and studies that used structured interviews were to be rated low risk of bias (if they also fulfilled other criteria for low risk of bias), there would be almost no data available for inclusion in the systematic review. Of the 77 trials included in the systematic review that were included in quantitative meta-analyses, only 4 were rated low risk of bias. Thus, while we agree with the commenter that there is a difference in reliability and validity of structured interviews and self-report scales, even those with good psychometric properties, distinguishing between them would have had no substantive impact on the systematic review. The goal of the item for assessing measurement in the risk of bias assessment was not to distinguish between excellent outcome measures and good outcome measures but to

distinguish between excellent or good measures and measures with poor or unknown psychometric properties.

Concern: There was no assessment of selective reporting bias

One commenter raised concern that there was no assessment of within-study reporting bias.

That is correct. The PTSD treatment systematic review did not assess within-study reporting bias.

We agree that selective reporting of data by randomized trials can introduce bias. However, we also agree with the comments in the Cochrane Methods Handbook: "Statistical methods to detect within-study selective reporting are, as yet, not well developed. There are, however, other ways of detecting such bias although a thorough assessment is likely to be labour intensive." (Higgins & Green, 2011). In the Cochrane review of psychological treatments for chronic PTSD, which did include assessment of selective reporting as part of the risk of bias assessment, the authors concluded, "It was difficult to draw any meaningful conclusions with regards to the issue of selective reporting. Very few of the included studies had published protocols available. It was therefore impossible to know whether prespecified outcome measures were adequately reported." (Bisson, Roberts, Andrew, Cooper, & Lewis, 2013)

Concern: Network meta-analysis, a controversial approach, was used in decisions about treatment recommendations

One commenter raised concerns that the network meta-analysis included in the systematic review was used as the basis for panel recommendations about pharmacological treatments.

However, that is not the case. Although the methodological framework for network meta-analysis has been growing more robust, we did not use the results of the network meta-analysis to make any decisions about recommendations for any treatments because the treatment comparisons for network meta-analysis are indirect. We relied exclusively on evidence from the systematic review of randomized trials in which treatments were compared directly in the same trial.

References

Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.handbook.cochrane.org.

Jadad, A.R., McQuay, H.J. (1996). Meta-analyses to evaluate analgesic interventions: a systematic qualitative review of their methodology. Journal of Clinical Epidemiology, 29, 235-243.

Bisson, J.I., Roberts, N.P., Andrew, M., Cooper, R., Lewis, C. Psychological therapies for chronic post-traumatic stress disorder (PTSD) in adults. (2013). Cochrane Database of Systematic Reviews. Issue 12. Art. No.: CD003388. DOI: 10.1002/14651858.CD003388.pub4.

Research funding impacts available research

Commenter: Mark Russell; mrussell@antioch.edu

Comment: First, I can appreciate the extensive time and effort that went into developing these guidelines and believe for the most part, this was a good-faith effort to help consumers.

Second, my initial comments are more general impressions and I will submit specifics later.

ZEITGEIST

The rich history of psychology describes the dangers of zeitgeist in scientific advancement. Tragically, if allowed to stand, APA's PTSD guidelines will ensure a victory for the zeitgeist favoring CBT and psychopharm paradigms, and a loss for consumers who have no bond in the politics of trauma.

In 1989 the first RCT on PTSD therapy was published by the Department of Veterans Affairs involving exposure therapy, followed by EMD(R)'s controversial emergence. As long as EMD invoked a CBT model of change it was viewed as a quirky, but tacitly acceptable modality worthy to be researched (Wolpe, 1991) by VA and other national research agencies. However, a heated controversy ensued once the CBT zeitgeist was challenged by Shapiro's deviation from an exposure-based model. Consequently, there has been persistent accusations of bias from both sides with ever evolving 'gold', 'platinum' and IOM standards for including/excluding research findings.

That's all fine, but what APA, IOM, and RTI-UNC fail to consider as they critique the quality and low volume of EMDR RCT, particularly with war veterans, is the VA, DoD, NIMH general refusal to approve and/or conduct EMDR research, and opting instead to spend $billions of federal resources researching favored treatments like exposure therapy, CPT, CT, and CBT.

Since 2004, the VA/DoD and every other domestic and international PTSD guideline, along with multiple meta-analyses all analyzed essentially the same handful of studies that APA/RTI-UNC analyzed, concluding as RTI-UNC did, that there is sufficient evidence of EMDR efficacy as a frontline PTSD therapy. The WHO (2013) agreed and recommended EMDR as one of two EBP therapies that should be offered before medications.

Despite 16 years of American war and well publicized epidemic in war stress injury, neither the VA or DOD has conducted a single RCT on EMDR even though its currently listed as tier one EBP (VA/DoD, 2010). Is that not clear proof of the inherent danger of zeitgeist? And now, APA's panel is prepared to contradict all other scientific panels and downgrade EMDR's status as "weak recommendation" (p. 18).

What will be the consequence of APA's decision? Assuredly, the VA/DoD will revised their practice guidelines to downgrade EMDR and provide rationale for avoiding any future research or access to non-CBT treatment for military and veterans.

Therefore, on moral and ethical grounds alone, the APA should respect the current scientific consensus of EMDR's efficacy and demand that the VA/DoD exercise due diligence and end their harmful bias against researching EMDR. Keeping in mind the last EMDR RCT by VA (Carlson, 1998) reported 77% of Vietnam veterans loss PTSD diagnosis which was 3-years before the Afghanistan war started.

Panel Response:

The panel will later address the many comments specific to its evaluation of the evidence for EMDR as well as concerns raised about the implications making any recommendations about treatment. However, the panel does want to acknowledge that inconsistencies do exist in the research literature regarding evaluation of many treatments. Some of this is due to the quality of available research, some due to the tradition of research behind different types of interventions, some due to the propensity of funders to support some types of research and not others. The panel hopes that its discussion of gaps in the literature may prompt researchers and funding agencies to devote resources to addressing those gaps. The panel hopes that new research will be encouraged and does not want treatment guidelines to be used to support only currently identified efficacious treatments at the expense of diminishing research on promising or innovative approaches.

SR and published paper

Commenter: Lynn Buhler, PhD; lynnbuhler@verizon.net

Comment: p. 24, lines 23 and 24, the claim that the guidelines include an independent and comprehensive systematic review of the PTSD treatment literature (and are hence an improvement over previously published guidelines) seems disingenuous, given that the approach appears to simply have used the data from the RTI-UNC review, and then added more recent studies which were "judged" by panel members as to whether each was of sufficient weight to modify the RTI-UNC results. This is particularly disturbing to me considering that both the RTI-UNC review, and a paper published by the same team reporting results of their review (Clin Psychol Rev. 2016 Feb;43:128-41.Psychological treatments for adults with posttraumatic stress disorder: A systematic review and meta-analysis. Cusack K1, Jonas DE2, et.al.) both find EMDR to be ranked in the same (moderate) category as CBT-based therapies.

Panel Response: *The panel did utilize the RTI-UNC systematic review which was independently conducted according to current best practices. The systematic review and the paper published by the same team did not assign global strength of evidence (SOE) ratings to treatments but instead applied SOE ratings for each of the outcomes assessed for each treatment. EMDR was rated low SOE for PTSD symptom reduction while CBT was rated moderate SOE for PTSD symptom reduction. Both EMDR and CBT were rated moderate SOE for loss of PTSD diagnosis and prevention/reduction of comorbid depression. Please see the table, below, for all SOE ratings for psychotherapies that received substantive recommendations by the panel.*

Creation of guideline recommendations involved additional steps beyond the systematic review. The systematic review reported the strength of evidence for different outcomes for treatments but did not weight or rank the outcomes for importance. Prior to evaluating the evidence for any treatment, the guideline development panel determined that two outcomes, PTSD symptom reduction and serious harms / adverse events, would be considered critical for the decision-making process and other outcomes, such as PTSD symptom reduction, remission, and others, would be considered important, but not critical outcomes. The panel also incorporated patient values and preferences and applicability (generalizability) into decision making.

EMDR was given a weak recommendation instead of a strong recommendation because it was rated low SOE for the critical outcome of PTSD symptom reduction. CBT and all of the other treatments that received strong recommendations received at least moderate SOE rating for the critical outcome, PTSD symptom reduction. Due to low certainty about patient values and preferences, they did not factor into decision making for any of the treatments evaluated.

Finally, because the systematic review was based on literature identified prior to May 2012, we conducted an updated search to identify randomized trials published between 2012 and June 2016 for those interventions that received substantive recommendations. We were not able to re-do the systematic review based on the trials identified, but we did use those trials to assess the degree to which we believed that our recommendations would stand based on new evidence. For EMDR, we identified one randomized trial (van der Berg, 2015) in the updated search. Since the sample size for the van der Berg trial (n=108) was almost the same size (n=117) as the four trials, combined, that were included in

the systematic review, and since imprecision (i.e., wide confidence interval) was one of the criteria that led to a rating of low SOE for PTSD symptom reduction for EMDR, we concluded that "there is insufficient evidence to determine whether the weak recommendation for EMDR efficacy would be likely to change (to a strong recommendation) as a result of the new trials."

Reference

van den Berg, D. P., de Bont, P. A., van der Vleugel, B. M., de Roos, C., de Jongh, A., Van Minnen, A., et al. (2015). Prolonged exposure vs eye movement desensitization and reprocessing vs waiting list for posttraumatic stress disorder in patients with a psychotic disorder: A randomized clinical trial. JAMA Psychiatry, 72(3), 259-267.

Table. Strength of evidence ratings for psychotherapies

Outcome	Cognitive Behavior Therapy	Cognitive Processing Therapy	Prolonged Exposure	Cognitive Therapy	Brief Eclectic Therapy	EMDR	Narrative Exposure Therapy
PTSD symptom reduction[1]	Mod	Mod	High	Mod	Low	Low	Mod
Serious harms / adverse effects[1]	Very low	Very low	Very low	Very low	Very low	Very low	Very low
Loss of PTSD diagnosis[2]	Mod	Mod	Mod	Mod	Low	Mod	Low
Remission[2]	Mod	---	Very low	---	Very low	---	---
Prevention / reduction comorbid depression[2]	Mod	Mod	High	Mod	Low	Mod	Very low
Prevention / reduction comorbid anxiety[2]	Low	Very low	--	Mod	Low	Very low	---
Prevention / reduction of comorbid pain[2]	---	---	---	---	---	---	Very low
Quality of life[2]	Very low	Very low	--	Very low	---	---	Very low
Functional impairment[2]	Low	---	Very low	Mod	---	---	--

Notes. [1] Critical outcomes. [2]Important outcomes

Other Reviews

Commenter: Emily Wood; e.f.wood@sheffield.ac.uk

Comment: Given that the Cochrane Collaboration updated their systematic review of PTSD treatments in 2013 I am not sure why you felt the need to do another review. The Cochrane review (http://www.cochrane.org/CD003388/DEPRESSN_psychological-therapies-chronic-post-traumatic-stress-disorder-ptsd-adults) is clear that the evidence is strong for TFCBT, CBT and EMDR. They are equally effective post treatment and that at 4 month follow up TFCBT and EMDR are superior to CBT.

You directly contradict this and it is unclear why.

Commenter: Dr. Amber Fougere; amber@lesleyhartman.ca

Comment: No I disagree with the summary of the research evidence presented. For example, researchers affiliated with the National Center for PTSD completed a meta-analysis comparing effectiveness of CPT, EMDR and PE. The meta-analysis demonstrated significant effect sizes for each:

INTERVENTION	EFFECT SIZE	CONFIDENCE INTERVAL
Prolonged Exposure (PE)	1.91 (very large)	1.52 - 2.30
Eye Movement Desensitization and Reprocessing (EMDR)	1.89 (very large)	1.07 - 2.71
Cognitive Processing Therapy (CPT)	1.81 (very large)	1.41 - 2.21
Other treatment	0.798 (medium - large)	0.68 - 0.92
No treatment	0.42 (small - medium)	0.33 - 0.53

To say the evidence for EMDR is less than the various forms of Cognitive Therapy is simply inaccurate.

Panel Response:

Both Dr. Wood and Dr. Fougere referenced other reviews relevant to the questions addressed in the RTI-UNC systematic review. The panel actually began its work prior to the publication of the Cochrane review and determined that it would work with the systematic review from RTI-UNC for reasons detailed at the beginning of this document (procedures for conducting the review, transparent process, etc.) An important difference between the Cochrane Collaboration systematic review of psychological therapies for PTSD and the RTI-UNC systematic review is that the Cochrane systematic review was limited to studies of participants with chronic PTSD (defined in that systematic review as PTSD of at least three months duration) while the RTI-UNC systematic review included studies that included participants with PTSD of any duration sufficient to meet DSM critieria for diagnosis. In addition, the Cochrane systematic review covered only psychological treatments but the RTI-UNC systematic review included both psychological and pharmacological treatments. Because our goal was to produce a guideline that addressed psychological and pharmacological treatments for PTSD and for PTSD of any duration, not just

chronic PTSD, the RTI-UNC systematic review was more suitable than the Cochrane Collaboration systematic review.

Dr. Fougere references a meta-analysis from researchers at the National Center for PTSD which we were able to locate but this too was published after the panel began its work.

Watts, B.V., Schnurr, P.P., Mayo, L., Young-Xu, Y., Weeks, W.B., & Friedman, M.J. (2013). Meta-analysis of the efficacy of treatments for posttraumatic stress disorder. Journal of Clinical Psychiatry, 74, e541-e550.

The panel recognizes that much research has been conducted in the area of PTSD treatment and appreciates the many individuals who highlighted additional research. Revisions to this guideline will benefit from these additional meta-analyses.

Concerns about value of RCTs

Commenter: Heidi Levitt; Heidi.levitt@umb.edu

Comment: The problem is that the purpose does not recognize the systematic biases in collecting and valuing research on a certain type as it impacts different psychotherapy orientations. Your questions seeking feedback do not provide a route to provide feedback on the mission as a whole. Here is some commentary:

Debates on the influence of psychotherapy orientation on treatment effectiveness have been longstanding and heated. Central in this debate are lists that have been generated to identify psychotherapies that have produced modest or strong evidence of their efficacy within randomized clinical trials (RCTs) or equivalent designs (www.div12.org/psychological-treatments). It has been exciting to see psychotherapy research growing and establishing the value and efficacy of multiple approaches to treatment. These lists are powerful evidence that can be used to argue for the value of broadening access to psychotherapy and for funding continued psychotherapy research to expand this compelling form of support.

Despite the utility of tracking mounting RCT evidence for psychotherapies, however, there are many reasons besides inefficacy for therapies not to appear on these lists. Reasons include the values and inquiry traditions of orientations that have emphasized sets of questions and research methods other than comparative outcome trials (e.g., Hill & Corbett, 1993; Bohart, Leitner & O'Hara, 1998), the lack of outcome measures tailored to assessing outcome in a manner that would reflect the goals of a therapy approach (e.g., Levitt, Stanley, Frankel & Raina, 2005), the lack of faculty diversity in therapy orientations within clinical graduate programs that has curtailed the potential for independent research programs across therapy traditions (Heatherington et al., 2012; Levy & Anderson, 2013), and the circular tendency of granting agencies to fund research on approaches already established as efficacious (e.g., www.pcori.org/research-results/research-we-support), rather than to direct funding to develop evidence across the main approaches to treatment. Also, important in interpreting and representing their meaning, lists of RCT studies cannot identify whether orientations remain superior after accounting for the significant role of researcher allegiance as they do not aggregate research studies. For this reason, they also do not comment upon the relative contributions of therapy orientations to the variance in client outcome in relation to therapist, client or other factors; this is the domain of meta-analyses.

An extensive body of quantitative meta-analytic research has supported the theory that there is general equivalence in outcome across the main psychotherapy traditions (e.g., Laska, Gurman, & Wampold, 2014). Although research into specific treatments is ongoing, the conclusion of the APA Resolution on Psychotherapy Effectiveness (APA, 2012) was that comparisons between valid and structured psychotherapy approaches tend to produce roughly equivalent findings that are often mediated or moderated by relational or contextual factors. To be clear, disputes have existed but these are usually focused on treatments within a few diagnoses and tend to center over the inclusion of non-bona fide therapies as control groups (e.g., Ehlers et al., 2010; Wampold et al., 2010). Although an in-depth review of these various disputes is not possible within the confines of this paper, in Wampold and Imel's (2015) review of the meta-analytic literature, they examined the relatively rare findings of non-equivalence in meta-analyses and concluded that these findings do not occur more than might be expected by chance. In short, these reviews have found that orientation is estimated to account for little, if any, of the variance in client change when looking across or within diagnoses (e.g., Wampold & Imel, 2015). This finding of equivalence has held up across meta-analytic studies assessing entire treatments as well as dismantling studies, focused on the effective components of orientations (e.g., Bell, Marcus & Goodlad, 2012). Still, it has been challenging for our field to shift away from the comparisons of psychotherapy orientations, and more fundamentally, the conceptualization of psychotherapy as synonymous with orientations, in order to claim a new agenda.

A sociological reason for this struggle may be that developing understandings of how multiple therapies function is challenging. Our identities as psychologists are tied to our psychotherapy orientation affiliations that often dictate our journals, societies, conferences, and the research we read (Gold, 2005). This trend to narrow our scope within one orientation has been exacerbated by the apparent vanishing of psychotherapy orientation diversity within US clinical psychology faculty (Heatherington et al., 2012; Levy & Anderson, 2013), restricting the depth of psychologists' understandings of multiple orientation cultures, endogenous values, and approaches towards research methods (e.g., Levitt, Frankel, Stanley & Raina, 2005). Other reasons might include the fragmentation of research paradigms (e.g., qualitative and quantitative researchers) and the challenges in speaking across epistemological differences. In addition, the conceptualization of variables in psychotherapy research may limit our professional imagination when we do seek alternate ways to study psychotherapy, as will be described.

Comment 2: The problem is that the evidence reviewed was inappropriate to answer the question being posed.

Despite the utility of tracking mounting RCT evidence for psychotherapies, however, there are many reasons besides inefficacy for therapies not to appear on these lists. Reasons include the values and inquiry traditions of orientations that have emphasized sets of questions and research methods other than comparative outcome trials (e.g., Hill & Corbett, 1993; Bohart, Leitner & O'Hara, 1998), the lack of outcome measures tailored to assessing outcome in a manner that would reflect the goals of a therapy approach (e.g., Levitt, Stanley, Frankel & Raina, 2005), the lack of faculty diversity in therapy orientations within clinical graduate programs that has curtailed the potential for independent research programs across therapy traditions (Heatherington et al., 2012; Levy & Anderson, 2013), and the circular tendency of granting agencies to fund research on approaches already established as efficacious (e.g., www.pcori.org/research-results/research-we-support), rather than to direct funding to develop evidence across the main approaches to treatment. Also, important in interpreting and representing their meaning, lists of RCT studies cannot identify whether orientations remain superior after accounting for the significant role of researcher allegiance as they do not aggregate research studies. For this reason, they also do not comment upon the relative contributions of therapy orientations to the

variance in client outcome in relation to therapist, client or other factors; this is the domain of meta-analyses.

What is Evidence Based?

Commenter: Heidi Levitt; Heidi.levitt@umb.edu

Comment: Misconception #1: What sorts of practices are evidence-based? When reading the term 'evidence based psychotherapy or practice,' many readers automatically think about psychotherapy as a set of orientations or interventions because there is a dominant focus on psychotherapy orientations and interventions in our literature. There is a substantial basis of meta-analytic literature, however, that demonstrates that relationship factors have a stronger impact upon clients' outcome than either psychotherapy orientation or interventions (as summarized by Norcross, 2011). This omission can allow readers to misunderstand the literature on the factors related to psychotherapy effectiveness outcome.

Correction #1: When describing 'evidence-based therapies or practices' explicating that practices can include technical methods, therapeutic relationships and individual therapist effects is clarifying. A statement like this might be employed: Evidence-based practices include practices related to interventions as well as therapist effects and relationship practices such as empathy, positive regard, and the therapeutic alliance that have been demonstrated to contribute relatively greater proportions of variance toward client outcome. I recommend that ethical scientific reporting of lists of therapies include descriptions of evidence-based therapies and practices that emphasize that meta-analytic research suggests that psychotherapy orientations and interventions contributes very little of the variance in client outcome and that relational factors appear to be much stronger determinants of client outcome (e.g., Wampold & Imel, 2015). In addition, I recommend that a statement be added to advocate or require training across empirically-based relationship processes. An example statement might read: Because meta-analytic research suggests that therapist and relationship factors contribute more to outcome than psychotherapy orientations or techniques, the current research indicates that training be focused upon helping students to develop skills in empirically based relationship qualities.

Misconception #2: What constitutes research evidence? Researchers and psychologists often are confused about what types of research constitute evidence and fall under the rubric of empiricism. For instance, there is a large body of qualitative research related to psychotherapy and the epistemological bases for these bodies of research are becoming mainstream – as noted by their increased publication in journals (summarized in Ponterotto, 2013; Gergen, Josselson, & Freeman, 2015) and the recent change in the name of APA's Division 5 to Quantitative and Qualitative Methods. Still, psychologists often will conflate empiricism with quantitative methods, belying a misunderstanding that qualitative epistemologies are not empirically-based. Meta-analytic qualitative research has found that qualitative findings can converge to contribute robust evidence to psychotherapy research and practice this evidence should not be discounted.

Correction #2: When describing 'research evidence', explicating that evidence can be based upon a wide range of epistemologies and methods can correct this misconception. The following statement can be inserted when describing evidence-based treatments: Evidence can be based upon quantitative or qualitative research and can be based within a wide range of epistemological positions. Also, I recommend a requirement for exposure to a variety of methods and epistemologies in training to expand the types of questions and problems to which psychologists can respond and literature that they can consume.

Misconception #3: Are psychotherapies "pure" or can they be integrative? When describing psychotherapy orientations, many psychotherapists automatically think about the major psychotherapy orientations that initial theories courses within graduate training focus upon and do not consider training within integrative psychotherapies – despite evidence that shows that most psychotherapists integrate processes or techniques from across psychotherapy orientations (Orlinsky & Rønnestad, 2005). Evidence suggests that many integrative psychotherapies are efficacious, such as emotion-focused psychotherapy (e.g., Angus et al., 2015), integrative cognitive therapy (Constantino et al., 2008), motivational interviewing (e.g., VanBuskirk, & Wetherell, 2014), multisystemic therapy (e.g., Shaeffer & Borduin, 205) and parent-child interaction therapy (e.g., Chaffin, Taylor, Wisdon & Igelman, 2007). To perform these therapies well, trainees should have in-depth exposure and training in the approaches that are their bases. The development of new integrative psychotherapy approaches can be supported by education in not only different types of psychotherapy but also on the process of integration.

Correction #3: When describing 'psychotherapy', explicating that this includes both singular as well as integrative approaches is helpful. Including statements such as the ones that follows is recommended: Empirical evidence supports the efficacy of psychotherapy orientations that include both singular as well as integrative approaches to treatment. Requiring training across multiple orientations and in psychotherapy integration is especially important in light of research suggesting that the majority of psychotherapists utilize integrative or eclectic approaches to treatment. Because most clinicians appear to function as integrative or eclectic psychotherapists, we recommend that training be required in a broad range of empirically-based psychotherapy approaches and that education on how to integrate forms of psychotherapy and on integrative models of psychotherapy is provided.

Misconception #4: Are psychotherapy approaches equally positioned to establish their empirical foundation using RCTs? The political contexts of the arguments related to empirical support are rarely discussed within graduate training or presented to the public. It is important to have an understanding of their profound impact upon the accumulation of evidence on efficacy.

(a) Types of Empirical Traditions Legitimated: Psychotherapy traditions evolved with endogenous research traditions that were based upon their own sets of values, conceptualizations of psychotherapy, and questions. For instance, psychodynamic researchers developed case methods that provide a rich hermeneutic understanding of change within clients and its interaction with therapists' interventions. Humanistic researchers focused upon developing methods of qualitative research and process research (often focused on the outcome of interventions rather than therapies). Cognitive-behavioral (CB) researchers generated randomized control trial technologies and experimental research approaches. All these research traditions have made important contributions to our conceptualization and understanding of therapy. When the movement for evidence-based psychotherapy began producing lists of approaches based within in RCT evidence, protests from non-CB orientations expressed concerned about the discounting of their own inquiry traditions and research cultures (e.g., Bohart, Leitner, & O'Hara, 1998). These lists can create a false impression that the reason why CB has produced more RCT support is due to the greater efficacy of these approaches instead of that the longer tradition that CB has in conducting this work and the synchrony of RCT methods with their values. I recommend that in discussions of evidence-based practice, a statement like the following be added: Historically, psychotherapy orientation have had research cultures that emphasized different questions, methods, and epistemologies and have bodies of research that are congruent with their own values. RCTs are one research method and, like all methods, are value-laden and their values do not fit with all orientations equally well. To develop an understanding of the evidence to support psychotherapies, researchers

should become familiar with multiple traditions of research, including process-outcome research that examines how processes work within therapies, qualitative research that explores clients and therapists experiences of therapy, and meta-analytic strategies that aggregate research across approaches.

(b) The Disappearance of Diversity in Theoretical Orientation: The movement to establish evidence-supported practices and the withdrawal of public funding for higher education in many countries has coincided with the winnowing of diversity of theoretical orientation diversity in US clinical psychology faculty (see Heatherington et al, 2013 and Levy & Anderson, 2013). This disappearance of theoretical orientation diversity is in spite of the wealth of meta-analytic research demonstrating the equivalence of the major psychotherapy orientations with CB (e.g., Wampold & Imel, 2015). While historically, many students could expect to learn multiple orientations by virtue of their faculty's diversity, the current numbers means that there are few faculty who are able to generate evidence for non-CB approaches, or to help incoming professionals to understand multiple psychotherapy orientations' values, clinical processes, and research traditions and how these approaches can be integrated coherently. When discussion empirically-based approaches are discussed in terms of graduate training, we recommend the inclusion of a statement: Students should not only be exposed to at the major psychotherapy orientations but should be encouraged to receiving a depth of training across multiple diverse psychotherapy traditions so that they can understand how orientations influence psychotherapy practice conceptualization, research conceptualization, and relationship processes. In addition, they should be exposed to the literature on integration and integrative psychotherapies.

(c) Systemic Barriers in Producing Clinical Trial Evidence. Although many non-CB psychotherapy orientations have rallied to produce RCTs and meta-analyses, they are systematically disadvantaged in their quest to be recognized as empirically effective as set forth by the Division 12 list. Systemic obstacles include: (1) the lack of support for the DSM diagnostic system by some orientations would make them unable to produce efficacy research that is organized by these categories yet there is not a format that enables their inclusion, (2) granting agencies wanting to fund research on approaches that already have developed a body of prior RCT research to cite in support of their applications -- this creates a vicious cycle where validated approaches yield more findings while ones with different research traditions are not provided a chance to be tested; (3) the difficulty of non-CB orientations to compete for grants to fund RCTs when the research supporting their equivalence to CB is not understood or recognized or when told that new treatments are not needed because treatments are already in place; (4) the difficulty for non-CB orientations to produce a literature base on their effectiveness when the numbers of non-CB clinical psychology faculty is a small and shrinking minority (Heatherington et al., 2013) and when demands for evidence from multiple independent research teams is required; (5) the challenge in having multiple faculty from a non-CB orientation who can collaborate to sustain such a program of funding in the face of this narrowing of faculty orientations; (6) These same barriers make it quite difficult to establish new approaches to psychotherapy, approaches to treatment that utilize long-term psychotherapy, and approaches that work toward healing severe psychopathology; and (7) the lack of full disclosure of the orientation diversity of the committees and orientations that put forward the requirements for inclusion on these lists. These systematic barriers do not function in an additive manner but work in an intersectional way to prevent many orientations from having access to resources to develop evidence of their efficacy or to gain recognition for the considerable evidence that has been accumulated. In keeping with these systemic barriers to resources for research and the definition of empirically supported treatments, lists of empirically supported approaches might properly be used to indicate which approaches have disproportionately received funding to drive RCT programs of research in order to direct funds to new innovative treatments under development and to deliberately develop inquiry into a range of innovative approaches that can develop

new clinical expertise and approaches that can meet a range of patient values, characteristics, and cultures.

Correction #5: I recommend that when 'evidence-based psychotherapies or practices' are mentioned, that a description of the preceding problems be described as well as a valuing of non-RCT traditions (e.g., case studies, process measure research, qualitative methods, effectiveness research). A statement like the following can be helpful: There are multiple systemic barriers to developing RCT support, including the disproportionately low numbers of non-CB faculty in clinical psychology who can produce evidence on their approaches, the framing of RCTS in terms of DSM diagnoses which is not consistent with many orientations' perspectives on psychopathology, and the tendency to fund RCT efforts to investigate approaches that already have prior RCT evidence. Graduate students should receive education on these systemic process and the psychotherapy orientations of professionals who create lists or requirements for therapies to be considered empirically validated should be made easily available in the public domain. Furthermore, it can be recommended that granting agencies focus funding on treatments that are promising and innovative but that have not had the opportunity to be explored.

By teaching students about systemic forces shaping our field, multiple theoretical orientations and psychotherapy integration, we can work to become competent consumers of multiple psychotherapy literatures and research traditions and provide students with a background in which they can develop an appreciation for multiple research traditions and therapy approaches. I hope that the next generation of clinicians can use this broad basis of understanding to deal with the complexities of psychological problems presented by their clients -- some that may benefit from a diversity of approaches. While some clients may respond to cognitive restructuring, others to mindfulness, others might respond to experiential work, bodily work, corrective relational experiences, insights based upon reflections on their personal history, or behavioral techniques. Depriving the next generation of clinicians of the rich theoretical and research traditions that constitute our heritage means depriving clients of the possibility of meeting persons who can adjust their practice to their needs. Since research suggests that most psychotherapists practice integrative approaches, recognizing the values that are the basis of different empirical traditions and appreciating their contributions in their own terms allows them to develop integrative and rich approaches to treatment that are informed by diverse clinical literatures.

Commenter: Carolynn R. Campbell, MSW RSW; carolynn@campbellrsw.com Comment: Yes I have a confidence the conclusions represent evidence that was reviewed, so I therefore begin to question how fully evidence was in fact reviewed. Who decided what was evidence?

Commenter: Robert Gangi; rgangi3@gmail.com

Comment: The striking problem with this document, in my mind, are the implicit epistemological assumptions that ignore, what seems to be the inconvenient complexity of the work of psychotherapy. One place this is evident is in the assumption that there exist clearly definable and standardizable "treatments" for a clearly standardizable condition, PTSD. Those who truly understand scientific methodology recognize the compromises that are made in external validity for the sake of internal validity. Perhaps in no other endeavor should recognition of this problem be greater than in our own. It it is highly disappointing that those entrusted with such an important task make the grave epistemological error of searching for their keys under the streetlight in failing to recognize the very real gap between the capacities of the scientific method and our need to understand and work with highly complex systems in our daily challenges as psychotherapists. The failure to recognize the inherent, striking simplifications of experimental models of mind and include references to the necessity of clinical judgement in evaluating and working with the enormous variability with which patients present,

appears to be painfully nearsighted, and a disservice to those who are committed to the day to day work of psychotherapy.

Commenter: Susanne Dillmann; info@drdillmann.com

Comment:

It is both stunning and gravely disappointing that the deep knowledge base within our field of the inherently human needs for the interpersonal (i.e. the need for attachment, mirroring, etc…) as well as the need for intrapersonal regulation (i.e. self regulation: affective, physical, etc…) is utterly ignored from both what treatments were looked at and therefore the final recommendations. There is ample research/evidence from the fields of affective neurology and attachment, which indicate that humans do not heal the deep wounds of trauma through CBT.

Panel Response: *While many important ideas have been generated regarding the development and understanding of emotional trauma and may be very informative to clinicians as they conceptualize and treat individuals with PTSD, in guideline development best practices (see Institute of Medicine, National Guidelines Clearinghouse, Guideline International Network), the primary evidence base for recommendations is one or more high quality systematic reviews. Rigorous processes are used to identify relevant treatment studies and evaluate those studies for inclusion in the review. Theoretical and conceptual articles without studies examining the effectiveness of defined interventions are not included in such reviews.*

Concerns about the value of RCTs

As the draft document explained, the APA adopted the IOM standards for "developing independent, reliable, and high-quality practice guidelines" (See section describing development process beginning on page 31). Although the panel recognizes that other guideline development processes could have been adopted instead, the many merits of the IOM process was compelling to the APA. As the IOM standards are quite detailed and prescriptive, adherence to this process necessarily precluded incorporation of many alternative approaches to assessing evidence, particularly those that do not depend on beneficial outcomes demonstrated through RCTs. Given the IOM's emphasis on identifying causal relationships between interventions and outcomes, only RCTs were eligible for analysis in the SR for assessment of the efficacy and comparative effectiveness of interventions because other research designs could only have received ratings of "very low/insufficient strength of evidence" (primarily owing to high risk of bias) in this respect. As a result, research designs outside of RCTs were unlikely to have qualified for analysis in the SR, and therefore to have affected the panel's recommendations in the guideline. Note, however, that the panel remains agnostic about whether interventions that were not eligible for inclusion in the SR are in fact efficacious; rather, the panel's recommendations are based on affirmative demonstrations of evidence in support of efficacy (based on systematic ratings of Strength of Evidence) for those interventions appearing in the corpus of eligible studies. Such evidence was in fact sufficient to answer the questions posed in the SR and subsequently to enable the panel to offer clear recommendations in this Guideline. Of course, such answers—and the recommendations based on them—are never complete or final. As additional research studies are undertaken, any new evidence in support of efficacy for additional interventions would be expected to alter the recommendations of this guideline in future revisions.

Study designs other than randomized trials were included in the systematic review to address the issue of harms of treatments because it was believed that insufficient information would be obtained from randomized trials. In addition, the panel included data from study designs other than randomized trials in assessment of patient values and preferences for the same reason.

Concern "What is Evidence-Based?"

It is correct that the recommendations in the Guideline depend on causal evidence of therapeutic efficacy that do not (and, indeed, cannot) draw on affirmative studies of other kinds of approaches and interventions that do not exist. Importantly, the panel remains agnostic about whether interventions that were not eligible for inclusion in the SR are in fact efficacious; rather, the panel's recommendations are based on affirmative demonstrations of evidence in support of efficacy (based on systematic ratings of Strength of Evidence) for those interventions appearing in the corpus of eligible studies. One benefit of adopting the IOM standards for producing this Guideline is that the panel's process is both documented and transparent. There can be no doubt that APA adoption of the IOM standards precludes other approaches to analysis of research evidence, and even delimits what counts as influential evidence of therapeutic efficacy, but the criteria that were applied and the evaluations that resulted by the panel are all described (and remain open to scrutiny and debate) in the Guideline itself. Moreover, the Guideline incorporates a brief discussion of the importance of "common factors" for desirable therapeutic outcomes (see section on "Considerations for Treatment Implementation" beginning approximately on pp. 60.

Complementary and Alternative Medicine

Some commenters believed that the guideline should address interventions for PTSD beyond psychotherapy and medications.

Commenter: Dr. Robert Howard Robson; howard.robson@doctors.org.uk

Comment: The decision to exclude complementary and alternative therapies only comes later, and is difficult to understand why therapies that have an evidence base should be excluded.

Commenter: Lorna Minewiser, PhD; lornaminewiser@gmail.com

Comment: The lack of inclusion of Alternative Therapies is a glaring weakness. Surveys show that between 30% and 80 % of respondents have used an alternative or complementary therapy in the previous 12 months. Dr. Bessel van der Kolk, one of the world's leading trauma experts, has extensively studied the use of complementary treatments for PTSD. The Guidelines should be amended to include the research on Alternative Therapies that has been published since 2013.

Commenter: Helena Kriel; Hkriel01@hamline.edu

Comment:
http://www.traumacenter.org/products/pdf_files/Peaceful_Embodiment_Through_Yoga_R0002.pdf

Commenter: David Emerson; demerson@jri.org; Jennifer Turner; yoginjenn@mac.com

Comment: Our work with yoga at the Trauma Center has added a significant piece to the treatment puzzle that should be made available to people whenever guidelines are suggested:

http://www.traumacenter.org/products/pdf_files/Yoga_Adjunctive_Treatment_PTSD_V0001.pdf

http://www.traumacenter.org/products/pdf_files/Yoga_Complementary%20Treatment_PTSD_West_W0002.pdf

http://www.traumacenter.org/products/pdf_files/Yoga_Chronic_PTSD_LTFU_Study_R0003.pdf

Commenter: Philip Friedman; integrativehelp@aol.com

Comment: I would strongly recommend a new section called: "Promising and Innovative Approaches to Treating PTSD and Trauma. I would add the energy therapies to that list especially EFT and TFT

Panel response:

The panel sympathizes with commenters who wished the scope of the guideline was broader. The panel considered a broader scope in terms of focusing on more than psychotherapeutic and psychopharmacological interventions for PTSD and anticipates that the next iteration of the guideline will consider reviewing the evidence for interventions such as complementary and alternative medicine, yoga and others. The panel hopes that the evidence base evaluating these interventions continues to grow in the meantime so that future panels will be able to make recommendations regarding the efficacy of a broader range of treatments.

Make up of Guideline Development Panel

Some commenters questioned who was selected to serve on the guideline development panel. Others raised concern about possible conflicts of interest of panel members.

Herbert Gingold; hgingold2@gmail.com

Comment: I am appalled that these guidelines seem to ignore the entire documented literature on effective psychoanalytic treatments for PTSD. I understand that contrary to the intent of APA guiidelines, the committee has virtually NO MEMBERS who are knowledgeable about these treatments and that APA's Division 39 has not been consulted despite being a significant repository of wisdom. Please send this draft back to committee and supplement the committee with a broader based membership before attempting another draft!!!!

Commenter: John G. Carlson, PhD; carlsonj003@comcast.net

Comment: A third source of apparent bias in the APA draft is the makeup of the GDP itself. First, the process of selection (if not actual recruitment) of members is not transparent. Specifically, who did the selection and what were the criteria beyond those stated in the document? For instance, were there steps taken to ensure that members of the GDP did not have preconceived treatment biases?

Second, the inclusion of "community members," while perhaps laudable in principle, is certainly inconsistent with efforts to produce a document that will influence mental health professionals to seek

training and apply skills to best help those with PTSD. What were the specific roles of the community members? It is one thing to seek input from consumers regarding satisfaction by, say, standardized, statistically valid assessment after treatment. Also, certainly the marketplace itself is a good judge of "what works." It is quite another thing to seek input from untrained individuals regarding the empirical bases and specifics of treatment methods—simply, I ask, what training and expertise qualify "community members" to evaluate data and make recommendations as to the best practices in the field of mental health? And, if that was not their role, then what was? That is not made transparent in the document.

Third, to specifically exclude individuals with "allegiance" to a specific practice rather than to best represent the field broadly in terms of those professionals with the best credentials/training in their specific area, deprives the GDP of the knowledge, experience, and expertise most needed to make sound judgments as to best practices. Again, this reduces the credibility of this effort to provide PTSD practice guidelines in our profession and gives the appearance of bias.

Commenter: Emily Orr, PhD; Emily.and.fez@gmail.com

Comment: Collaboration with clinicians and/or patients who are actively using a non-CBT approach in the treatment of PTSD.

Commenter: Hope; anchorhope@bellsouth.net

Comment: Unclear how skilled the therapists were working within each type of therapy compared for treating PTSD; strength of the studies defined.

Commenter: Gary B. Bailey, MS, MSW, LCSW; gary.bailey@alamancelifeworks.com

Comment: I would suggest including more practitioners in the study to develop more expert Q-Methodology expert participant driven research questions.

Conflicts of Interest of Panel Members

Commenter: Dr. Benjamin Ose; bose001@hotmail.com

Comment: In the section on conflicts of interest, it would be helpful to know any and all financial disclosures related to the panel and their prior research studies. Additionally it would be exceedingly helpful to know which panelists are in clinical practice and what type of treatment modalities the panelists themselves use in clinical practice.

Commenter: Dr. Joseph Graca; rekindleyoursoul.com

Comment: Did each committee member have to report whether they had a financial interest in any of the therapies being reviewed? This includes doing training or providing consultation.

Commenter: Kelsey Emhardt; kschroth1112@gmail.com

Comment: CBT is used by all therapists. CBT is useful and beneficial and it also is supported for insurance reimbursement, so I am sure that therapists on your panel for drafting this document use therapies that are cognitively based. Do any of the therapists use EMDR therapy? Are they adequately trained? The article indicates a lack of knowledge and understanding of EMDR therapy, which would indicate a conflict of interest and lack of diversity for compiling the draft.

Panel Response:

The call for nominations for the CPG was disseminated broadly within APA, including divisions, and to organizations external to APA that might be interested in treatments for people with PTSD. The final composition resulted in a panel with broad-based representation. Bios of panel members can be found online and brief versions have been included in the document for reference. Panel members possess a range of clinical expertise and training in various theoretical orientations (for instance, Brown, Cook, & Courtois are not analysts but are trained in psychodynamic theory and methods—see their respective writings on the treatment of PTSD; several have either Level 1 or Level 2 certification in EMDR; others work in a variety of settings including primary care, VA, internationally). Individuals were not selected to represent particular constituencies, such as the membership of a division, but rather were selected on the basis of their broad knowledge and capacity to evaluate the research literature.

Additionally, while familiarity with clinical intervention is important, it is also important that panel members do not have a strong intellectual allegiance to any one particular approach to treatment. For this reason, panel members' real and perceived intellectual and financial conflicts of interest (COI) were assessed prior to appointment to the panel and panel members updated the COI disclosure annually. Please see Appendix J for a copy of the Conflict of Interest Policy and Declaration of Interests and the discussion of COI review and management beginning approximately page 92. Additionally, panel members completed a training module on conflicts of interest prior to participating in guideline development. Finally, panel members represented clinicians, researchers and community members from a variety of backgrounds. All underwent similar training and orientation to the process of guideline development. While community members did not have the research background of some panel members they were provided with sufficient support to understand the process of guideline development and participate fully in evaluation of the literature and formulation of recommendations.

Outcomes, drop outs, harms, burdens

Commenter: Rosalie Thomas; rthom@centurytel.net

Comment: The selection of critical items introduces bias into the guidelines and further restricts its application. In the identification of critical items, the GPD has identified the reduction of symptoms as critical, but not the remission of symptoms, nor the complete loss of symptoms so that patients no longer meet criteria for diagnosis. This biases the Guidelines in favor of those therapies that focus only on symptom reduction rather than trauma resolution. As a clinician, I fail to see why these are considered separately, rather than on an outcome continuum, with resolution of trauma and loss of diagnosis being the most important.

Further, harm/ adverse events are seen as critical, but considered not critical are adverse events leading to discontinuation of treatment (drop-out rates). This is problematic in evaluating the effectiveness of therapies which have a larger drop-out rate, such as prolonged exposure, and inappropriately skews the data. In a clinical setting, drop-out rate is critical since those patients who have "failed" in a treatment, either by attrition or felt lack of improvement, will be most likely to suffer a continuation or worsening of symptoms and will be least likely to seek other treatments that could offer success. The exclusion of accurate data on drop-out rates is a disservice to patients and clinicians alike.

Along the same lines, additional harms and burdens are of great importance when faced with the necessary choices being made by individuals, health care programs and third-party payers. Issues of dosing, recommended length of treatment, requirement of homework, and ultimate cost are also important considerations and should be included in the analysis.

Commenter: Richard F. Murphy, Jr., PhD; rfmurphyjr@aol.com

Comment: Yes 1. "…adverse events leading to withdrawals (treatment discontinuation), and other adverse events, and burdens. (p. 10)" "The panel found no other interpretable evidence of serious harms. There was low strength of evidence that exposure therapy is associated with increases in PTSD symptoms in some patients. (p. 53)"
These statements are Incorrect, misleading, not empirically valid.
Drop-out rates for CBT and PE are extremely large: 60%, (Congressional Budget Office, Feb 2012); 38% (Schurr et al, 2007); Patient drop-out (VAMC): CPT 68% vs EMDR 100% (Garcia et al, APA Psychol Services, 2011); CBT/PE Patient completion rate—private practice: 28% (Zayfert et al. (2005) J. Traumatic Stres). Whereas for EMDR, drop-out rates are very low: 3% drop out (Carlson, et al, 1998); 82% completion of 8 EMDR sessions (Van der Kolk et all, 2007)

On p. 44, the report states harm is "extracted from data, such as dropout."… Garcia et al (2011) reported 79 of 117 CBT/PE clients dropped out from the San Antonio VAMC program. Compared with completers, these clients were significantly more depressed, more socially introverted, and had more severe PTSD symptoms, and more substance abuse. Without treatment, they are a high risk for further psychopathology: depression, substance abuse, family violence, suicide, to name a few. Again, with these high dropout rates and the client characteristics identified in the Garcia study indicate a significant imbalance between benefits vs harms/burdens. Clearly, this is contrary APAs conclusion (see quote above p.53)

Rachel Walker; rache@rachelwalkermft.com

Failure to use M-PTSD measuring tool.

Lewis Kirshner *lewis_kirshner@hms.harvard.edu*

Finally, many traumatized patients seek meanings in their experience or to understand the nature of their relationships (as in psychodynamic, IPT, and psychoanalytic therapies). Why in the world would APA want to discourage patients from pursuing these avenues of change?

Jamie Zabukovec *zabuk@aol.com*

There are articles on research that has been done by the Department of Defense on EMDR that was not included. Steenkamp's (2015) article in JAMA sheds some light on PTSD treatment. We need to also examine research on the treatment of all types of trauma, including betrayal trauma and moral injury, for which those treatments that only attend to anxiety or anger-based trauma are ineffective.

Deborah Molik, LCSW *deborah.molik@gmail.com*

It is important to note that maintenance of treatment gains was not considered important in making the APA recommendations for effective treatment modalities. Longitudinal studies have shown that EMDR treatment gains are more often maintained than CBT treatment gains. Relapse prevention is an important factor not considered in the meta analysis.

Critical v important outcomes

Mary Beth Shea; mary.shea@va.gov

I am surprised that maintenance of treatment gains (draft CPG, page 28, line 23) was not considered to be sufficiently important to include in the process of making recommendations. In terms of treatment efficacy AND cost efficiency, if the gains don't last, it's not a good choice.

Commenter: Nikolas Frost; ndfrost@wisc.edu

Comment: Yes The guidelines reflect the evidence reviewed (albeit limited evidence). However, the relative weighting of outcome domains appears to be problematic. PTSD symptom reduction is considered a critical outcome while "loss of PTSD diagnosis" and "remission" are not. It is unclear why these two domains are not also considered critical if the treatment is intended to treat PTSD.

Commenter: Leah Cochrane; leahcochrane@icloud.com

Comment: Secondly, I have a concern regarding the selection or prioritization of outcomes for studies. Several outcomes labeled "important but not critical" would in my opinion be better placed in the "critical" category and expanded. Those are "disability and functional impairment" and "co-morbid" conditions. It has been my experience that for a patient with PTSD symptoms who progresses to experience co-morbid conditions and increasing disability and/or functional impairment, treatment that missed the mark in the beginning leads to treatment that is too little and too late. I have worked with patients who have faced an entire adult lifetime completely derailed by a single traumatic event, or a relatively small window of events (such as deployment to combat), who believe, as do I at this point, that had they gotten the right treatment at the right time, things would be a lot better than they are. Thus, having the treating professionals and their referring colleagues to completely understand these issues is in my opinion vitally important, even "critical."

Commenter: Elaine Ducharme; elaine.ducharme@yahoo.com

Comment: The use of the word harms is odd. Negative side effects seems more appropriate. It is unclear if the "harms" were actually from the treatment of from lack of a particular treatment or poor relationship or some other issue. Some patients make suicide attempts no matter what the treatment.

Language...Do serious harms of treatments...Just say what you mean...negative side effects of a particular type of treatment

Commenter: Stacy Raymond; Drstacyraymond@gmail.com

Comment: Some important research on CBT is clearly omitted from APA's report.

Citation: Appendix C

Dropout rate for Exposure Therapy/CBT:

The dropout rate from CBT therapy and studies of CBT has been underemphasized in the proposal. This oversight or avoidance of the issue clearly favors the presentation of CBT. In one of the largest published studies of CBT for PTSD over 1/3 of the patients dropped out. Several subjects reported adverse reactions. After three months only 15 % were free from major PTSD symptoms. Citation: P. Schnurr et al., "Cognitive Behavioral Therapy for Post Traumatic Stress Disorder in Women", JAMA, 297, no. 8 (2007): 820-830.

For subjects with a history of childhood abuse, CBT outcomes are not always strong. Of the PTSD subjects who complete the study, only about one third show improvement.

Citations: A. McDonagh-Coyle, et al., "Randomized Trial of Cognitive-Behavioral Therapy for Chronic Posttraumatic Stress Disorder in Adult Female Survivors of Childhood Sexual Abuse", Journal of Consulting and Clinical Psychology, 73, no. 3 (2005): 515-524.

Institute of Medicine of the National Academies, "Treatment of Posttraumatic Stress Disorder: An Assessment of the Evidence" (Washington, DC: National Academies Press, 2008).

Commenter: Kirk Schneider; kschneider56@gmail.com

Comment: Yes Yes, but this is part of the problem. The scope of objectives is basically confined to overt and measurable symptom changes, and not the more subjective and complex affects, such as impact on clients' sense of meaning and purpose toward living, the deeper associational effects of trauma, and the impact on clients' internal sense of freedom.

The draft should include an equal emphasis on qualitative investigation to address the more complex and implicit impacts of trauma, as described above, and that are treated by modalities, such as psychodynamic, intersubjective, and existential therapies that address complex life issues. Otherwise, we are missing the deeper conflicts as well as possibilities that cam arise in the context life-trauma. Qualitative indices should be valued on a par with the quantitative, so that levels of traumatic impact, as well as converging lines of evidence can be sorted and addressed.

The purpose of this treatment guideline should be broadened to include qualitative indices of traumatic impact on a par with the quantitative. The medical template for treatment efficacy should be revised to a psycho-social template reflective of the broad and diverse theoretical and treatment modalities informing psychology, not so much medicine or psychiatry. Such areas as quality of life should be seen as "critical" to the criteria for PTSD treatments, not secondary, which also means that studies should look at longer term, intensive therapies using mixed methods as well as longitudinal follow up to compare and contrast them with the data associated with the shorter term CBT and solution-focused treatments.

Commenter: Elliot Merrick; mftonwheels@gmail.com

Comment: I can absolutely attest from 1st hand and from NUMEROUS sessions with other former veterans, their family and police officers that EMDR is nothing more than a bandaid!!! I speak to this constantly that only long term therapy (I use the recover model) works and that PTSD CAN BE managed but NOT fully eradicated!! It takes someone who's experienced TRUE chronic trauma to understand this as our veterans and LEO's. If you want a quick reduction in symptoms EMDR is the trick BUT 1 yes 1 trigger will crumble those walls and begin to send the individual right back to where they were. In simple terms… theory of adaptation!! Feel free to contact ANYTIME. EMDR is NO cure!!

Panel Response:

One of the challenges in guideline development is that a panel cannot address all questions of interest. This guideline development panel determined that it would focus on the efficacy of psychological and pharmacological interventions for the treatment of PTSD. The panel considered an array of possible outcomes of treatment and ultimately selected two outcomes that are critical in decision making about care and several other outcomes that are important for decision making. The panel then reviewed the treatment literature and the evidence that a particular intervention had an impact on these outcomes. Many outcomes of interest to the panel have not been assessed in the treatment literature. For instance,

not all studies even assessed change in PTSD symptoms and very few studies- especially psychotherapy studies- reported on possible harms/ adverse events/ burdens of treatment ("harms" is a term routinely used in guideline development although it is less frequently used in psychotherapy research.) When the panel did not have any information about the effect of a particular treatment on a critical outcome, it had insufficient evidence for that particular domain. While certainly many outcomes are very important- and patient functioning and overall sense of well- being were endorsed by all panel members as relevant- few studies evaluated these outcomes, rendering it impossible to draw conclusions about the interventions effect on the outcomes. If the panel wanted to make decisions about treatments and their impact on such things as a client sense of meaning or moral injury, the task would have been very difficult because so few studies routinely assess these domains. Similarly, some studies used the M-PTSD but not all, making reliance on one measure not useful for this purpose.

The full draft document describes the process the panel utilized to identify critical and important outcomes on approximately page 15. Best practices in guideline development involve identifying critical outcomes for decision making in intervention planning. Many outcomes are relevant but not all outcomes are critical to decision making. Early in the guideline development process, the panel had to decide whether loss of PTSD diagnosis and remission should be considered critical outcomes or important outcomes. Our primary reason for considering them important but not critical outcomes is that we believed that a treatment that resulted in a meaningful reduction in PTSD symptoms but did not result in loss of PTSD diagnosis or remission would still be worthy of recommendation (provided that the treatment met the other criteria we used for treatment recommendation). If, say, loss of diagnosis had been considered a critical outcome and a treatment produced a large and clinically meaningful reduction in PTSD symptoms but not loss of diagnosis, it would be difficult to make a strong recommendation for that treatment. In other words, the panel believed it was too strict a criterion to require that a treatment produce loss of diagnosis or remission in order to recommend that treatment. There was unanimity on the panel, though, that both of those outcomes were important and should play a role in the process of determining whether and how strongly a treatment should or should not be recommended.

A second (and less important) reason that neither of them were considered critical outcomes is that many of the studies included in the systematic review did not include those outcomes in the study. An important part of the guideline development process is that if the strength of evidence is insufficient for a critical outcome, the guideline developers are then limited in making recommendations. If we had included loss of diagnosis and remission as critical outcomes, we would have been unable to make recommendations about the majority of treatments that we had evaluated.

The panel agrees that long-term outcomes are important and should be considered in making recommendations about treatments. The problem, though, is that there is no standard, agreed-upon time after completion of treatment that has been used for assessing long-term response to treatment in randomized trials of PTSD treatments. Since patient outcomes might very well be different at one month after treatment than one year after treatment, the systematic review pooled results for the only time that was similar across trials, i.e., the end of treatment. As the panel notes in the section of the report on Future Research Needs, it would be ideal for the PTSD research community to define optimal follow-up assessment times and for randomized trials to include those assessments. Then, future systematic reviews will be able to pool results across studies for those standard follow-up times and much-needed data on long-term outcomes will be available for future guideline panels.

The panel absolutely agrees that a wider range of options is necessary to best determine course of treatment and urges researchers, as well as clinicians, to expand the range of outcomes collected in trials

and gathered in clinical practice settings. Additionally, the panel very much wishes that treatment research followed patients over a long period of time. A better understanding of the long term impact of treatment, and its relationship to different interventions and different "doses" of care, would be beneficial.

Regarding this issue of dropout: Detailed information on dropouts from studies of each treatment is included in the Decision Table for each treatment, included in the Appendices. The panel considered this information in its overall evaluation of each intervention.

The term "harms" is a term used in the guideline development field that has a shared meaning across disciplines. Harms can encompass negative side effects along with other considerations. It is true that suicide attempts and other "adverse effects" may not be due to the treatment itself but when gathered across multiple studies, these low base rate outcomes can be measured to determine whether they are more likely for individuals receiving one intervention over another. More critically, however, is that harms are very inconsistently reported, especially in psychotherapy research. It is often not reported at all and rarely is it reported by treatment arm with sufficient explanation and documentation to determine whether or not it is an effect of the treatment. The panel calls for greater reporting of such outcomes in all research as the possibility of "harm" is very important when deciding which intervention to offer to someone.

Substance Use and PTSD

Commenter: Tammy Barnes (on behalf of the Committee on Rural Health); tbarnes@apa.org

Comment: Yes It did provide treatment recommendations but through a narrow focus. For example, substance abuse issues and suicidality are common in this population yet those issues were "beyond the scope of the guideline" lines 6-10 p.16 and lines 5-7 p.88. Therefore, the APA Committee on Rural Health (CRH) feels these issues cannot be compartmentalized.

Thus CRH offers a strong recommendation to address these issues at least through referral to another provider specializing in the needed area. CRH provides this suggestion in respect to its mission toward "...[e]ncouraging collaborative and interprofessional models of care, that may include traditional and non-traditional healing practices, to reduce behavioral health care stigma and to meet the diverse multicultural and linguistic needs of rural and remote populations, respecting diverse and intersecting identities; ..."

Panel Response:

The panel recognizes the high incidence of substance use problems for people with PTSD. One challenge of effectively evaluating the research is that in some studies, individuals with substance use disorders have been excluded from research samples so that it becomes more difficult to determine the efficacy of treatments for these individuals. This is an area of needed research and addressed briefly in the Discussion section of the document.

Referring individuals to the appropriate provider with the appropriate skills can be critical in managing and treating disorders. The document describes some of the training needs for providers of PTSD treatments but issues related to implementation of treatments, interprofessional models of care and similar concerns will be more fully addressed in the materials being developed to facilitate dissemination and implementation of these guidelines.

IOM

Mark G. Doherty *mdoherty@emdria.org*

The APA draft guidelines on PTSD treatment rely in part on the work of the Institute of Medicine (now the National Academy of Medicine) reports. The discussion that follows clearly points out errors, omissions, misrepresentations, and misunderstandings in the portrayal of eye movement desensitization and reprocessing (EMDR) therapy in IOM reports and provides information that correct these inaccuracies and deficiencies. In response to the Institute of Medicine's (IOM) July 2012, publication, Treatment for Posttraumatic Stress Disorder in Military and Veteran Populations: Initial Assessment, the Eye Movement Desensitization and Reprocessing International Association (EMDRIA) noted specific errors and omissions in the portrayal of EMDR therapy in the IOM reports; it believed that the misrepresentation of EMDR in the 2008 document unfortunately had been perpetuated in the 2012 Initial Assessment. In the following, we have identified several specific statements in the IOM report that misquote or misrepresent the original EMDR research papers. The inaccuracy of the quotes are serious enough to bias the conclusions of the IOM report and call into question the validity of the document.

Panel response:

The APA guideline on PTSD did not rely on the IOM reports on the treatment of PTSD. The development process for the guideline was based on the 2011 IOM report, Clinical Practice Guidelines We Can Trust. http://nationalacademies.org/HMD/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx

NREPP

Odet Beauvoisin; odetbeauvoisin@gmail.com

TFT has been evaluated by the National Registry of Evidence-based Practices and Procedures (NREPP) as having demonstrated "effective outcomes" in trauma treatment. EFT is currently under review by NREPP and has even stronger evidence.

Panel Response: *NREPP's process of evaluating the research literature is intermediate to guideline development. It does identify treatments with some documented support; however, it does not have the same rigor in evaluation of the research so the level of confidence in the assessment of treatments is not as high as those evaluated through the CPG process.*

Disclaimer

Several commenters raised concerns about the implications of releasing guidelines that recommend specific interventions.

Commenter: Harold Kudler, MD; hkudler@duke.edu

Comment: To make the guideline clearer, I recommend that a statement or statements be included in both the Introduction and in the Generalizability Section of the Discussion section to amplify a core

principle already implicit in the Disclaimer: That this guideline (like all guidelines) was not designed to be all inclusive or intended to dictate or limit practice. I suggest that specific language be added that states that the panel recognizes that, given the rigors of the research methodology used to construct this and other clinical practice guidelines, community standards of practice are broader than what can be covered within the guideline. Its intended function, therefore, is to enrich practice in concert with clinician judgement and client characteristics and preferences rather than limit practice to those therapies for which a sufficient evidence-base is currently available. Other practices (including but not limited to Stress Inoculation Therapy, Brief and Long Term Psychodynamic Psychotherapy, and Image Rehearsal Therapy as well as psychopharmacological interventions not recommended in this guideline) are widely practiced and are in no way contraindicated by this guideline.

Commenter: Laurie Donovan, LMFT, LCSW; ldonovanlmft@gmail.com

It would need a disclaimer that in the interest of methodological strength, many studies and much research and clinical work were not considered; the conclusions reflect a bias in that sense.

Dana Cason *dr.dana.cason@gmail.com*

Limiting research to RCT and excluding patients with comorbid conditions limits the generalizability of this research. I would like to see this acknowledged in the guidelines.

Lynn Buhler, PhD; lynnbuhler@verizon.net

Indicate that therapies that have been existence longer (and hence have longer research histories) would be expected to have more research conducted, and would hence have statistically stronger results, even if they were no better than (or even inferior to) newer therapies.

Make clearer the relationship between the RTI-UNC review and that conducted by the APA panel.

Brett Gorkin *bgorkin@gmail.com*

your guidelines will be used by insurance companies and government agencies amongst others as definitive for how PTSD should be treated. It seems to me that a partisan narrowing of recommended treatments for PTSD needlessly and recklessly disadvantages the very group of traumatized people who already receive altogether too little of the care that they need.

Susan C Warshaw, EdD, ABPP, Past President, Division of Psychoanalysis, NY State Psychological Association *drswarshaw@gmail.com*

Were these guidelines to be released as written, disclaimers and all, those of us who deal daily with insurance companies and governmental agencies concerned with cost containment, anticipate the use of these guidelines for the purpose of dictating treatments, requiring a variety of forms of "step therapies". These companies, and the consumer's who are influenced by them, inevitably exclude psychodynamically based treatments which oddly are not mentioned by you at all, despite the rootedness of many of the assessed therapies in psychodynamic principles, and despite your significant emphasis on the power of relatedness and relationship, the bedrock of psychodynamic therapies. There is no nuance in dealing with for profit or government health insureres, who will be only too happy to issue their own guidelines, reference theAPA as a source, and eliminate all of your caveats. Sadly, these

proposed guideline read as a wonderful academic exercise, carefully delineating all of the problems with the current document and the limitations of the conclusions which it draws. Unfortunately, despite all your awareness to the contrary, the Guidelines have the potential to injure real people who will be gang pressed into treatments which by your own statement are not assessed as dealing with "quality of life, functional impairment or tailored to best meet the needs of individual patients. Despite your acknowledgement, and awareness of the reality of clinical practice, and the problem with moving from research protocols to actual clinical work, the listing of recommended treatments effectively will be all that those that are used by those who develop the algorithms and count the beans.

Disclaimer/ Restriction of Care

Commenter: Dr. Benjamin Ose; bose001@hotmail.com Comment: No Of note, I am a board certified psychiatrist who has extensive training in CBT and EMDR and use both in private practice. This guideline is intended to be aspirational and is not intended to create a requirement for practice. It is not intended to limit scope of practice in licensing laws for psychologists or for other independently licensed professionals, nor limit coverage for reimbursement by third party payers. This section from your disclaimer will likely be overlooked by 3rd party payers who use treatment guidelines in part to determine reimbursement.

Commenter: Kelsey Emhardt; kschroth1112@gmail.com

Comment: Only labeling cognitive based therapies for trauma treatment as strong will have a negative impact. How often do clients present with knowledge that their cognitions are flawed and ample skills from CBT therapy and still struggle? If you work with clients who have experienced trauma, I am sure you know that many people have been in therapy for years without marked improvements. Every therapist uses CBT, but what about when that is not enough? Labeling other treatments as weak leaves no option in a nation/world that rely heavily on the report you are going to release. How many more veterans need to have limits options for treatments?

Panel Response: *APA has long been aware of the challenges of guidelines- while APA considers any guideline to be aspirational and a tool that a clinician uses in making decisions about the treatment offered to individuals- there is a risk that others may hold guidelines up to be standards, that is a directive that is mandatory and must be followed. This is problematic in that each clinical situation presents unique challenges and any independently licensed provider needs to be able to exercise appropriate judgment. However, guidelines provide benefit as well in terms of educating patients and providers, providing some synthesis of the ever expanding treatment evidence base, and making clear statements that treatments do work. For these reasons, APA has determined that the development of clinical practice guidelines is important. Yet, recognizing some of the concerns articulated by commenters, the panel has attempted to address these with additional language in the final document.*

Updated Review

Several commenters suggested additional studies that could have been reviewed by the panel. Additionally, some individuals did not seem to understand the purpose of the panel's updated review.

Andrew M. Leeds, Ph.D. *andrewmleeds@gmail.com*

Three RCT on EMDR therapy have been published since 2013 and therefore are not being considered in the APA report, which is based on an outdated Agency for Healthcare Research and Quality Studies published in 2013. These three studies should be reviewed and included in the APA report. .
Acarturk, C., Konuk, E., Cetinkaya, M., Senay, I., Sijbrandij, M., Gulen, B., & Cuijpers, P. (2016). The efficacy of eye movement desensitization and reprocessing for post-traumatic stress disorder and depression among Syrian refugees: Results of a randomized controlled trial. Psychological Medicine, 46(12), 2583.
Capezzani, L., Ostacoli, L., Cavallo, M., Carletto, S., Fernandez, I., Solomon, R., . . . Cantelmi, T. (2013). EMDR and CBT for cancer patients: Comparative study of effects on PTSD, anxiety, and depression. Journal of EMDR Practice and Research, 7(3), 134-143. doi:10.1891/1933-3196.7.3.134
van den Berg, D. P., de Bont, P. A., van der Vleugel, B. M., de Roos, C., de Jongh, A., Van Minnen, A., & van der Gaag, M. (2015). Prolonged exposure vs eye movement desensitization and reprocessing vs waiting list for posttraumatic stress disorder in patients with a psychotic disorder: A randomized clinical trial. JAMA Psychiatry. doi:10.1001/jamapsychiatry.2014.2637

Rose Hickman Rigole *rose@counselingsocal.com*

See above re consideration of new trials. Why this is so important in my comments is that it is so important for us, as clinicians, to provide effective treatment for PTSD. Cursory consideration of newer studies and overly weighing the prior recommendations, as the draft guidelines admit, jeopardize this very important goal, causing the older of the therapies (and possibly least effective) to continue to occupy the preferred slots. During the consideration for the next recommendations, this recommendation will also be overly weighed. With all of the care taken to avoid bias in this recommendation, this appears to embed it in the very structure. If the more recent research is not equally reviewed and the older literature reviewed anew, a structural bias will continue to jeopardize treatment of these suffering individuals.

Susan Gantt *sgantt@emory.edu*

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Sloan, Feinstein, Gallagher, Beck, and Keane (2013) conducted a meta-analysis of RCTs of group treatment studies for PTSD.

Panel response:

The panel did not have the time or resources to re-do the meta-analyses reported in the RTI-UNC systematic review by incorporating relevant studies published after May 2012. In the search update process, we did, however, identify articles published between May 2012 and June 2016 that would have met inclusion criteria for the systematic review; we then used data from those studies to assess the likelihood that the recommendations, based on the RTI-UNC systematic review, would or would not change as a result of the new data. Table 6, in the main report, shows a summary of the conclusions from the search update process and Appendix H shows details, for each recommendation, of the new studies identified and their potential impact on recommendations.

Statement regarding lack of evidence and newer treatments

Commenter: Norman M. Camp; normancamp@comcast.net

Comment: The CPG's omission of psychodynamic psychotherapy for trauma-related psychological disturbances, including what is now labeled PTSD, is tantamount to discrediting such a treatment approach and its methodology. Since many respondents have already complained that the CPG committee has selectively (mis)used the empirical evidence that would justify psychodynamic psychotherapy, my opposition will hinge on an ethical stance: (1) Although psychodynamic psychotherapy, which utilizes theories of psychic development and conflict, has been reported for generations to be effective for many people with these conditions, it faces new calls to substantiate its effectiveness via models of so called, evidence-based empirical science (there are persisting disputes, including politically-based ones, as to which "evidence" to privilege); (2) While parties such as the AP(psychology)A's draft PTSD treatment CPG deliberate--parties who would control systems of care delivery--an ethical principle should predominate. In instances when a treatment that has been perceived as effective in the past but which cannot be easily, quickly, or even practically proven to be effective through standard empirical science, it should be acknowledged that lack of proof of effectiveness does not substantiate that it is not effective. Therefore it follows that (3) It is unethical to oppose or undermine the continued provision of said treatment until science can prove that it is not effective.

Commenter: Betty Bracht; info@bettybracht.com

The APA continues to show a bias toward newer modalities, regardless of their effectiveness, in treating PTSD.

Commenter: Lewis Aron PhD and Susan Washaw, EdD; drswarshaw@gmail.com

Comment: Psychoanalytically oriented treatments do have scientifically recognized evidentiary support over multiple decades, but randomized clinical trials are often difficult to obtain, or are not able to fully capture the complexity of the issues at hand, or remain insufficient at this time. A statement should be inserted which indicates that nothing in these guidelines should be taken as dismissive of other treatment approaches, including psychoanalytic and psychoanalytically informed treatments.

Commenter: Kathryn Bell; kbell626@capital.edu

Comment: Although briefly acknowledged earlier in the document, no discussion of a potential "file-drawer effect" is mentioned in the discussion/limitations section. Exclusion of unpublished findings from clinical trials (especially findings that do not find a treatment effect) could result in certain treatments appearing to have a stronger treatment effect than is actually real. Additionally, exclusion of unpublished clinical trial findings could result in certain treatment harms not being identified in the review process. Minimally, it seems like these limitations should be acknowledged. Ideally, it would be beneficial to have unpublished clinical trial data considered in the review to determine the extent to which a file-drawer problem might exist (and, if so, the extent to which this problem might impact treatment recommendations).

Panel Response: *The panel is aware of these concerns and has expanded its discussion in the Guideline Summary and Future Directions section (beginning approximately page 90.) The panel also refers commenters to APA's policy statement and report on evidence-based practice in psychology for a discussion of these issues. http://www.apa.org/practice/resources/evidence/index.aspx*

What the guideline addresses

Commenter: Andrew M. Bezooyen; andrew@community-solutions.ca

Comment: The draft guideline clearly identifies the many limitations of the review, and when all these limitations are considered, the usefulness of the guidelines is greatly reduced. The danger here is that many readers will not take the identified limitations into consideration when referring to the conclusions as their rationale for applying one treatment approach over another.

For example, a clinician may refer to the guidelines as their rationale for trying to apply CBT with a traumatized child or someone with subclinical PTSD, when these groups have been excluded from the analysis.

AS a clinician, a document that clearly outlines strategies that are potentially harmful to the client and have proven to be ineffective would be much more useful.

Panel response:

The section, Guideline Scope: What the Guideline Addresses and What It Does Not, clearly specifies that the Guideline does not address subthreshold PTSD or PTSD treatment for children.

Recommendations against txs without plausible mechanism of effect

Scott Lilienfeld *slilien@emory.edu*

My lone major suggestion for these otherwise excellent practice guidelines for PTSD is to inform practitioners and would-be consumers of the potential hazards of treatments that lack a remotely plausible theoretical rationale. A number of relatively recent writings in medicine (Atwood, 2008) and in psychotherapy (David & Montgomery, 2011; Lilienfeld, 2011) more specifically have underscored the importance of considering not merely the evidence base for a given intervention in controlled trials but also broader scientific evidence bearing on its theoretical plausibility. Some scholars have termed this combined approach, increasingly favored in many domains of medicine, "science-based medicine" or "science-based practice" to distinguish it from 'evidence-based medicine" or "evidence-based practice," respectively (Ingraham, 2014)

In fairness, healthy debate continues to revolve around the likely therapeutic mechanisms of prolonged exposure and other beneficial interventions for PTSD. At the same time, certain widely used interventions for PTSD and allied conditions are underpinned by theoretical rationales that conflict with extremely well-established principles of basic science. As a consequence, they almost certainly cannot operate by means of their posited mechanisms. In particular, a wide range of energy therapies, such as Thought Field Therapy and Emotional Freedom Techniques, purport to treat, if not cure, PTSD symptoms (as well as symptoms of other anxiety-related conditions) by manipulating and unblocking invisible energy fields surrounding the patient's body (Pignotti & Thyer, 2009). Such energy fields have never been detected and violate the known laws of physics; moreover, advocates have offered no compelling means of detecting them, either directly or indirectly.

Practice guidelines for PTSD would therefore be wise to note that energy therapies and allied treatments for PTSD rest not merely on an exceedingly implausible theoretical rationale, but on one that completely violates extremely established scientific principles. From the standpoint of "science-based medicine," such treatments should be regarded as falling well outside the mainstream of scientifically

grounded psychological practice. If such treatments do any good at all for PTSD, it almost certainly because of nonspecific variables (e.g., placebo effects) or adventitious exposure offered during the intervention; in these interventions, such exposure is almost always delivered unsystematically and in weak doses, and is therefore far from ideal for therapeutic purposes.

Panel response:

These are reasonable suggestions but they are beyond the scope of our mandate. We did not consider mechanism of effect or plausability in assessing intervention effectiveness. Further, complementary and alternative interventions were not included in the RTI-UNC systematic review that served as our evidence base.

Definition of trauma/ PTSD

Several commenters noted concerns with the panel's operating definition of trauma or PTSD. A few comments follow.

Commenter: Elaine Ducharme; elaine.ducharme@yahoo.com

Comment: Trauma definition can vary based on client experience of the event. This could be a bit clearer.

Commenter: Bradley Boivin, PsyD; bradleyboivin@me.com

Comment: Lastly, I think it would be in the best interest of the Association, its members, and the patients we treat, to make a clear distinction between Adult-onset PTSD and adults experiencing trauma symptoms secondary to adverse childhood experiences (see van der Kolk, 2014). As a psychologist who has worked first hand with inmates in a maximum security prison who have experienced significant symptoms due to early childhood trauma, it is my opinion that many of the treatments recommended in these guidelines are significantly limited due to the fact that the initial trauma occurred prior to language development. It is quite challenging to engage in EMDR, Prolonged Exposure, or even CBT interventions when the patient lacks any clear verbal memory of or narrative for their trauma. I have found Psychodynamic, relational and certain humanistic approaches to be most effective in my clinical work with these adult patients who experienced early childhood trauma. It is stated that these recommendations are not intended for children, but what seems to be lacking is the fact that children who experience trauma eventually become adults and their PTSD symptoms look, present, and are experienced very differently than PTSD acquired as an adult.

Commenter: Janice Scott; therapywest7@gmail.com

No I find it disturbing to see that the APA seems to be moving towards a pattern of health provision, which in the UK, has been recognised as seriously lacking. Where patients are rejected if they are deemed unlikely to meet the 'targets' of treatment.

Such a retrogressive step has profound implications for mental health care provision.

Horace Benefield mikeb-oakleaf@sbcglobal.net

Posttraumatic Reactions and Diagnoses (draft Page 21). Recommend that DSM-5 PTSD effects by different target traumas be clearly expressed as either non-dissociative or dissociative. DSM-5 clustering accommodates such a higher level of classification, and includes such important areas as

mortal self-harm. Available DSM-5-based PTSD checklists accommodate measure access for both categorizations.

Commenter: Lilli Friedland; lillif@aol.com

Comment: No It does not include whether the ICD-10 definition (no duration requirements), etc. As we are required to use this classification system it would be helpful and necessary to include this.

Commenter: Charles W. Hoge, MD; Charles.w.hoge.civ@mail.mil

Comment: The draft CPG also does not acknowledge potential serious clinical concerns raised recently with the DSM-5 PTDS definition (see Hoge, et. al. JAMA Psychiatry 2016, Friedman, et. al. rebuttal, and additional letters by Hoge and others). These concerns include exclusion of a large proportion of patients who would meet the older definition (and for whom there is an extensive RCT literature to support evidence-based treatments), lack of evidence that the new definition improves clinical utility, and potential problems with generalizability of clinical trials based on DSM-IIIR/IV to patients diagnosed under DSM-5. Clinicians need to be aware of these concerns, so as to ensure that patients who do not meet DSM-5 definition, but would meet the DSM-IV definition if this was used, are not denied evidence-based treatments validated under DSM-IV (or insurance reimbursement), and to understand potential problems with generalizability of older clinical trial literature to patients diagnosed under DSM-5.

Commenter: Jasmine Alexander MA RPC RCC CCC CCPCPR; jasminerose@shaw.ca

Comment: No The introduction is missing information pertaining to dissociation and the role dissociation plays in PTSD

Commenter: Frances Doughty; fdpubs@gmail.com

Comment: No The purpose is the problem. It still views trauma as "the event", despite evidence from the ACE and many other studies that adverse childhood experiences are varied, correlated, and result in serious emotional/cognitive/health problems in adult life. The reset of the document continues the traditional approach to trauma, neglecting the rapidly growing evidence for both mental and physical health consequences in adults of early childhood adverse experiences. No single adult treatment can address this range of issues.

Complex PTSD

Commenter: Sheila A.M. Rauch, PhD, ABPP: Sheila.a.m.rauch@emory.edu

Comment: Page 83 mentions "complex PTSD" as a potential mediator of treatment response. The definition of complex PTSD is not well accepted or even established between groups that say they are studying this phenomenon. in addition, the research suggesting this impedes treatment response is poor (See de Jogh review in Depression and Anxiety In- Press). I suggest removing this.

Commenter: Helena Kriel; Hkriel01@hamline.edu

Comment: Given that the pending ICD-11 will include complex PTSD, it would be ideal also to include at minimum a definition and discussion of CPTSD in this guideline as well--and even better, to include recommendations for treatment of CPTSD vs. PTSD.

Commenter: David Emerson; demerson@jri.org

Comment: PTSD is not the only relevant iteration of trauma. Many people suffer from complex trauma (also called interrelational trauma or, more recently Developmental Trauma). The research is very

compelling that we need to take a broader view of exactly what trauma is and how it impacts individuals.

Panel Response:

The APA Clinical Practice Guideline for the Treatment of Posttraumatic Stress Disorder (PTSD) in Adults focuses exclusively on recommendations for treatment of PTSD in adults. While assessment of PTSD is a key clinical activity, this Guideline does not address diagnosis or classification. Regarding the comment on applicability of results to patients who meet criteria for DSM-5, we already included a paragraph on that topic in the report and concluded that the findings from the systematic review and this corresponding guideline based on that systematic review, are likely to be applicable to patients who are diagnosed with PTSD based on DSM-5.

Treatment other than Individuals/ Target of Treatment

Commenter: Dr. Suzanne B. Phillips; suephil@optonline.net

The guidelines are also a concern in terms of the limitation of only addressing individual patients with a Diagnosis of PTSD. We live in a world that has been punctuated by terrorism, violence, school shootings, political and racial unrest. Why would APA at this time, limit its consideration of guidelines to address PTSD to one possibility - the single practitioner with the diagnosed client? Group programs that have been utilized by the American Group Psychotherapy Association across the time line of trauma from acute stage to Anniversary Events offer options in the wake of terrorist attacks, natural disasters, and violence. Such programs can make possible the availability of Group Psychological First Aid, Large Group Psycho-education, Family Programs etc. that in the aftermath of traumatic events mediate the impact and degree of PTSD and provide a stepping point for higher levels of treatment and care. Why are such programs not being considered? Why are they not part of the scope of interventions that impact the treatment of PTSD?
A recent article published in American Psychologist (Blanco A., Blanco, R., & Diaz, D, 2016, Vol.71, No.3, 187-198.) is entitled " Social (Dis) Order and Psychosocial Trauma: Look Earlier, Look Outside and Look Beyond the Persons." It's consideration of intentional collective violence shouts out to us that our treatment of trauma must extend beyond the office and single patient. With reference to human rights violations, peritraumatic factors as life threat rooted in political or social belonging as suffered by millions of people in Latin America and elsewhere, the authors suggest that the main targets of therapeutic intervention must be " to help victims restore the network of social and emotional ties destroyed by collective violence."
" There was a general agreement that the group and community setting is the best place for achieving these goals."

Panel Response:

The systematic review that served as the evidence base for the Guideline did not exclude trials of treatments that were administered in group formats. Those treatments were not analyzed separately from other treatments. However, as noted in the section, Guideline Scope: What the Guideline Addresses and What It Does Not, the Guideline does not address interventions designed to reduce the risk of development of PTSD among those exposed to trauma but not diagnosed with PTSD.

Recommendations

Nancy Greene *greenenancy@roadrunner.com*

Why not list various ways therapists work with patients with PTSD without weighing strengths or recommendations.

Commenter: Charles M. Lepkowsky, Ph.D.; clepkowsky@gmail.com

Comment: I support the committee's inclusion of a variety of evidence-based treatments for PTSD. Hopefully, formalizing this specific recommendation will lead to an expansion of the treatment modalities considered 'reimbursable' or 'allowable' by insurers, e.g., beyond EMDR or PET only for extended sessions.

Commenter: Julian Ford; jford@uchc.edu

Comment: No The aggregation of a wide variety of "CBT" treatments fails to describe the often very different types of psychotherapy actually provided under this generic rubric. Thus, practitioners may be using a wide variety of actual therapeutic methods while claiming to be providing "evidence-based CBT."

There is an important and growing research base for two distinctive approaches to PTSD psychotherapy that were arbitrarily excluded: affect/interpersonal therapies (e.g., IPT, STAIR, TARGET) and present centered therapies.

The summary of research on the most extensively studied psychotherapy models fails to describe the degree of selectivity in enrollment of subjects in the RCTs, most of which excluded far more applicants than were enrolled thus severely limiting the external validity of the findings.

External validity of the findings on sustained benefits (which is limited and mixed to begin with) is very poor due to not encompassing (a) worsening of symptoms or impairment amongst those lost to attrition during follow-up, (b) receipt of other/additional treatment during follow-up.

The exclusion of studies that enrolled subjects with partial/subthreshold PTSD arbitrarily excludes several studies in which the vast majority of subjects had full PTSD and baseline symptom levels and impairment were comparable or greater than that of many of the included studies.

Commenter: Julian Ford; jford@uchc.edu

Comment: No The evidence for NET is incorrectly classified as weak but should be strong.

The evidence regarding recipient preferences is very limited and is given only token consideration.

The evidence for any pharmacotherapy is correctly stated as weak at best, but in the introductory summary these therapies are described as recommended with comparable strength to the recommendation for psychotherapies that have much stronger evidence (e.g., NET, EMDR).

Commenter: Loretta Malta; lsmaltaphd@gmail.com

Comment: No I don't know. However, at least three well-controlled RCTs with Veterans have demonstrated outcomes for CBT/exposure therapy that were substantially inferior to RCTs with civilian populations. Specifically, the rates of remission are much lower, the drop out rates are higher, and in the case of a study of PTSD/SUD, CBT/exposure therapy was not superior to the control treatment condition. I am unclear why three (or more) well-controlled studies was not deemed sufficient for the

panel to conclude that there is some evidence that Veteran populations do not benefit from CBT/exposure to the same extent as civilians.

Panel response:

If the final document listed treatments that therapists use without providing recommendations about which treatments therapists should use, this effort would not be a guideline.

The panel is making no recommendations about which treatments should be reimbursed by insurance companies.

We agree that a wide variety of treatments are subsumed within the rubric "CBT". There is no universally accepted approach to categorizing psychotherapies.

Interpersonal therapy (IPT) was not excluded. Please see the comments and panel response devoted specifically to IPT. Present-centered therapies were not evaluated as treatments. Present-centered therapy was used as a comparison group treatment in some of the trials included in the systematic review.

Randomized trials, with the exception of large practical trials, typically exclude a larger number of potential participants than they include. That feature does not, in itself, limit the generalizability of the findings. Lack of generalizability implies that there is treatment effect heterogeneity (i.e., that the magnitude of the treatment effect varies across specific subgroups) and that there are differences in those subgroup characteristics between the samples in the trials or a systematic review of trials and the external population. The systematic review that served as the evidence base for the Guideline concluded, "We recognize the hypothesis that treatments proven to be effective for adults with PTSD should be applicable to all adults with PTSD, but we did not find evidence to confirm or refute this hypothesis".

Attrition would affect internal validity, not external validity. Trials with high attrition (and/or high differential attrition across treatment groups), lack of intention to treat and use of completers only analyses were rated high risk of bias and were only included in the sensitivity analyses.

NET was given a weak recommendation rather than a strong recommendation because although there was moderate strength of evidence for PTSD symptom reduction, there was low or very low strength of evidence for other outcomes. All other treatments that received a strong recommendation had at least moderate strength of evidence for PTSD symptom reduction and moderate strength of evidence for at least one other important outcome.

RE subthreshold PTSD: As noted in the comments, the systematic review did exclude trials that included participants who met subthreshold but not full diagnostic criteria for PTSD. That is a not unreasonable decision and created more homogeneous groups for assessing the effectiveness of treatments for PTSD. Further, that decision may have led to larger effect sizes for PTSD treatments. There is evidence that persons with subthreshold PTSD have less severe symptoms (Breslau, Lucia & Davis, 2004). There is evidence from meta-analyses that psychological (Driessen, Cuijpers, Hollon, & Dekker, 2010) and pharmacological (Fournier et al., 2010) treatments for depression are more efficacious among patients with higher severity at baseline. If the finding that the treatment is more effective among persons with higher baseline severity is also true for persons with PTSD, the exclusion from the systematic review of studies that included persons with subthreshold (and therefore lower severity) PTSD might have led to larger effect sizes for PTSD treatments than if those studies had been included.

RE: Patient preferences: While there is a growing literature of patient preferences for treatment (Simiola, Neilson, Thompson & Cook, 2015) most of the data on patient preferences was not relevant to the

comparisons addressed in the systematic review or the Guideline. As a result, patient preferences did not play a large role in any of the panel's recommendations. We are hopeful that as more data on patient preferences becomes available, they will play a larger role in future treatment guidelines.

Breslau N., Lucia V.C., Davis G.C. (2004). Partial PTSD versus full PTSD: an empirical examination of associated impairment. Psychological Medicine, 34,1205-1214.

Driessen, E., Cuijpers, P., Hollon, S. D., & Dekker, J. J. (2010). Does posttraumatic severity moderate the efficacy of psychological treatment of adult outpatient depression? A meta-analysis. Journal of Consulting and Clinical Psychology, 78(5), 668-680. doi: 10.1037/a0020570

Fournier, J. C., DeRubis, R. J., Hollon, S. D., Dimidjian, S., Amsterdam, J. D., Shelton, R. C., et al. (2010). Antidepressant drug effects and depression severity: A patient-level meta-analysis. JAMA, 303(1), 47-53. doi:10.1001/jama.2009.1943

Simiola V., Neilson E.C., Thompson R., Cook J.M. (2015). Preferences for trauma treatment: A systematic review of the empirical literature. Psychological Trauma, 7, 516-524. doi: 10.1037/tra0000038.

RE subgroup analyses for combat trauma vs other trauma types: Please see p 121 of the systematic review for a discussion of assessment of treatment effect heterogeneity by trauma type (combat vs other).

Recommendation language

Commenter: Jeffrey J. Bruno, spiralhope@att.net

Comment: The problem is most people are not going to read the details, but merely look at the recommendation bullet points. When words like "Strongly For" versus "Weak For" are used it creates an impression of vast superiority of the former therapy methods over the later, when the actual effectiveness may be actually better captured by relationship factors between therapist and client. I believe if you're trying to boil down findings more moderate language in making distinctions needs to be considered.

Commenter: Mary Beth Shea; mary.shea@va.gov

Comment: In the Jonas study, the Key Question 1 is answered: "Among the psychological treatments, the strongest evidence of efficacy for improving PTSD symptoms and achieving loss of PTSD diagnosis was for exposure-based therapy (high and moderate SOE, respectively). Evidence of moderate strength also supports the efficacy of CPT, CT, CBT-mixed therapies, EMDR, and narrative exposure therapy for improving PTSD symptoms and/or achieving loss of PTSD diagnosis" (page ES-9). Yet, the CPG repeatedly lists the recommended treatments in alphabetical order, eliminating the fact that exposure therapies were more highly rated than any of the cognitive, cognitive behavioral, or other therapies, and further, burying the exposure recommendation behind all those cognitive recommendations. There must be a better, more accurate way of presenting these data.

Commenter: Jeffrey Lackner; lackner@buffalo.edu

Comment: More definitive distinctions between level of evidence for therapies; the document conveys a level of equivalence across top two groups of therapies; this will be problematic for payers including managed care, medicare, etc

No I think this is an excellent document - I have not had a chance to review it extensively and in this way I am like many decision makers who will cut to the case and look for the bottom line conclusion In this respect the below suggests a level of equivalence in the two groups of therapies which the review does not support What is the difference between suggests the use and strongly recommends? The lack of distinction will be problematic for health care decision makers

Panel Response:

The panel chose to use two levels of recommendation: strong and conditional (previously weak). In general, treatments that received strong recommendations had at least moderate strength of evidence for the critical outcome of PTSD symptom reduction and at least moderate strength of evidence for at least one important outcome. Treatments that received conditional (weak) recommendation had either low strength of evidence for the critical outcome of PTSD symptom reduction or had moderate strength of evidence for PTSD symptom reduction but low or very low strength of evidence for other important outcomes. Treatments that are strongly recommended and treatments that are suggested both have evidence of efficacy- the evidence base and the confidence in the recommendation is stronger for the former.

Comments on IPT

Commenter 1: John Markowitz, MD; jcm42@cumc.columbia.edu

Comment:

It partly achieves its intended purpose, but its scope seems overly narrow. Your review and recommendations for psychotherapies for PTSD expectedly focused on exposure-based therapies: hence the restricted list of search terms on page 45 of your draft document. Had you included the term "interpersonal," and had you extended your search beyond 2014, you would have located multiple studies on Interpersonal Psychotherapy (IPT) as an alternative treatment for PTSD, tested in randomized trials. I am somewhat surprised that your group of experts did not consider this and the guidelines make no mention of IPT. They should.

Krupnick and colleagues (2008) showed that group IPT was superior to a waiting list control in a randomized clinical trial of 48 multiply traumatized, non-treatment seeking, socially deprived women recruited from public primary care and gynecology clinics. Campanini and colleagues (2010) added this group approach to pharmacotherapy for 40 patients (6-8 per group) who had not responded to a twelve week adequate trial of pharmacotherapy for chronic PTSD and reported that Clinician-Administered PTSD scales fell from 72.3 (SE= 4.4) to 36.5 (5.4). Markowitz and colleagues found individual IPT non-inferior to Prolonged Exposure and superior to Relaxation Therapy in a randomized trial of 110 unmedicated patients with chronic depression. Moreover, there were suggestions of advantages for IPT in patients with comorbid major depression, as well as (non-significantly) lower dropout and higher response rates.

Key references:

Krupnick JL, Green BL, Stockton P, Miranda J, Krause E, Mete M: Group interpersonal psychotherapy for low-income women with posttraumatic stress disorder. Psychother Res 2008;18:497-507

Campanini RF, Schoedl AF, Pupo CM, Costa AC, Krupnick JL, Mello MF: Efficacy of interpersonal therapy-group format adapted to post-traumatic stress disorder: an open-label add-on trial. Depress Anxiety 2010;27:72-77

Markowitz JC, Petkova E, Neria Y, Van Meter P, Zhao Y, Hembree E, Lovell K, Biyanova T, Marshall RD: Is exposure necessary? A randomized clinical trial of interpersonal psychotherapy for PTSD. American Journal of Psychiatry 2015;172;430-440

Commenter 2: Alexandra Rafaeli, Alexandra.rafaeli@gmail.com

Comment 1:

If the goal is to provide treatment recommendations for PTSD, I would expect that IPT also be considered as an alternative to Exposure based approaches.

Comment 2:

I'm sure there are others, but as a therapist on Dr. Markowitz's IPT-PTSD NIMH study. I'm personally aware of the following and would suggest they be read and considered (included those listed above as well):

Rafaeli, A; Markowitz, J.C.: The development of an evidence-based treatment for ptsd: Interpersonal therapy (IPT). Future Directions in Post-Traumatic Stress Disorder: Prevention, Diagnosis and Treatment, Springer publishers¬ Eds: Helene S. Wallach, Marilyn Safir, Albert Rizzo

Rafaeli, A; Markowitz, J.C.: Case presentation: IPT for PTSD. Future Directions in Post-Traumatic Stress Disorder: Prevention, Diagnosis and Treatment, Springer publishers Eds: Helene S. Wallach, Marilyn Safir, Albert Rizzo

Rafaeli, A; Markowitz, J.C: Interpersonal Psychotherapy (IPT) for PTSD: A case study – American Journal of Psychotherapy. Volume 65, Number 3, pp. 205-223(19)

Commenter 3: Holly A. Swartz, MD; swartzha@upmc.edu

Comment 1:

Failure to include the search term “interpersonal” in the search rubric inappropriately limits the scope of therapies included in the finally document. By doing so, the search produced recommendations biased toward cognitive and exposure-based treatments for PTSD, potentially misleading potential patients, providers, and payers. Interpersonally-focused approaches now have well-established efficacy for PTSD. Also of importance, prolonged exposure treatments have had poor uptake in the VA system, despite extensive training initiatives. Thus, it is imperative to accurately represent the full range of evidence-based treatments for PTSD, providing choices for therapists and patients who cannot tolerate or prefer to have alternatives to exposure-based treatments.

Krupnick and colleagues (2008) showed that group IPT was superior to a waiting list control in a randomized clinical trial of 48 multiply traumatized, non-treatment seeking, socially deprived women recruited from public primary care and gynecology clinics. Campanini and colleagues (2010) added group IPT to pharmacotherapy for 40 patients (6-8 per group) who had not responded to a twelve week adequate trial of pharmacotherapy for chronic PTSD and reported that Clinician-Administered PTSD scales fell from 72.3 (SE= 4.4) to 36.5 (5.4). Markowitz and colleagues found individual IPT non-inferior to Prolonged Exposure and superior to Relaxation Therapy in a randomized trial of 110 unmedicated patients with PTSD. Moreover, there were suggestions of advantages for IPT in patients with comorbid

major depression, as well as (non-significantly) lower dropout and higher response rates. In addition there are several smaller or open trials of IPT for PTSD.

Key references:

Campanini RF, Schoedl AF, Pupo CM, Costa AC, Krupnick JL, Mello MF: Efficacy of interpersonal therapy-group format adapted to post-traumatic stress disorder: an open-label add-on trial. Depress Anxiety 2010;27:72-77

Cloitre M, Koenen KC, Cohen LR, Han H: Skills training in affective and interpersonal regulation followed by exposure: a phase based treatment for PTSD related to childhood abuse. J Consult Clin Psychol 2002; 70:1067-74.

Krupnick JL, Green BL, Stockton P, Miranda J, Krause E, Mete M: Group interpersonal psychotherapy for low-income women with posttraumatic stress disorder. Psychother Res 2008;18:497-507

Markowitz JC, Petkova E, Neria Y, Van Meter P, Zhao Y, Hembree E, Lovell K, Biyanova T, Marshall RD: Is exposure necessary? A randomized clinical trial of interpersonal psychotherapy for PTSD. American Journal of Psychiatry 2015;172;430-440

Watts BV, Shiner B, Zubkoff L, Carpenter-Song E, Ronconi JM, Coldwell CM: Implementation of evidence-based psychotherapies for posttraumatic stress disorder in VA specialty clinics. Psychiatr Serv 2014 65:648-53

Comment 2: Failure to include in the review evidence-based, IPT-focused, therapies for PTSD yields biased results. Absence of a discussion of these alternative approaches does a disservice to patients who should have information about the full range of therapeutic options available to them. As written, these guidelines will be obsolete and misleading before they are ever released.

Commenter: Janice L. Krupnick, Ph.D.; krupnicj@georgetown.edu

Comment: It is not surprising that the APA guideline on the treatment of PTSD focuses on exposure therapy since this treatment methodology has a good deal of research evidence to support it and was recommended by the Institute of Medicine as the only intervention with a substantial evidence base. However, it seems to me that the APA recommendation for the guideline is overly narrow in that it does not take into consideration the growing evidence base for Interpersonal Psychotherapy (IPT) for PTSD. A number of researchers, including myself (Janice Krupnick, Ph.D.) and colleagues, John Markowitz and colleagues, and Companini and colleagues have demonstrated the efficacy of IPT for PTSD, not only in civilians, but also possibly in veterans, in the U.S. and other countries, and in individual and group formats. Several pilot studies, including Bleiberg and Markowitz (2005), Krupnick, Green, Stockton, et al., (2008), and Companini, Schoedl, Pupo, et al. (2010), demonstrate the effectiveness of IPT for PTSD in individual and group formats. Talbot and colleagues (2005) demonstrated the effectiveness of IPT for depression in helping women with PTSD in community health clinics and Cort et al., (2014) showed that IPT could help women with histories of interpersonal partner violence. Further, Markowitz, Petkova, Neria, et al., (2015) demonstrated outcome equivalence between IPT for PTSD and Prolonged Exposure in a large-scale randomized clinical trial, demonstrating that exposure is not needed for symptom and functional improvement in patients with PTSD. Krupnick, Melnikoff, and Reinhard (2016) found that IPT for PTSD was effective as a treatment for women veterans. This method is now being tested in a 2-site study for male and female veterans, comparing the outcomes of IPT for PTSD with exposure therapy as practiced in the VA system. Since no one treatment option works equally well for all patients with PTSD (as well as other problem areas), it is important to have alternatives to exposure therapy as well as other

cognitive behavioral options. IPT for PTSD is emerging as a treatment option that should be considered for individuals who may not choose and may not benefit from exposure treatment. Growing evidence shows that it may be more tolerable and just as effective as prolonged exposure for the treatment of PTSD.

Panel Response:

As noted in Table 3, p 11 of the systematic review that served as the evidence base for this report, randomized trials of the following psychological treatments were eligible for inclusion in the systematic review:

- *Brief eclectic psychotherapy*
- *Cognitive-behavioral therapy*
- *Cognitive restructuring*
- *Cognitive processing therapy*
- *Exposure-based therapies*
- *Coping skills therapy*
- *Stress inoculation training*
- *Relaxation*
- *Eye movement desensitization and reprocessing*
- *Hypnosis or hypnotherapy*
- *Interpersonal therapy*
- *Psychodynamic therapy*

Randomized trials of interpersonal therapy were indeed eligible for inclusion in the systematic review.

The terms on page 45 cited by the commenter were not the terms that were used in the search by the systematic review. As stated in the text, those were the terms that were used to identify articles that might include data on adverse effects for those treatments for which we made recommendations. Interpersonal therapy was not included in the list because we did not make recommendations for interpersonal therapy.

The search terms used the RTI-UNC Evidence-Based Practice Center to identify randomized trials for the systematic review are shown in Appendix B of the systematic review (pages B1 – B19). The terms "interpersonal therapy" and "interpersonal psychotherapy" were used in that search as shown on the following pages:

Page B1, Search #23, Medline

"interpersonal therapy" OR "interpersonal psychotherapy"

Page B3, Search #25, Cochrane Database

"interpersonal therapy" OR "interpersonal psychotherapy"

In addition, on page B4, Search #7, for IPA, CINAHL, and PsycINFO includes the major descriptor "Psychotherapy" as a search term; the thesauraus for those databases indicates that "interpersonal therapy" is one of the terms that is subsumed by the major descriptor, "Psychotherapy".

The systematic review identified three trials of interpersonal therapy that were considered initially eligible for inclusion: Meffert (2011), Schaal (2009) and Krupnick (2008). Meffert (2011) was excluded because a screening test, not a diagnostic test, was used for assessment of baseline PTSD; only trials that used a diagnostic assessment were included in the systematic review. Schaal (2009) was excluded because participants aged 14 – 28 were included; the systematic review included only RCTs in which participants were 18 years of age or older. Krupnick (2008) was excluded from the systematic review because it was rated high risk of bias for the following reasons: "High risk of selection bias due to attrition. "Very high attrition and high differential attrition (% completers by group: 63 vs. 44). Regarding 'other' method of handling dropouts: imputed missing scores as the application of the observed group mean change." (p. E-26).

The Campanini trial cited by the commenter would not have been eligible for inclusion in the systematic review because it was not a randomized trial.

The trial by Markowitz and colleagues (2015) was not included in the systematic review because the search conducted by the systematic review ended May 24, 2012. However, we did identify the Markowitz (2015) paper in our search update, designed to assess whether any of our recommendations changed as a result of new evidence. (As described in the Guideline, we conducted an updated search to identify trials published between May 25, 2012 and June 1, 2016 that met inclusion criteria for the systematic review and included evidence relevant to any of our recommendations.) The Markowitz trial included three intervention groups: 1) exposure; 2) interpersonal psychotherapy; 3) relaxation. Since we had made a recommendation, based on evidence from the systematic review, for comparative effectiveness of exposure vs relaxation, we included data from the Markowitz paper in our assessment of whether new evidence was likely to change that recommendation based on evidence in the systematic review. However, we did not assess the interpersonal therapy vs exposure comparison or the interpersonal therapy vs relaxation comparison because we did not assess any data for any treatments or treatment comparisons for which we had not previously made a recommendation on the basis of data from the systematic review.

Even if we had decided, for the search update process, to assess the data on treatments that had not been assessed in the systematic review, the interpersonal therapy vs. relaxation comparison and the interpersonal therapy vs. exposure comparison, from the Markowitz (2015) paper, would have been rated moderate risk of bias using the Risk of Bias assessment used in the systematic review (Owens et al., 2009; Berkman et al., 2015). The Markowitz paper reported 25% overall attrition and greater than 15% differential attrition (i.e., across intervention groups). For the systematic review that served as the evidence base for the APA Guideline, overall attrition greater than 20% or differential attrition greater than 15% warranted a rating of high risk of bias if the trial did not use statistically appropriate methods for handling missing data. Since the Markowitz (2015) trial used rigorous and appropriate methods for handling missing data, the high overall attrition and high differential attrition would justify a rating of moderate risk of bias rather than high risk of bias.

Using the Strength of Evidence rating system used by all of the AHRQ-funded Evidence-based Practice Centers (Owens et al., 2009; Berkman et al., 2015), the data from the Markowitz paper would have been rated as low strength of evidence. Risk of bias, as noted above, would likely be rated as moderate. Consistency would have been rated as unknown, based on evidence from a single trial. (As noted above, two of the other trials on IPT were not included in the systematic review because they did not meet

inclusion criteria and one was excluded because of high risk of bias). Since confidence intervals for the difference in mean CAPS score at outcome, between interpersonal therapy and relaxation and between interpersonal therapy and exposure were not reported in the Markowitz paper, precision (one of the four major criteria used to assess strength of evidence) cannot be assessed. Directness, one of the four major criteria for strength of evidence rating, would be rated direct.

It is important to note that the criteria used for assessment of risk of bias and strength of evidence in the systematic review are used by all thirteen of the AHRQ-funded Evidence-based Practice Centers (EPCs). The EPCs have published more than 600 reports on assessment and management of a wide variety of physical and mental health conditions since 2000. The criteria that the EPCs use for assessing risk of bias and strength of evidence are similar, with minor exceptions, to the criteria used by the The Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group and the Cochrane Collaboration.

The systematic review that served as the evidence based for the guideline did not focus on exposure-based therapies and the guideline that we developed did not focus on exposure-based therapies, as asserted in the comments.

Psychoanalysis/ psychodynamic/ self psychology

Several individuals expressed concern that psychoanalysis or psychodynamic treatment were not explicitly recommended as treatments for individuals with PTSD. Numerous individuals sent in the same lengthy comment and others sent more individualized comments. The primary themes are included in the points below.

Commenter: Robert D. Stolorow; robertdstolorow@gmail.com

Comment: I find it vexing that in its narrow focus on so-called "evidence-based" treatments, the Guideline omits any mention of recent advances in the psychoanalytic understanding and therapeutic approach to emotional trauma. I myself have been a major contributor to these developments. Here is a link to my recent article providing an overview of the development of my ideas: "A Phenomenological-Contextual, Existential, and Ethical Perspective On Emotional Trauma": https://www.academia.edu/16799301/A_Phenomenological-Contextual_Existential_and_Ethical_Perspective_on_Emotional_Trauma

Panel Response:

While many important ideas have been generated regarding the development and understanding of emotional trauma and may be very informative to clinicians as they conceptualize and treat individuals with PTSD, in guideline development best practices (see Institute of Medicine, National Guidelines Clearinghouse, Guideline International Network), the primary evidence base for recommendations is one or more high quality systematic reviews. Rigorous processes are used to identify relevant treatment studies and evaluate those studies for inclusion in the review. Theoretical and conceptual articles without studies examining the effectiveness of defined interventions are not included in such reviews.

Commenter: *Ryan D. Kuehlthau, PsyD; ryan@doctorryank.com*

Comment: No I find it highly concerning that not one reference regarding the treatment of trauma was made to psychoanalysis given how highly influential this modality is not only to those who benefit from its treatment, but by how many of the so-called evidence-based theorists have as well (e.g. John Bowlby, Aaron Beck). In many circles of trauma treatment, Judith Lewis Herman's "Trauma and Recovery" and Bessel van der Kolk's "The Body Keeps the Score" are, for example, widely cited and deeply influenced by psychoanalytic principles that, for years, have guided theory and practice within this specialty. To disavow these voices within a treatment guideline seems both costly and cursory and something no introductory caveat can wash over.

Matt Aibel, LCSW; mbaibel@aol.com

Supports (and reproduced) Diane Gartland's comments.

Commenter: Lawrence O. Brown, PhD; dr.lb@wawhite.org (exact comment submitted by others as well)

Comment: The draft proposal for the new APA Clinical Guidelines for Treatment of Traumatic Stress Disorder is inadequate because it does not even mention Psychodynamic/psychoanalytic therapy as a treatment. APA is intentionally ignoring or disregarding the clinical expertise, practice, and extensive theoretical knowledge of thousands of its members. Division 39 alone has over 3,000 members. The guidelines as proposed establish an insurmountable bias against psychodynamic/psychoanalytic treatment for Post Traumatic Stress Disorder that delegitimizes it without providing evidence to support the position that it is not an effective treatment for PTSD.

By omitting psychodynamic/psychoanalytic therapy in this newly proposed clinical guideline that therapeutic approach is categorized as a non-recommended treatment for PTSD, despite the fact that it is at its root a trauma-centered treatment. A key psychoanalytic concept is that traumatic experiences -- whether occurring early or late in life -- affect current and future psychological development and adjustment, and later functioning. One of the goals of any psychodynamic/psychoanalytic treatment is to learn about and work through these traumas by addressing those memories and the concomitant thoughts and feelings.

"All of these guidelines have found evidence in support of several trauma-focused psychological interventions, (i.e., those that treat the symptoms of PTSD by directly addressing thoughts, feelings, or memories of the traumatic event) as first-line treatment," (Page 23, Line 23 of the Introduction Section). Since this well describes and recommends fundamental techniques of psychodynamic/psychoanalytic psychotherapy, including and explicitly naming psychoanalytic/psychodynamic psychotherapy would be entirely consistent with APA's own description of recommended treatments for PTSD.

Additionally you note that good psychotherapies have common features; these features happen to also be the very features that have long been the hallmark of and essential components of psychodynamic/psychoanalytic therapy: (page 73, line 9) relationship factors such as the therapeutic alliance, empathy, and the collection and utilization of client feedback (in psychoanalytic terminology- the use of transference and countertransference in which the patient's fantasies AND real experience of the therapist are directly pursued).

The panel's decision to include only randomized studies in the meta analysis on which this guideline is based, as you note on page 38, is subject to questions of applicability of its results to the "real world." This question of applicability outside the research setting is no small matter, yet it is put aside. Clinicians deal with the real world which most of the time does not approximate the research setting.

Although this guideline offers recommendations that make comparative statements about various treatments, NO comparative treatment studies are included in the meta analysis that compare treatments for PTSD. All of the studies compare a particular treatment to NO treatment. This meta analysis offers no basis for conclusions that state the comparative effectiveness of one treatment over another. But even more egregious is that NO study of psychodynamic/psychoanalytic treatment for PTSD was included in the meta analysis. Thus, the APA guideline leaves out the recommendation of psychodynamic/psychoanalytic therapy for the treatment of PTSD as though there was bona fide evidence that it should not be employed as treatment for PTSD. These recommendations and exclusions in the proposed guidelines are the best APA can do in the best interests of the public for which the biases inherent in the construction of those guidelines will be invisible?

Commenter: Peter Kotcher; pkotchermd@gmail.com

Comment: Thank you for this opportunity to review the draft version of APA's "Clinical Practice Guideline for the Treatment of Posttraumatic Stress Disorder (PTSD) in Adults". The draft Guideline has spurred conversation among colleagues nationally and internationally including clinicians, researchers and members of the Special Interest Group on Psychodynamic Treatment and Research of the International Society for Traumatic Stress Studies (ISTSS) and the Service Member and Veterans Initiative of the American Psychoanalytic Association as well as staff of the U.S. Department of Veterans Affairs (VA). What follows is a distillation of their discussions to date.

In brief, we are concerned that, although psychodynamic psychotherapy is a widely-practiced therapy for PTSD and is endorsed in the VA/DoD Clinical Practice Guidelines for PTSD and the ISTSS Clinical Practice Guidelines for PTSD as an evidence-based psychotherapy, it is nowhere mentioned in the new draft APA Guidelines. This is all the more concerning given that the Agency for Healthcare Research and Quality (AHRQ) source document developed to support the construction of the new Guideline mentions the term “psychodynamic” 30 times and “psychoanalytic” 33 times. While we realize that the rules of evidence adopted for this review excluded a substantial body of research and clinical reports supportive of psychodynamic treatments, it is, none-the-less, surprising to us that neither term is used even once in the Guideline; not even to offer a reason for its exclusion.

Further, the AHQR source document specifies that “Brief eclectic psychotherapy is a 16-session manualized treatment for PTSD that combines cognitive-behavioral and psychodynamic approaches (p.3).” Brief eclectic psychotherapy (BEP) is endorsed in the new guideline but its psychodynamic properties were somehow left out of the discussion of this treatment. According to Prof. Berthold Gersons (personal communication with Lutz Wittmann, 2012), BEP can be categorized as a psychodynamic treatment by the same reasoning that it has been included as trauma-focused cognitive behavioral approach in the meta-analysis by Bisson et al (2013) (Bisson et al. Cochrane Database Syst Rev. 2013 Dec 13;(12):CD003388. doi: 10.1002/14651858.CD003388.pub4). At the least, this component of brief eclectic psychotherapy deserves mention and its connection to psychodynamic theory and practice deserve consideration.

Further, on page 372 of the Full PTSD Appendices, the section on Patient Values and Preferences notes that “(B)rief eclectic psychotherapy may be preferred if patients value reflection on the trauma story and its meaning for their lives,” (Nijdam et al., 2012). Becker (2009)’s study… found that CPT and exposure were most preferred followed by psychodynamic [emphasis added] which in turn was preferred to SER, BEP, and EMDR.” This preference for psychodynamic psychotherapy would seem to

deserve mention in the Guideline, itself.

Commenter: Lutz Wittmann; lutz.wittmann@ipu-berlin.de

To: Steven Hollon, Ph.D.
Vanderbilt University
Chair, APA Advisory Steering Committee for the Development of Clinical Practice Guidelines

Dear Dr. Hollon,

Thank you for this opportunity to review the draft version of APA's "Clinical Practice Guideline for the Treatment of Posttraumatic Stress Disorder (PTSD) in Adults". The draft Guideline has spurred conversation among colleagues nationally and internationally including clinicians, researchers and members of the Special Interest Group on Psychodynamic Treatment and Research of the International Society for Traumatic Stress Studies (ISTSS) and the Service Member and Veterans Initiative of the American Psychoanalytic Association as well as staff of the U.S. Department of Veterans Affairs (VA). What follows is a distillation of their discussions to date.

In brief, we are concerned that, although psychodynamic psychotherapy is a widely-practiced therapy for PTSD and is endorsed in the VA/DoD Clinical Practice Guidelines for PTSD and the ISTSS Clinical Practice Guidelines for PTSD as an evidence-based psychotherapy, it is nowhere mentioned in the new draft APA Guidelines. This is all the more concerning given that the Agency for Healthcare Research and Quality (AHRQ) source document developed to support the construction of the new Guideline mentions the term “psychodynamic” 30 times and “psychoanalytic” 33 times. While we realize that the rules of evidence adopted for this review excluded a substantial body of research and clinical reports supportive of psychodynamic treatments, it is, none-the-less, surprising to us that neither term is used even once in the Guideline; not even to offer a reason for its exclusion.

Further, the AHQR source document specifies that “Brief eclectic psychotherapy is a 16-session manualized treatment for PTSD that combines cognitive-behavioral and psychodynamic approaches (p.3).” Brief eclectic psychotherapy (BEP) is endorsed in the new guideline but its psychodynamic properties were somehow left out of the discussion of this treatment. According to Prof. Berthold Gersons (personal communication with Lutz Wittmann, 2012), BEP can be categorized as a psychodynamic treatment by the same reasoning that it has been included as trauma-focused cognitive behavioral approach in the meta-analysis by Bisson et al (2013) (Bisson et al. Cochrane Database Syst Rev. 2013 Dec 13;(12):CD003388. doi: 10.1002/14651858.CD003388.pub4). At the least, this component of brief eclectic psychotherapy deserves mention and its connection to psychodynamic theory and practice deserve consideration.

Further, on page 372 of the Full PTSD Appendices, the section on Patient Values and Preferences notes that “(B)rief eclectic psychotherapy may be preferred if patients value reflection on the trauma story and its meaning for their lives,” (Nijdam et al., 2012). A study by Becker et al. (2009; Behaviour Research and Therapy 47, 245–253) found that CPT and exposure were most preferred followed by psychodynamic which in turn was preferred to SER, BEP, and EMDR. This preference for psychodynamic psychotherapy would seem to deserve mention in the Guideline, itself.

Following on this point, we believe that clinical practice guidelines should be designed to balance evidence derived from randomized trials and evidence derived from effectiveness studies, single case

studies, case series and naturalistic studies. Without such contributions, we question if they are really clinical guidelines in any practical sense.

Even if there are no studies which meet the methodological standards applied in generating this CPG, it still seems unreasonable that there is literally no mention of psychodynamic therapy anywhere in the document. We have developed a spreadsheet of research which we believe supports the value of psychodynamic psychotherapy for your review (attached). While your team may argue that none of these studies meets the necessary level of current methodological rigor, we believe that they provide clear evidence that psychodynamic psychotherapy for PTSD is too important to be completely absent in the new APA CPG.

In their 2010 review, "A Guide to Guidelines for the Treatment of PTSD and Related Conditions"), (J. Traum. Stress, 23: 537–552. doi:10.1002/jts.20565), Forbes et al. endorse revision of the methodology by which guidelines are constructed to include: "… effectiveness research that explores the application of evidence-based treatments in routine clinical practice settings. … the data from those studies provide crucial information about the practical applicability of the intervention and could reasonably serve as a useful complement to RCT studies in establishing the evidence base for key clinical questions and Level I recommendations. This would require changes to the evidence rules governing virtually all existing trauma-related guidelines. Whereas this might be met with some opposition, most would agree that a compromise is required—the findings of RCTs and other carefully designed research are of vital importance in guiding clinical decision making, but they must be translated and applied with caution."

On a broader level, there are serious implications for future practice, research, education, training, clinical supervision and reimbursement for psychodynamic psychotherapy in the U.S. and around the world if the APA were to pursue its present course. We consider such an omission to be inconsistent with the core purpose of a clinical practice guideline which is to provide clinicians with a full range of treatment options accompanied by evidence for or against each. In their current form, the proposed APA Guidelines fail to acknowledge the very existence of psychodynamic psychotherapy for PTSD even though it is among the most widely practiced and, as per your own sources document, highly preferred treatments for PTSD.

On these grounds, we strongly urge you to incorporate discussion of psychodynamic psychotherapy within the new APA guidelines and stand ready to assist in any way.

Harold Kudler, M.D.
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Faculty of Medicine, Dalhousie University
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Commenter: Ricardo Winkel, PhD; ricardowinkel@gmail.com

Comment:

The draft excluded extensive outcome studies regarding psychodynamic treatments and research data comparing it with CBT, including results that show (1) even though CBT and Narrative Therapy may show fast improvement in the weeks or months after treatment begins, those results tend to dissipate over the long term, (2) a high proportion of patients treated with CBT relapse over time, (3) psychodynamic treatments show sustained improvement over time and (4) fewer relapses. In this context, it is worth noting that psychodynamic treatment outcome research data is as objective and scientific as that reviewed in the draft. In addition, the draft associates the term "evidence based" only with those approaches reviewed therein (i.e., variants of CBT and Narrative Therapy) and ignores the fact that although psychodynamic treatments define “evidence” differently from CBT and Narrative modalities, they are as "evidence based" as those included in it. The total omission of psychodynamic treatments from the draft appears to reflect bias against it and in favor of shorter treatment – which not incidentally is shared by third-party payors. According APA's own code of ethics, this kind of bias is unethical and the improbable exclusion of a major form of treatment makes the entire document flawed and its conclusions misleading. While those who prepared the draft are entitled to their own preferences, APA is an organization that includes psychologists of different theoretic persuasions. As such, it has an obligation to avoid representing views held by a fraction of the entire membership as if they represented all. This, in and of itself, contradicts APA’s statements against bias, discrimination and exclusion. Moreover, by completely excluding psychodynamic treatment, the draft makes it "invisible", which may contribute to discrediting it, deliberately or otherwise. This, in turn, is likely to negatively affect the work and therefore the livelihood of those who practice it. Lastly, in spite of the disclaiming language surrounding it, the statement "...professionals are expected to take this guideline fully into account" is unacceptably coercive and may place psychologists who do not abide by it in ethical and legal jeopardy.

Commenter: Katherine Marshall Woods; k.marshallwoods@psychgroupdc.com

Comment:

Yes I am encouraged to read such guidelines for PTSD. Yet, I wonder whether psychodynamic and psychoanalytic practice will be considered in the treatment of PTSD in future revisions.

Commenter: Carl Shubs; drshubs@drcarlshubs.com

Comment:

It ignores any application of psychoanalytic approaches to working with trauma and instead presents other approaches as the standard of care.

Commenter: Elaine Ducharme; elaine.ducharme@yahoo.com

Comment: There is no inclusion of psychodynamic treatment. For victims of long term trauma, this is a critical part of treatment.

Commenter: Deborah K. Every, Psy.D.; deborahevery@yahoo.com

Comment: Individuals suffering from multiple traumas in their childhood and then suffering multiple traumas over an extended period as young adults (such as Vietnam veterans) are unique in several respects. These individuals experience PTSD somewhat differently than the person traumatized once as an adult (such as rape, witnessing a natural disaster, etc.). Combat veterans are often traumatized by what they had to do to others as opposed to being traumatized by what was done to them. They often suffer deep moral injury and disillusionment and mistrust/severe withdrawal. They often present as more aggressive/hostile than as fearful. They have complex trauma. Although I cannot provide hard-core research, it is my experience that these individuals need long-term therapy that is more relational and exploratory, such as psychodynamic and interpersonal orientations. Sharing their story in a safe therapeutic environment over an extended period at a pace that is manageable for them is often critical. They also benefit from process-oriented group therapy with other combat veterans. Looking at maintenance of treatment gains is critical with this population because if symptom reduction lasts only a short period after a course of prolonged exposure, CPT, EMDR, the individual is likely to experience shame and have additional hesitation with trust of the therapist. From my view it is critical that long-term relational therapy be included as a possible treatment for individuals suffering from PTSD. It is harder to do research on this psychotherapy orientation but that does not mean this orientation should be ignored. Jonathan Shedler in his article on the efficacy of psychodynamic therapy provides some data. His article also helps one to consider not only the absence of PTSD symptoms but the presence of indicators of mental health. For example, if an individual with PTSD has a decrease in nightmares but is still not capable of sustaining a meaningful love relationship or is still unable to find meaning or satisfaction in his life, has he been successfully treated? Thank you for considering my comments.

Commenter: Kristin Matteson, PhD; kmattesonphd@roadrunner.com

Comment: The contribution of Self Psychology techniques to be one prong of treatment for PTSD need to be included. Self Psychology is a harder treatment to research and thus is has fewer evidence-based studies to show its effects. To omit Self Psychology treatment from the list of useful and effective treatments for PTSD is poor work on the part of this committee.

Panel Response:

The APA PTSD Guideline Development Panel issued recommendations for any treatments for which there was at least low strength of evidence in the systematic review that served as our evidence base. The search process for the systematic review did, in fact, use search terms to identify randomized trials of psychodynamic treatments for PTSD. The search terms used the RTI-UNC Evidence-Based Practice Center to identify randomized trials for the systematic review are shown in Appendix B of the systematic review (pages B1 – B19).

The following searches were conducted for psychodynamic treatments as part of the systematic review: Page B1, Medline searches: #15 psychodynamic[All Fields] AND ("therapy"[Subheading] OR "therapy"[All Fields] OR "therapeutics"[MeSH Terms] OR "therapeutics"[All Fields]) #16 psychodynamic[All Fields] AND ("psychotherapy"[MeSH Terms] OR "psychotherapy"[All Fields]) #17 Search ("psychoanalytic"[All Fields] AND "psychotherapy"[All Fields]) OR "psychoanalytic psychotherapy"[All Fields] #18 Search ("psycho-analytic"[All Fields] AND "psychotherapy"[All Fields]) OR "psycho-analytic psychotherapy"[All Fields] #19

"psychoanalytic therapy" #20 "psycho-analytic therapy" Page B3, Cochrane Database searches #17 psychodynamic[All Fields] AND ("therapy"[Subheading] OR "therapy"[All Fields] OR "therapeutics"[MeSH Terms] OR "therapeutics"[All Fields]) #18 psychodynamic[All Fields] AND ("psychotherapy"[MeSH Terms] OR "psychotherapy"[All Fields]) #19 ("psychoanalytic"[All Fields] AND "psychotherapy"[All Fields]) OR "psychoanalytic psychotherapy"[All Fields] #20 ("psycho-analytic"[All Fields] AND "psychotherapy"[All Fields]) OR "psycho-analytic psychotherapy"[All Fields] #21 "psychoanalytic therapy" On page B4, Search #7, for IPA, CINAHL, and PsycINFO includes the major descriptor "Psychotherapy" as a search term; the thesauraus for those databases indicates that "psychodynamic psychotherapy" is one of the terms that is subsumed by the major descriptor, "Psychotherapy". Page B15, PILOTS Database searches: Query #19 psychodynamic AND (DE="psychotherapy" OR psychotherapy) Query #20 psychodynamic AND (therapy OR therapeutics) Query #21 psychoanalytic AND (psychotherapy OR "psychoanalytic psychotherapy") Query #22 psycho-analytic AND (psychotherapy OR "psychoanalytic psychotherapy") Query #23 "psychoanalytic therapy" Query #24 "psycho-analytic therapy"

Based on that search process, the systematic review identified the following articles on psychodynamic treatment of PTSD:

Rose DS. (1991) A Model for Psychodynamic Psychotherapy with the Rape Victim. Psychotherapy. 28, 85-95. PMID: WOS:A1991EZ39100011.

Sachsse U., Vogel C., Leichsenring F. (2006). Results of psychodynamically oriented trauma-focused inpatient treatment for women with complex posttraumatic stress disorder (PTSD) and borderline personality disorder (BPD). Bulletin of the Menninger Clinic. 70, 125-144.

Abbass A.A., Hancock, J.T., Henderson J, et al. (2006). Short-term psychodynamic psychotherapies for common mental disorders. Cochrane Database of Systematic Reviews. 2006(4)PMID: CD004687

Brom, D., Kleber, R.J., Defares, P.B. (1989). Brief psychotherapy for posttraumatic stress disorders. Journal of Consulting and Clinical Psychology. 57, 607-612. PMID: 2571625.

Rose (1991) was excluded because it did not include original data (page C-4, systematic review). Sachsse (2006) was excluded because it was not a randomized trial (page C-10, systematic review). Abbass (2006) was excluded because it did not meet the population inclusion criteria established by the systematic review (page C-12, systematic review). Brom (1989) was excluded because it was rated high risk of bias; it was rated high risk of bias because it used a completer analysis rather than intention-to-treat, did not assess fidelity and the two subscales on the instrument used to measure PTSD symptoms (the Dutch translation of the Impact of Event Scale) had low reliability.

We did make a recommendation for brief eclectic psychotherapy, a treatment that combines elements of cognitive behavior therapy and psychodynamic approaches. While many assert that psychodynamic treatment and other, traditionally longer, forms of psychotherapy are necessary for people who have experienced chronic trauma, little systematic data exists to indicate what treatment, and length of treatment, might be necessary. In fact, definitions of chronic or long term trauma are not well established, which is an important first step in defining the problem and investigating what approaches are most helpful to individuals.

Future revisions of this document will likely use the same, or an expanded set of, search terms in order to capture all the relevant studies pertaining to psychological treatment of PTSD.

Further, it is not accurate to say that APA is "intentionally ignoring or disregarding the clinical expertise, practice, and extensive theoretical knowledge of thousands of its members." Certainly, many clinical traditions have informed the development of interventions and the knowledge base in clinical practice but explicating that is not the purpose or function of a clinical practice guideline. The document and subsequent recommendations are based on an evaluation of the research literature regarding treatment efficacy.

EMDR

Many, many comments were received on the topic of EMDR; most comments urged that EMDR should also have a strong recommendation and provided a variety of supporting documentation for that view point. Many individuals referenced or submitted a variation of the comments submitted by Drs. Lee, Maxfield or Shapiro so their entire comments (while overlapping) are presented below but duplicate other comments are not reproduced here. The panel appreciated the considerable time and effort reflected in Drs. Lee, Maxfield and Shapiro's comments and, as with all comments, reviewed them carefully.

EMDR

Commenter: Lisa Robinson; agcrps@gmail.com

Comment: No Very concerned about the downgrading of EMDR. There exists significant evidence to support this intervention. As a provider that is certified in PE and CPT and working towards certification in EMDR, I have found EMDR to allow recovery in patients where CPT and/or PE failed or resulted in incomplete recovery or was so aversive that patients dropped out. In addition, recovery appears more complete in EMDR (e.g., reduction of SUDS to 40 in PE and reduction of SUDS to 0 in EMDR). The downgrading of EMDR feels like a result of political issues, which has unfortunately been a problem in the history of EMDR both at the VA and in the broader trauma field.

Commenter: Mary L. Greiner, LCSW; Mary.greiner.lcsw@gmail.com

Comment: No Please reconsider the nature of the recommendation regarding evidence of the efficacy of EMDR in treating PTSD. There are abundandant studies in the literature provided by EMDRIA.org on the effectiveness of EMDR.

On a personal level, I am "in the trenches" working with active duty military and their families. There is no doubt in my mind that EMDR is effective, efficient, and minimizes the re-triggering of trauma in the course of treatment. It is also effective with treating the secondary PTSD commonly found in family members.

Commenter: Gary Quinn, MD; gary.quinn.MD.EMDR@gmail.com

Comment: No EMDR should be a recommended intervention for PTSD

www.emdr.com to see the supporting research

Commenter: Mark Russell; mrussell@antioch.edu

Comment: Russell, M. C. (2008). Scientific resistance to research, training and utilization of EMDR therapy in treating post-war disorders. Social Science and Medicine,67(11), 1737-1746.

Commenter: Francine Shapiro; f.shapiro.phd@gmail.com

Comment: No Obviously, it is critical that the APA guidelines be geared to disseminate correct information about the various therapies. However, numerous errors mar this draft:

1. The description of EMDR therapy in the proposed guidelines bears no resemblance to actual clinical practice.

2. The overly stringent criteria have skewed the evaluation of the EMDR therapy research, resulting in findings that contradict the domestic and international guidelines conducted over the last decade.

3. It appears that evaluation standards have not been applied equally across all therapies.

It is self-evident that the goal of the APA guidelines is to educate and make recommendations to patients and clinicians on the basis of accurate assessments rather than misinformation. Although, the practice guidelines are meant to inform, they mislead instead.

A person familiar with EMDR therapy, the clinical issues and the various supporting studies should be involved in the direct assessment of the data. Numerous errors in the evaluation exist because of this oversight. For instance, the discussion of "information on harms from published studies" (p.330) is misleading, given the fact that it states, "In a 5-year follow-up study excluded for "wrong study design," there was an overall worsening of PTSD symptoms for the EMDR group." The Macklin et al (2000) study was a follow-up of a component analysis (Pitman et al., 1996) which used standard EMDR procedures in one condition to treat only one memory in multiply traumatize combat veterans. A complex eye fixation condition (which is not used in EMDR) was employed in the control condition, and the combined data was evaluated at follow-up. This study was faulted in the 2009 ISTSS Practice guidelines for inadequate fidelity and/or treatment duration. Naturally, participants in the Macklin et al. (2000) study would be expected to be worse five years later, since they thought they had been adequately treated but were still being triggered by unprocessed memories.

Additional errors that have severely marred these proposed guidelines will be identified in the following comment section. Consequently, I would recommend that Charles Figley, PhD be invited onto the committee, given his stature in the field of PTSD and his knowledge of both CBT and EMDR therapy research. He has indicated a willingness to join.

Further, it is erroneous for the proposed APA guidelines to state that they are "largely consistent" with other extant guidelines (p.76). This is inaccurate since all of the referred to guidelines since 2004 have given EMDR and CBT equal (first-tier) status as empirically supported treatments for PTSD. For the APA guidelines to give EMDR therapy second-tier status directly contradicts the cited guidelines of the following organizations:

World Health Organization (WHO, 2013)

US Department of Veterans Affairs/Department of Defense (VA/DOD, 2010),

International Society for Traumatic Stress Studies (ISTSS, 2009),

Australian National Health and Medical Research Council (NHMRC, 2007)

UK National Institute for Health and Care Excellence (NICE, 2005)

In fact, a recent update of the Australian NHMRC guidelines in 2013 re-confirmed the 2007 rating of EMDR as a Grade A treatment for PTSD.

Although it is clear that a great deal of effort has gone into formulating these guidelines, the overly stringent inclusion criteria have severely skewed the results. Further, clinically relevant details have been overlooked in evaluating the RCTs and their outcomes.

While seven RCTs were included in these guidelines, there are approximately 30 RCTs and 22 nonrandomized studies that have supported the efficacy of EMDR as a therapeutic treatment for psychological trauma. (For an annotated bibliography see: http://www.emdrhap.org/content/what-is-emdr/research-findings/).

It is important to note that of the seven RCTs included in these guidelines, all found EMDR efficacious. The fact that all seven included RCTs reported positive effects for EMDR therapy would argue for a first-tier recommendation. The fact that some studies reported lower SMDs than others is attributable to the type of participants evaluated. For instance, of the 4 RCTs included in the analysis of "Is EMDR efficacious for adults with PTSD?" (p. 147), the study that was rated as “0.33 lower” is the Carlson (1998) RCT that utilized chronic, multiply traumatized combat veterans. The other three studies evaluated civilian PTSD. Therefore, differences in the variance of outcome would not be unexpected. The fact that the 4 EMDR RCTs are evaluated as resulting in low evidence is unreasonable, given that the same or greater level of variance was deemed “moderate” in the evaluation of cognitive therapy.

It appears that the evaluation standards have not been consistently applied. EMDR was rated second-tier despite showing clear evidence of loss of diagnosis and major changes in secondary measures and an SMD for PTSD symptoms of a large magnitude (i.e., -1.08). This appears to be due to the SOE for PTSD symptoms being inappropriately rated as low (see table 6, p23). Specifically, on page 68 it is stated that this is because “a lack of precision and inconsistency”. However, in the main body of the APA report (p35) these terms are defined as:

Consistency is the degree to which the direction of effect is the same or different in the studies included in a body of evidence. If several studies find that an intervention leads to a reduction in PTSD symptoms but other studies find that the intervention leads to an increase in PTSD, the body of evidence is rated as inconsistent.

Precision of an estimate is based on the width of the confidence interval around the estimated summary effect size in a meta-analysis; the narrower the confidence interval, the greater the precision.

In fact, there is no basis to conclude that the findings from EMDR either lack consistency or are any more imprecise than other CBT findings given a moderate SOE:

1) Regarding consistency, every study comparing EMDR to a control (see figure 17) is in favor of EMDR, so consistency is not an issue. Further, the magnitude of these effects ranged from ‘small to very large’, as they do within the same domain for cognitive therapy.

2) Precision of the EMDR findings is actually better than for CT, CPT or mixed CBT which were rated as moderate SOE. The heterogeneity for the EMDR results was at 70% (p.68) while the heterogeneity for CT was worse, at 79.6% (figure 4), CPT was 86.5% (figure 3) and the same is true for mixed CBT at 87% (figure 15).

It is clear that for both consistency and precision this rating was not applied equivalently to all treatments. Rather, by the delineated standards, EMDR should have been given a comparable moderate SOE rating.

Two other included studies appear to be rated as low evidence because each of the evaluations was made in different categories and important clinical issues were ignored.

1) The Nijdam et al, (2012) RCT comparing EMDR and BEP reported: "Although both treatments are effective, EMDR results in a faster recovery compared with the more gradual improvement with brief eclectic psychotherapy" (p.224). However, the proposed APA evaluation does not reflect this. For instance, despite the article stating, "Analysis by time point revealed that SI-PTSD scores were significantly lower for EMDR than for brief eclectic psychotherapy at the first post-assessment, but at the second post-assessment the difference was no longer significant (Table 2). Improvement effect sizes from baseline to second post-assessment were large for both treatment conditions (Cohen's d = 1.95 for brief eclectic psychotherapy and Cohen's d = 2.43 for EMDR)" (p.228), the guidelines rate this as "very low evidence." The stated description is "Among completers, EMDR vs. BEP 92.2% vs. 52.3%, p<0.001 at the first assessment; No significant difference at the second assessment: 93.7% vs. 85.7%, p=0.30." Hence, despite the large effect sizes and the 92.2% elimination of PTSD in the EMDR group versus 47.7% in the BEP group at the first assessment (mean @ 6 sessions), "very low" rating was given because BEP "caught up." The difference in response rates is clearly relevant to practicing clinicians, as is the information that both therapies are effective in the treatment of PTSD. These large effect sizes should not be ignored and dubbed as merely "very low evidence."

2) Van der Kolk et al. (2007) RCT comparing EMDR, fluoxetine and pill placebo: As indicated in the guidelines (p.121), this study is one of the only two RCTs overall that examined treatment outcomes with complex PTSD. However, in the evaluation of EMDR treatment, the clinical issues involved in this population are not taken into account. Consequently, the evidence level is rated at "very low" despite the fact that at follow-up 88.9% of the child-onset trauma group treated with EMDR no longer had PTSD compared to 42.9% in the fluoxetine group. Further, 33.3% were asymptomatic in the EMDR group compared with 0% in the fluoxetine condition. Likewise, for those participants with adult-onset trauma, although there was comparable loss of diagnosis (91.7% v 90.9%), 75% of the EMDR group were asymptomatic compared to zero in the fluoxetine condition. Given that only eight EMDR sessions were administered, these outcomes regarding loss of diagnoses and asymptomatic status for both adult and child onset trauma certainly appear to warrant more than "low evidence." In addition, the 17% dropout rate of combined adult and child onset EMDR treatment is certainly worthy of note.

EXCLUDED BUT RELEVANT STUDIES

Also of concern are the studies that were excluded from analysis. Two RCTs reporting additional data in separate publications appear to have been overlooked and improperly excluded from analysis.

1) Wilson, S., Becker, L.A., & Tinker, R.H. (1997). Fifteen-month follow-up of eye movement desensitization and reprocessing (EMDR) treatment of post-traumatic stress disorder and psychological trauma. Journal of Consulting and Clinical Psychology, 65, 1047-1056.

The original RCT was apparently excluded because it did not report PTSD diagnoses. However, this study should have been included since it reported posttest and follow up scores for the PTSD participants in the original evaluation (Wilson, Becker & Tinker, 1995):

"The present study is a 15•month follow-up of the effects of eye movement desensitization and reprocessing (EMDR) therapy on the functioning of 66 participants, 32 of whom were diagnosed with posttraumatic stress disorder (PTSD) prior to treatment. PTSD participants improved as much as those without the diagnosis, with both groups maintaining their gains at 15 months. At I5-month follow-up, the three 9O-min sessions of EMDR previously administered (S. A. Wilson, L. A. Becker, & R. H. Tinker, 1995) produced an 84% reduction in PTSD diagnosis and a 68% reduction in PTSD symptoms. The

average treatment effect size was 1.59; the average reliable change index was 3.37. Implications of the maintenance of EMDR treatment effects are discussed. (p.1047)

As indicated in the original study, “EMDR worked equally well whether the participant had previous therapy or not and for those diagnosed as PTSD versus those who did not receive that diagnosis” (p. 935). Additionally, this might reasonably be argued would make the entire sample relevant.

2) Marcus, S., Marquis, P. & Sakai, C. (1997). Controlled study of treatment of PTSD using EMDR in an HMO setting. Psychotherapy, 34, 307-315.

The study appears to have been excluded from the guidelines because of issues related to masking. However, as reported in Marcus, S., Marquis, P. & Sakai, C. (2004). Three- and 6-month follow-up of EMDR treatment of PTSD in an HMO setting. International Journal of Stress Management, 11, 195-208:

“A significant strength of this study is that it compares EMDR to a standard HMO treatment in an actual treatment setting with a clinical population, demonstrating excellent external validity. . . . Though attempts were made to keep the independent assessor unaware of the treatment condition, client revelations made this impossible. However, the assessor was funded by Kaiser Permanente, which, if anything, would have biased in favor of [standard care]” (p.205)

Therefore, the RCT should not be eliminated for reasons of bias. Funded by Kaiser Permanente, the results show that 100% of single-trauma and 77% of multiple-trauma survivors were no longer diagnosed with post-traumatic stress disorder after six 50-minute sessions. Further: "A 3- and 6-month follow-up of individuals randomly assigned to either EMDR treatment or standard care (SC) treatment for posttraumatic stress disorder (PTSD) indicates that significantly greater improvements found with EMDR at posttreatment in an earlier article (S. Marcus, P. Marquis, & C. Sakai, 1997) were maintained on measures of PTSD, depression, anxiety, and general symptoms." (p.195)

The outcomes of these two studies are clearly consistent with the 90% remission of single-trauma PTSD and decrease in trauma systems reported by Rothbaum (1997) in a comparable time (@ 5 hours of treatment). The substantial reductions of symptoms in these three studies should be included in the guideline calculations.

In addition, two other RCTs were excluded for dubious reasons.

1) Ironson, G.I., Freund, B., Strauss, J.L., & Williams, J. (2002). Comparison of two treatments for traumatic stress: A community-based study of EMDR and prolonged exposure. Journal of Clinical Psychology, 58, 113-128.

This study is faulted for an inadequate randomization when the article stated a clinically coherent reason for the assignment of two patients: “After 20 patients had been randomly assigned to PE or EMDR, we noted more dropout in PE. To get a reasonably equivalent number of completers in both groups, the next two patients were assigned to PE.” (p.117)

This RCT is further faulted for differential attrition rates. This may be reasonable in an evaluation of pharmaceuticals. However, it is of great interest in studies comparing psychotherapies when there are significantly more dropouts in one condition then the other. The fact that EMDR therapy has been found to have a lower rate of premature discontinuation than full CBT, CPT, and exposure in a meta-analysis (Swift & Greenberg, 2014) should be of interest. Further, fidelity of the PE condition was monitored by the second author who “was trained by Drs. Foa and Rothbaum (key developers and researchers for PE) and was a protocol therapist for Dr. Foa on PTSD grants for eight years” (p.118) and self-report measures were used that would minimize bias in favor of EMDR. In addition, an intention to

treat analysis was irrelevant in the EMDR condition because it had zero dropouts. This study also addresses the issue of PTSD symptom reduction and treatment efficiency.

(2) Lee, C., Gavriel, H., Drummond, P., Richards, J. & Greenwald, R. (2002). Treatment of post-traumatic stress disorder: A comparison of stress inoculation training with prolonged exposure and eye movement desensitization and reprocessing. Journal of Clinical Psychology, 58, 1071-1089.

This RCT was excluded due to issues of masking. However, this was compensated for by additional measures to avoid bias: "Although independent raters were initially used to score participant's responses, this was not always possible and so most of these data were collected by the treating practitioner. Regular reviews every two weeks of these assessments of client symptoms were done to ensure consensus. These subjective measures were supplemented by a set of standardized objective measures" (p. 1074).

(3) van den Berg, D.P.G., et al. (2015). Prolonged exposure versus eye movement desensitization and reprocessing versus waiting list for posttraumatic stress disorder in patients with a psychotic disorder: A randomized clinical trial. JAMA Psychiatry, 72(3):259-267.

This study was excluded from additional analysis because there was "Insufficient evidence to determine whether the weak recommendation for EMDR . . . would be likely to change" (p.67). However, the report says, "If a new meta-analysis were to be done… the confidence interval would be narrower and it is possible that the SOE might be upgraded from low to medium as a result" (p.622) It is clearly a matter of science to test this hypothesis.

SUMMARY & CONCLUSIONS

In conclusion, the seven included studies, as well as each of the additional 5 RCTs that appear to have been mistakenly excluded present sufficient evidence for EMDR therapy to be strongly recommended in the guidelines.

Despite the fact that statements in the document indicate that reductions in PTSD symptoms for EMDR therapy were reported in all seven trials, the conclusion is: "Evidence supports the efficacy of EMDR for reduction of PTSD symptoms, but SOE is low because of some inconsistency and imprecision."(CER-27)

However, these conclusions fail to take in the clinical realities of the RCTs evaluated. Specifically, as indicated in Figure 17 (p. 68) analysis of 4 trials, the RCTs with the lowest SMD are Hogberg (-0.68 (-1.51, 0.15)) and Carlson (-0.19 (-1.03, 0.65)). The participants in the Carlson study were multiply traumatized combat veterans and many in the Hogberg study were involved in "under the train" accidents, potentially involving death and a sense of moral injury, who received only five sessions of treatment. One would therefore reasonably attribute differential outcomes to differences in population and treatment doses. The fact that all seven studies, as well as each of the five excluded ones, reported a greater reduction in PTSD symptoms then the controls, argues for a moderate SOE for EMDR as was given to cognitive therapy and mixed CBT under the same conditions.

Further, the evaluation standards have not been applied evenly. To reiterate,

1) Regarding consistency, every study comparing EMDR to a control (see figure 17) is in favor of EMDR, so consistency is not an issue. Further, the magnitude of these effects ranged from 'small to very large', as they do within the same domain for cognitive therapy.

2) Precision of the EMDR findings is actually better than for CT, CPT or mixed CBT which were rated as moderate SOE. The heterogeneity for the EMDR results was at 70% (p.68) while the heterogeneity for CT was worse, at 79.6% (figure 4), CPT was 86.5% (figure 3) and the same is true for mixed CBT at 87% (figure 15).

Additionally, the five studies previously listed as excluded for dubious reasons in these overly stringent guidelines also report decreases in trauma symptoms and PTSD diagnosis, which further supports a "strong recommendation" of EMDR at the same level as these other treatments.

Combined with the evidence for loss of PTSD diagnosis, the statement in the guidelines: "Evidence supports the efficacy of EMDR for achieving loss of PTSD diagnosis and improving depression symptoms (moderate SOE for both)" (p.27) should be extended to include an evaluation of moderate SOE for the decrease in PTSD symptoms. Overall, this should result in a recommendation of EMDR therapy at the same level as the listed first-tier CBT treatments, which would be consistent with the practice guidelines of:

World Health Organization (WHO, 2013)

US Department of Veterans Affairs/Department of Defense (VA/DOD, 2010),

International Society for Traumatic Stress Studies (ISTSS, 2009),

Australian National Health and Medical Research Council (NHMRC, 2007, 2013)

UK National Institute for Health and Care Excellence (NICE, 2005)

Haute Autorité de la Santé (France) (2007).

Association of the Scientific Medical Societies in Germany (2011)

Dutch National Steering Committee Guidelines Mental Health Care (2013)

Louise Maxfield, PhD, Psychologist

EMDR has top tier recommendations in treatment guidelines for PTSD, around the world. This reflects its well-established efficacy for PTSD, with large effect sizes in many RCTs. Although the proposed APA guidelines recognize its "large effect size for PTSD symptom reduction," EMDR was given "a weak recommendation rather than a strong recommendation … because the strength of evidence (SOE) … was rated as low. The low SOE was due to imprecision (i.e., a confidence interval that was wide enough to permit clinically distinct conclusions) and inconsistency (i.e., large differences in the effect sizes from the included RCTs)." (Appendices, page 622. See also AHRQ, p. 27, pp 65-71).

There are many problems with the method used by the panel in this process, and the conclusions are therefore faulty. Problems include the exclusion of appropriate studies, the miscalculation of SMD in one study by using the wrong measure, possible bias in "precision" assessments, inappropriate methods for determining patient preference, and overassessment of "high risk for bias" in multiple studies.

EXCLUSION OF APPROPRIATE STUDIES
(1) Although AHRQ included the van der Kolk et al. study, 2007, it omitted the EMDR vs placebo comparison, even though comparisons were made of other studies with three arms (conditions). (Examples: Taylor et al, 2003, Marks et al., 1998). This comparison should be added to the analysis and

doing so will increase EMDR's SOE. See Christopher Lee's Comments in this form for information regarding this.

Panel Response: This is correct that these studies were not used in the assessment of EMDR efficacy because they compared EMDR to active comparators.

(2) In APA's own analysis of the effects of adding the van den Berg et al. 2015 study, they wrote "If a new meta-analysis were to be done, including the one new trial (van den Berg) the confidence interval would be narrower and it is possible that the SOE might be upgraded from low to medium as a result." (Appendices, p. 622). This study should be added to the analysis.

Panel Response: No, this study was included in the supplementary review and was not included in the RTI-UNC review; therefore, it should not be included in the analysis.

USING THE M-PTSD INSTEAD OF IES IN CALCULATIONS

The measure used to calculate the SMD for the Carlson et al. 1998 study should be changed to M-PTSD instead of IES, because the M-PTSD provides a more accurate assessment of PTSD symptoms. Making this change increases EMDR's precision and increases its SOE. See Christopher Lee's Comments in this form for information regarding this.

Panel Response: It is correct that the Carlson et al 1998 study used the M-PTSD and the IES. That study did not specify a priori which of the instrument was considered the primary outcome. The systematic review did report the data from the M-PTSD in the systematic review but used the IES scale for calculation of the overall effect size for EMDR efficacy because the IES scale was used by many more studies than the M-PTSD and was considered a more standard instrument. The Carlson et al. 1998 trial was the only study included in the entire systematic review that used the M-PTSD while the IES was used by many studies included in the systematic review. It would be inappropriate to select the findings from the M-PTSD from the Carlson et al. study for calculating the overall effect size for EMDR rather than the findings from the IES simply because the findings from the M-PTSD were stronger.

RECALCULATION OF META-ANALYSIS BY LEE & DOMINGUEZ

See Christopher Lee's Comments in this form for information regarding reworked meta-analysis by Dominguez & Lee. It contains the above three modifications, and states:
"Finally redoing the analysis for all 6 studies that compared EMDR to a control condition and using the more appropriate M-PTSD measure for the Carlson study (see Figure 1 below) the SMD is -0.99 and the confidence interval is from -1.41 to -0.58 (I2=57%). This is the best reflection of the state of the literature today. This is the result that should have been used by the APA. This data means that consistency for EMDR is better than CT, CPT and mixed CBT and EMDR has more precision than CT or CPT."

APA should redo the meta-analysis to include these studies and to use the M-PTSD measure.

Panel Response: See comments above.

It would be inappropriate for the panel to re-do meta-analyses for any interventions to make the results more favorable for that intervention.

POSSIBLE BIAS IN "CONSISTENCY" ASSESSMENTS

The proposed Guidelines used different standards in their ratings of the consistency of CT and EMDR. Using only the data in the AHRQ report, if the same standards for "consistency" were applied to EMDR as were used in the evaluation of CT, this would change EMDR's SOE from Low to Moderate. CT had high heterogeneity (I2 = 79.6%) (Table G-2, Appendices). This was rated as Some Inconsistency, with a note: 'Direction of effects were consistent; magnitude of effects ranged from very large to small'. (See similar notes on Tables G-1 and G-13 where studies with high heterogeneity were rated as Consistent or Some Inconsistency). In contrast, EMDR, on the same measure, had lower heterogeneity (I2=70%), and the direction of the effects from EMDR studies was consistent and the magnitude of these effects ranged from 'almost small to very large'. EMDR's consistency rating should follow the same criteria as that used for CT and should be changed from Inconsistent to Some Inconsistency. It should also be noted that EMDR, with its seven studies, has similar effect sizes to CT, which has only four studies. However, because of the miscalculation of EMDR's consistency, EMDR was given a much lower SOE than CT. See also Christopher Lee's Comments in this form for information regarding this.

Panel Response: Consistency is based on homogeneity / heterogeneity of effect sizes in individual studies (as reflected by the I-squared) but also by the range of effect sizes. For EMDR, the lack of consistency assessment was based not only on the I-squared measure but also on the fact that the effect sizes of the included studies ranged from small to large.

PATIENT PREFERENCES

The determination of patient preference "relied on a recently conducted systematic review (Simiola et al., 2015)" (page 45 APA summary). Although one would expect that the goal would be to evaluate patient experience, 29% of Simiola's included studies "used analog methods (i.e., asking participants to imagine what treatment they would choose) that included samples of undergraduate students…" (p. 517). Unfortunately, all three studies used to evaluate EMDR were analog studies in which university students were provided with researcher-generated descriptions of various treatments and asked to rate them preferentiality. For example, the cognitive therapy description stated: "People who have been traumatised tend to show distorted patterns of thinking which trigger complex negative emotional responses and biases. Distortions in thought process result from interpretations of the trauma and its aftermath and thus contribute to posttraumatic stress. Treatment attempts to make people aware of these distortions and normalise thinking so as to restore emotional balance. It involves learning how to deal with patterns of negative thinking" (Tarrier et al., 2006, p. 1652). However, the EMDR description is of very different quality – it provides no rationale and no expected outcome (p. 1651). It contains errors and is biased, asserting EMDR is "controversial" and of limited efficacy. Further, the Tarrier et al. description does not even call the treatment by its correct name, and makes undocumented false assertions about side effects: "Some people report mild headaches or feelings of nausea." No wonder the students did not choose EMDR.

It is unfortunate that Simiola et al., 2015 did not review the qualitative studies that actually investigated the phenomenological experience of EMDR patients. Among these are the qualitative RCT (Edmond et al., 2004) comparing EMDR and eclectic treatment (n=59) and the qualitative case series (n=10) by Marich (2010). For example, "although all of the women who received EMDR (n=20) spoke highly of their therapist, they did not attribute the success they experienced in therapy to either the personal qualities of the therapist or to the therapeutic relationship, but rather to the technical EMDR process and/or to how well the respective therapist followed the procedural protocols." "Those who received EMDR reported changes that ranged from a complete eradication of the issues to major changes in their

perceptions of self and others." (Edmond et al. 2004, pp. 266, 269). For example, "All 10 of the (participants) ….expressed positive sentiments about their EMDR experiences, and in various degrees, they credited their EMDR treatment with being a crucial component of their addiction continuing-care processes" (Marich, 2010, p. 504).

One would also expect that patient preference would be evaluated by identifying which of the various AHRQ RCTs conducted comparisons of treatment credibility and then reviewing and analyzing these results. For example, Taylor et al. (2003) reported that exposure therapy, EMDR, and relaxation therapy "did not differ in participant-rated credibility: $F(2, 51) = 0.36$, $p > .1$" (p.333).

In addition to the Simiola et al. review, APA preference ratings included the "perspectives" voiced by "clinicians and consumers on the (APA) panel, about preferences for different interventions as well as the value that patients might place on different outcomes or harms/burdens associated with particular treatments" (page 46). Given that no EMDR experts were on the panel, this process appears to have been dominated by misperceptions about the treatment. Such misinformation is apparent in the extremely flawed description of the treatment (Appendices, page 3) and the uninformed comments re preference (Appendices, page 333). This process appears to have been highly biased against EMDR.

The process used to determine EMDR patient preference used the opinions of poorly informed nonpatient university students, and misinformed members of the APA panel. These opinions are the source of all data on EMDR patient preference. This process is not scientific and completely unacceptable.

Panel Response: As noted in the decision table for EMDR, patient preferences did not play a role in the panel's decisions.

OVERASSESSMENT OF "HIGH RISK FOR BIAS".

Marcus et al. (1997, 2004) See AHRQ, p. 67, E-26
Excluded because of high risk of bias (e.g., outcome assessors were not blind), However:
• "A significant strength of this study is that it compares EMDR to a standard HMO treatment in an actual treatment setting with a clinical population, demonstrating excellent external validity. . . . Though attempts were made to keep the independent assessor unaware of the treatment condition, client revelations made this impossible. However, the assessor was funded by Kaiser Permanente, which, if anything, would have biased in favor of [standard care]"(Marcus et al. 2004, p.205)
• Follow-up study, in a separate publication, was overlooked – Marcus et al. (2004)

Panel Response: It is not accurate to state that the Marcus article was rated high risk of bias only because of non-blinded outcome assessment. It was rated high risk of bias for the following reasons:

"No data reported to allow assessment of how groups compare at baseline,

how many patients dropped out after randomization, or how many people are in the 2 groups.

Attrition information not reported; does not describe use of ITT analysis; Outcome assessors

were not masked, increasing potential for measurement bias; did not report adequate treatment fidelity." (Jonas et al, 2013; p E-26).

In addition, the RTI-UNC systematic review did not make any assumptions about the potential direction of bias introduced by non-blinded outcome assessors. To our knowledge, no systematic review has done that or would do that. A non-blinded outcome assessment is a non-blinded outcome assessment and there is no speculation permitted about the potential bias introduced by the allegiance of the non-blinded assessor.

Ironson et al., (2002) See AHRQ, p. 67, E-25.
Excluded because of high risk of bias. Criticized for inadequate randomization. However:
• "After 20 patients had been randomly assigned to PE or EMDR, we noted more dropout in PE. To get a reasonably equivalent number of completers in both groups, the next two patients were assigned to PE."
Criticized re differential attrition rates. However:
• Fidelity in the PE condition was monitored by the second author who "was trained by Drs. Foa and Rothbaum (key developers and researchers for PE) and was a protocol therapist for Dr. Foa on PTSD grants for eight years" (p.118)
Criticized because of the intention to treat analysis. However:
• The EMDR condition had no attrition.

Panel Response: The Ironson study was rated high risk of bias for the following reasons:

" High risk of selection bias; randomization compromised by adding more

participants to PE group to achieve equal group numbers; high overall and differential attrition

(and 50% dropouts from the PE group); marked differences in baseline severity of PTSD and

depression between groups (otherwise, minimal baseline data reported to allow comparison of groups); completer analysis; no handling of missing data." (Jonas et al., 2013; p E-25).

Lee et al., (2002). See AHRQ, p. 67, E-26.
Excluded because of high risk of bias. (e.g., outcome assessors were not blind). However, this was compensated for by additional measures to avoid bias:
• "Although independent raters were initially used to score participant's responses, this was not always possible and so most of these data were collected by the treating practitioner. Regular reviews every two weeks of these assessments of client symptoms were done to ensure consensus. These subjective measures were supplemented by a set of standardized objective measures" (Lee et al., p. 1074).
• Other concerns about this paper are addressed by Christopher Lee, in these Comments.

Panel Response: The Lee paper was rated high risk of bias for the following reasons:

"Inadequate randomization procedure (alternating); no allocation concealment,

no blinding of outcome assessors; unclear whether groups were similar at baseline for several characteristics; details of analysis and missing data were NR; differential attrition data unclear." (Jonas et al., 2013; p E-26).

Wilson et al. (1995, 1997), See AHRQ, p. C-17.
Excluded because of "wrong population" (i.e., participants included those without a PTSD diagnosis).
• A follow-up study, in a separate publication, was overlooked in which participants diagnosed with PTSD were separately evaluated. Wilson, Becker, & Tinker (1997)

Panel Response: We reviewed the follow-up study described by Wilson, Becker & Tinker (1997). As the commenter reports, the article does report post-treatment data for people with full threshold PTSD separate from those with subthreshold PTSD. However, there are multiple reasons that the study would not be eligible for inclusion in the systematic review:

1. None of the outcome measures reported in the study are acceptable measures for assessing PTSD symptom reduction, as required by the systematic review. The study reports the outcomes measured with the SUD, which is not a measure of PTSD symptoms and it reports the outcomes for the IES-intrusion subscale and the IES-avoidance subscale, but it does not report the outcome for the total IES.

2. Although risk of bias rating was not performed by the RTI-UNC Evidence-based Practice Center on the original Wilson study from 1995, because it was excluded due to inclusion of persons with subthreshold PTSD), we looked at the Wilson study and believe it had multiple methodological flaws that likely would have resulted in a high risk of bias rating, including:

Was randomization adequate? *Unclear (details not reported)*

Was allocation concealment adequate? *Unclear (details not reported)*

Were groups similar at baseline? *Unclear (baseline covariates balance not reported)*

Were outcome assessors masked? *No*

Were care providers masked? *No*

Were patients masked? *No*

Was overall attrition 20% or higher? *Unclear (not reported)*

Was differential attrition 15% or higher? *Unclear (not reported)*

Did the study use intention-to-treat analysis? No

Did the study use adequate methods for handling missing data? No (Appeared to use completer analysis)

Were outcome measures equal, valid, and reliable? Yes

Did study report adequate treatment fidelity (therapist adherence) based on measurement by independent raters? No

Taylor et al. (2003).
Was included, but further examination by Christopher Lee suggests high risk of bias, identifying errors in the AHRQ evaluations. See Christopher Lee's comments for more information.

Panel response: There do not appear to be errors in the systematic review assessment of risk of bias of the Taylor et al. (2003) study.

Edmond, Tonya, Lacey Sloan, and Dawn McCarty. 2004. Sexual abuse survivors' perceptions of the effectiveness of EMDR and eclectic therapy. Research on Social Work Practice 14, (4) (07): 259-272.
Marich, Jamie. 2010. Eye movement desensitization and reprocessing in addiction continuing care: A phenomenological study of women in recovery. Psychology of Addictive Behaviors, 24 (3): 498-507.

Panel Response: As noted above, patient preferences did not factor into the panel's decision for EMDR, as noted in the Decision Table for EMDR, available in the Appendix to the report.

Commenter: David House; dhouse.ceas@yahoo.com

Comment: In APA's own analysis of the effects of adding the van den Berg et al. 2015 study, they wrote "If a new meta-analysis were to be done, including the one new trial (van den Berg) the confidence interval would be narrower and it is possible that the SOE might be upgraded from low to medium as a result." (Appendices, p. 622). This study should be added to the analysis to better reflect EMDR's effectiveness.

Commenter: Christopher W Lee; chris.lee@uwa.edu.au

Comment: The APA Practice Guideline Development Panel for the Treatment of Posttraumatic Stress Disorder (PTSD) concluded that there was strong evidence for cognitive behavioural therapy, cognitive processing therapy, cognitive therapy and exposure therapy yet weak evidence for EMDR. This is in spite of the findings of a systematic review of the evidence for treatment conducted by the Research Triangle Institute- University of North Carolina Evidence-Based Practice Center (RTI-UNC EBPC) which concluded that EMDR leads to significant loss of PTSD diagnosis and reduction in symptoms and greater reduction than controls on depression scores. In that review EMDR was marked down on strength of evidence (SOE) for symptom reduction for PTSD. However there were several problems with the conclusion of that review. Firstly, in assessing the evidence in one of the studies the reviewers chose an incorrect measure that skewed the data. We recalculated a meta-analysis with a more appropriate measure and found the SOE to improve. Secondly even if the original measure was chosen we highlight inconsistencies with the way SOE was assessed for EMDR and cognitive therapy and cognitive processing therapy. Thirdly we highlight two papers that were omitted from the analysis. We again recalculated the meta-analysis and found that this also had an effect on SOE. The resultant standard mean difference and confidence intervals were actually better for EMDR (more precision) than for cognitive processing therapy or cognitive therapy. Therefore, the SOE should have been rated as medium in that Agency for Healthcare Research and Quality report and rated as strong in the APA guidelines given it was at least equivalent to these CBT approaches. This would bring the APA guidelines in line with other recent practice guidelines from other countries. Less critical but also important, were several inaccuracies in the risk of bias in some studies and the failure to consider studies supporting strong gains of EMDR at follow-up.

1. USING A MORE APPROPRIATE MEASURE IN AN INCLUDED STUDY[1]

The RTI-UNC review (Figure 17) referred to mean changes in PTSD symptoms for EMDR versus control comparisons. There are 4 studies listed and changes were assessed in each of the studies on identified primary measures. For example in the Rothbaum study [2] this was the Clinician Administered PTSD Scale (CAPS). The primary outcome measure for the Carlson study [1] was also the CAPS and this is reported in the original article for pre and follow-up data. The effect size is large (Cohen's d=1.8). However, CAPS scores were not collected at post-treatment. A battery of self-report measures were collected at post-treatment including the Mississippi Scale for Combat Related PTSD (M-PTSD) and the Impact of Events Scale (IES). However, in the RTI-UNC analysis the IES was chosen above the M-PTSD. Why is difficult to fathom. The M-PTSD is more comprehensive than the IES, and similar to the CAPS it is based on the DSM. A review article at the time recommended the M-PTSD above all other self-report measures for assessing PTSD [3]. Furthermore, when the RTI-UNC reviewers were describing which studies were included in their analysis and wanted to compare the severity of PTSD symptoms at baseline for each study, they chose the M-PTSD over the IES (see Table 9 and 18). Also later in the report

when assessing the effectiveness of relaxation they again use the M-PTSD (p70). So why they reverted to the IES in the middle of the report when assessing change in the PTSD symptom level for this study is perplexing.

Changing the outcome measure from the IES to the M-PTSD significantly changes the results with regards to PTSD symptom reduction following EMDR. If this correction is utilized the effect size, precision, and consistency are all improved [SMD, -1.28 (-1.81 to -0.74); I2=43%].

RTI-UNC guidelines define precision as the width of the confidence interval and consistency is the number of studies in the same direction and appears to take into account the heterogeneity (The RTI-UNC quote heterogeneity when discussing consistency in appendix 1). Therefore, heterogeneity at 43% for EMDR is better than mixed cognitive behavioural therapy (CBT), cognitive therapy (CT), and cognitive processing therapy (CPT) where heterogeneity was significant and ranged between 80 and 87%. In addition to EMDR being more consistent the precision improves to 1.07 (difference between lower and upper end of the confidence interval), which is better than both CPT (1.1) and CT (1.38). Therefore, there is no basis to argue SOE is better for these CBT therapies.

Finally changing the outcome measure to the more comprehensive measure of the M-PTSD provides a result more consistent with the rest of the data from the study. The effect size for the CAPS at follow-up was 1.82 for the EMDR treatment and there were large effect sizes for both depression and anxiety measures post-treatment in comparison to control making the IES result an anomaly.

2. STRENGTH OF EVIDENCE USING ONLY THE DATA SUPPLIED IN THE RTI-UNC REPORT.

There appears to be differences in how the consistency domain was rated with respect to SOE for PTSD symptom reduction. This section only refers to the analysis on the 4 included studies in the RTI-UNC report not an analysis that should have included the 6 studies described later in this report. With regards to PTSD Symptom Reduction the RTI-UNC study rated EMDR as Inconsistent. This is based on the heterogeneity of the related studies, the direction of the effects and the magnitude of these effects. Examination of the impact of CT on PTSD symptom reduction suggests that there is high heterogeneity in the evidence for both scales (I2 = 79.6%), as shown on Table G-2. However, rather than Inconsistent, this category has been labelled Some Inconsistency. The annotation of this table indicates that the 'Direction of effects were consistent; magnitude of effects ranged from very large to small' (page G-4). Similar annotations have been made on Table G-1 and G-13 resulting in studies with high heterogeneity obtaining ratings of Consistent or Some Inconsistency.

These annotations have not been applied to the analysis of EMDR. With regards to impact on PTSD Symptom Reduction, while the heterogeneity of EMDR results is high (I2=70%), this is lower than the same measure for CT mentioned above. Further, the direction of the effects from EMDR studies is consistent and the magnitude of these effects ranged from 'almost small to very large', which is similar to related results for CT. This suggests that the Consistency domain for EMDR on PTSD Symptom Reduction should have been moved from Inconsistent to Some Inconsistency, to ensure uniformity in rating across therapies.

A change of the Consistency domain would mean that the domains for PTSD Symptom Reduction following EMDR would be comparable to that for CT across all measures. Following this would move the SOE for EMDR for PTSD symptom reduction from Low to Moderate.

It may have been argued that this annotation may not apply to the EMDR results with regards to Symptom Reduction as one of the studies [1] had a confidence interval where the lower point falls below zero. However two of the studies in CBT- Mixed Interventions [4, 5] have their confidence

intervals falling below zero, and this intervention is still rated as consistent. Further, if the outcome measure analysed for this study was altered, as suggested from the IES to M-PTSD, this would no longer be the case.

3. OMISSIONS OF RCT STUDIES RELEVANT TO THE RESEARCH QUESTIONS.

An additional error in the analysis occurs in the RTI-UNC report is the failure to include two studies relevant to the issue of whether EMDR leads to more symptom reduction than a control condition. The report purports to assess, as its first research question, the effectiveness of psychological treatments "compared with wait list, usual care (as defined by the study), no intervention, placebo," (pES-5). Yet a significant study was excluded from the analysis represented in Figure 17. The study omitted is van der Kolk et al. [6]. This study is reported in Table 18, however it is inexplicably missing from the meta-analysis. The study by van der Kolk [6] had three arms to it. Participants were randomised to either EMDR or SSRI treatment condition, or a placebo control. In the RTI-UNC review, Figure 17 refers to mean changes in PTSD symptoms for EMDR vs control comparisons. As placebo is clearly a control condition Figure 17 should include the data from this study.

This omission cannot be justified on a basis of methodological procedures because other studies that included multiple arms were utilised in more than one place in order to answer key questions. For example, Marks et al. [7] appears in Table 9 when discussing coping skills trials, and again in Table 13, looking at the efficacy of exposure trials [8]. This suggests that there is no methodological issue that would result in the exclusion of van der Kolk et al. [8] data. The inclusion of this study into the analysis, with regards to PTSD symptom reduction for EMDR, would change the conclusions of SOE in the report. When we calculated the new confidence interval it was from -1.56 to -0.37 which is better precision than CPT and heterogeneity improved from just the 4 studies to remain better than CPT or CT

Another important study omitted from the meta-analysis was published in 2015 [9]. A problem with the APA guidelines is that, although they are based on the review by RTI-UNC published in 2013, they won't be made available until 2017. This means that while readers may believe they are reading 2017 guidelines, they are actually 4 years out of date. Three recent randomised control trials [9-11] that support EMDR as evidence based are not considered in these conclusions. One study in particular, by van den Berg and colleagues [9] meets a high methodological standard. Indeed, in the RTI-UNC appendices this study is highlighted. The APA committee in reviewing the RTI-UNC findings acknowledged that the addition of this study to the analysis was likely to narrow the confidence interval and therefore impact on precision and would also improve consistency. "If a new meta-analysis were to be done… the confidence interval would be narrower and it is possible that the SOE might be upgraded from low to medium as a result." (p. 622). This would have a significant bearing on SOE. However, seemingly paradoxically, after highlighting the impact of the addition of this study, they then conclude that there is insufficient evidence to determine whether the study would change the recommendation for EMDR. Moreover, they acknowledge that if the effect size stayed at medium/large and given the increased sample size that the SOE would be changed.

Testing the idea of whether precision improves and the effect size stays the same is a science issue. It is not difficult or time consuming to do the analysis. We used Comprehensive Meta-Analysis software (CMA) and input the same effect sizes reported in Figure 17, with the addition of CAPS scores and confidence intervals from the studies of van der Kolk and van den Berg. The RTI-UNC review reports the following effect size, confidence intervals, width of this interval, and heterogeneity respectively; CPT [SMD -1.40 (-1.95, -0.85); 1.10; 87%], CT [SMD -1.22 (-1.91, -0.53); 1.38; 80%], CBT-Mixed [SMD -1.09 (-1.4, -0.78); 0.62; 87%] and EMDR [SMD -1.08 (-1.83, -0.33); 1.50; 70%]. Our analysis shows that the addition of van der Kolk study yields the following results [SMD -.97 (-1.56, -0.37); 1.19; I2=69%].

Further with the addition of both the van der Kolk and van den Berg, the effect size remains large [SMD -.89 (-1.34, -0.44)]. In addition, the confidence interval difference decreased to just .9 and I2=66%. Using the RTI-UNC own guidelines of assessing SOE, EMDR is doing better than both CPT and CT in both consistency and precision. In fact this analysis of all six EMDR studies yields results is closer to CBT-Mixed in precision than CPT or CT. Even more compelling is the heterogeneity, which at 66% is better than mixed CBT, CT and CPT (heterogeneity was used in the RTI-UNC as an indication of consistency, see appendix 1). The total N is also substantial at 284. It is not possible from a science point of view, to rate CPT and CT higher in SOE than EMDR.

Finally redoing the analysis for all 6 studies that compared EMDR to a control condition and using the more appropriate M-PTSD measure for the Carlson study the SMD is -0.99 and the confidence interval is from -1.41 to -0.58 (I2=57%). This is the best reflection of the state of the literature today. This is the result that should have been used by the APA. This data means that consistency for EMDR is better than CT, CPT and mixed CBT and EMDR has more precision than CT or CPT.

4. PAPERS INAPPROPRIATELY INCLUDED IN THE ANALYSIS OF THE RTI-UNC REVIEW.

In examining the papers included from the analysis in the RTI-UNC review [8] there appear to be errors made in the inclusion of certain studies from the analysis of evidence. An example of this is the inclusion of Taylor et al. [12], despite several significant validity concerns and concerns regarding the interpretation regarding psychometric properties.

In Table E1 of the RTI-UNC paper there is a category that examines whether the participant groups in the study were equivalent at baseline [8]. On page E-21, this category for the study by Taylor et al., [12] was rated as yes [8]. However, no pre-treatment test scores analysis for treatment conditions is reported. The only pre-treatment analysis reported is that there are no significant differences between dropouts and completers—regarding demographics and primary measures of interest. Furthermore, Figure 2 indicates that the participants in the exposure group reported less symptoms than those in the EMDR group at pre-treatment [12]. The confidence intervals on the bar graph show the mean score for the exposure group was outside the standard error of the EMDR group at pre-treatment for Hyperarousal, Re-experiencing, and Avoidance symptoms.

The bias in the Taylor [12] study is further inflated as it relied on a treatment completer analysis rather than an intent-to-treat analysis. This is critical in that given EMDR was more severe to begin with but the PE had a higher dropout rate (11% greater), the chance of systematic bias is elevated.

An additional error in the rater's assessment of this study was the judgment that the providers of the therapy were masked. However logic asserts that this assessment is not possible in a design comparing two psychological treatments. Given these errors in the risk of bias the Taylor et al. [12], study should be reclassified from a medium to high risk of bias.

Thus the information on Table E-21 regarding Taylor et al. [12] is wrong in two categories. The study clearly has a high risk of bias not medium. Therefore, it should not have been used in decisions regarding CBT—Coping Skills (Table 9). Nor should it be included in any discussion on Change in CAPS for exposure therapy compared with relaxation therapy (Figure F-36). In this analysis the failure to find a significant difference between relaxation and exposure was at odds with the more methodological sound study by Marks et al [7] .

With respect to findings related to EMDR, removing this study changes the interpretation of the RTI-UNC report with regards to EMDR and PTSD Symptom Change. The conclusion that all studies found a greater reduction in PTSD symptom scores in favour of EMDR over comparators (p. 67) still stands.

However, the qualifying statement that not all differences reached statistical significance would now misrepresent the data. A more accurate statement is that in all bar one study the differences reached statistical significance. Clearly this results in a different sense of SOE with respect to consistency of results.

Another conclusion in the RTI-UNC report that needs adjusting by the removal of Taylor study is 'Percentage of subjects achieving loss of diagnosis for exposure compared with EMDR' (p53) as Taylor should not be included here which increases the effect size in favour of EMDR. Also it should be removed from the discussion of 'PTSD symptom reduction for EMDR compared with relaxation' (p F-73) and 'Loss of PTSD diagnosis at 3 month follow-up for EMDR compared with relaxation' (p. F-74). Similarly to Taylor being at odds with other better studies on loss of diagnosis comparing exposure therapy and relaxation the same is true that is at odds when comparing relaxation therapy with EMDR or exposure.

5. PAPERS INAPPROPRIATELY EXCLUDED FROM THE ANALYSIS OF THE RTI-UNC REVIEW.

In examining the papers excluded from the analysis in the RTI-UNC report [8] there appears to be errors made in the exclusion of some studies from the analysis of evidence. Research by Lee and colleagues [13] was assessed as a high risk of bias however as explained below there appear to be errors in the examination of the results of this study.

Firstly, in Table E1 on the RTI-UNC paper there is a category that examines whether the participant groups in the study were equivalent at baseline. On page E-13, this category for the study by Lee et al. [13] was rated as unclear. However page 1077 of the Lee et al. [13] article reports,

"Independent t-tests were used to investigate differences between the groups on pre-treatment measures. No differences were found for the IES (t(22)=.11, p=91), BDI (t(22)=1.05, p=.31), SI-PTSD (t(22)=1.63, p=.12), or MMPI-K (t(22)=1.31, p=.21). Therefore, the groups appeared to be equivalent on major variables."

Therefore, the raters made an error in asserting that the paper was not clear on whether there were differences at baseline. This is in sharp contrast to the Taylor et al. [12] study where no baseline comparison data was analysed.

The raters of Lee's study also marked it down saying that that the differential attrition data was unclear. However, the study clearly indicates that 24 participants entered the study, 12 were assigned EMDR and 12 were assigned to CBT, with three people dropping out, leaving 21 completers [13]. On page 1075 it is stated that 21 participants completed the study, 11 for stress inoculation with prolonged exposure and 10 from EMDR. The article then describes how one of the EMDR non-completer was sent to prison. It does not make sense that the raters can claim that the attrition is not clear.

Given the above two errors the risk of bias in the study deserves to be reclassified from high risk of bias to moderate. Following, it should be moved from Table 19 to Table 18 and included in the analysis. This inclusion strengthens the evidence base for a reduction in PTSD symptoms and for loss of diagnosis for EMDR.

The inclusion of Lee et al. [13] and the exclusion of Taylor et al. [12] together would have a very substantial effect on conclusions of the SOE. However, the removal of just Taylor makes a substantial difference.

So the final number of randomized control trials that the APA should considered when assessing for evidence for EMDR is 8 if using the RTI-UNC criteria. Six of these [1, 2, 6, 9, 14, 15] included a waitlist or

other minimal intervention control and 5 of these 6 compared EMDR to another manualised active treatment. Two trials [13, 16] compared EMDR to another manualised treatment only.

6. LACK OF ATTENTION TO FOLLOW UP DATA

In the RTI-UNC analysis it sates “Our meta-analysis (Figure 17) found greater reduction in PTSD symptoms for EMDR than for controls…. Treatment gains were maintained for studies reporting follow up at 3, 6, or 9 months (p. 67).

This statement ignores the considerable data that EMDR treatment gains are maintained far beyond end of treatment time points. At the very least the follow up study on the Högberg data [17] which reported treatment gains for EMDR were maintained at 37 months should have been mentioned. However there is a case that other data such as that presented in Wilson’s study [18, 19] should have been included. In this study EMDR achieved large treatment effect sizes for both participants who all met the criteria for PTSD and for those that didn’t quite make the diagnosis. In fact, whether participants met full diagnostic criteria or not did not have any significant effect on treatment outcome. In a follow-up article they give separate figures for both groups of participants showing that the treatment gains were maintained at follow-up (15 months) with large effect sizes.

CONCLUSION

The APA guidelines are utilised worldwide and the accuracy of the document and the data it contains is crucial. This review highlights some inaccuracies regarding the way studies were handled in the statistical review of papers particularly with respect to evidence concerning EMDR. Therefore, the subsequent conclusions of the draft guidelines are flawed. These flaws explain why the proposed 2017 guidelines are at odds with other best practise guidelines from other countries and international based guidelines such as the World Health Organisation in 2013 [20]

References.

1. Carlson, J.G., et al., Eye movement desensitization and reprocessing (EDMR) treatment for combat-related posttraumatic stress disorder. Journal of Traumatic Stress, 1998. 11(1): p. 3-24.

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Patient Values and Preferences EMDR

Commenter: Corine Brown, LCSW; cbrown2@tulane.edu

Comment: “Treatment is unknown, components are unconventional, concept is ‘alien,’ does not give people the chance to talk about the event to the extent that trauma therapies do”

Such commentary should be removed altogether. It speaks to a complete bias against the modality and gives the impression that practitioners are some how denying their clients the ability to verbally process through concerns as needs. Most who are drawn to this modality appreciate the fact that are not forced to incessantly recount past traumas and the fact that many feel the benefits far quicker than in more traditional forms of talk therapy just speaks to its power.

Commenter: Melinda Taylor; Melinda.taylor@suddenlink.net

Comment: The guidelines do not list the 3 studies in which it is stated that EMDR is less preferred by clients. I would like to see the studies. That has not been my experience as a therapist or as a client.

My experience is that no client's want Prolonged Expoxure therapy and the dropout rate is incrediabley high. The VA in Little Rock has a long waiting list for veterans wanting EMDR. I have a waiting list for clients that are waiting to get EMDR Therapy from me. They are coming to my clinic for EMDR specifically.

Commenter: Stephanie Baird; sbaird@gmail.com

Comment: The APA report claims that in three studies that looked at EMDR, it is ranked lowest among treatment choices among patients compared to other PTSD treatments. (See Appendix C page 210-214 of PDF or page 333-337 of Appendices of Guidelines.) However, they do not identify the studies so their design and credibility are unknown. The APA report is inferring that the better-known CBT, exposure and cognitive therapy are preferential treatments of clients and clinicians; however, the lack of a preference for the lesser known EMDR therapy should not be a consideration. The rationale that some patient’s report includes, “Tx is unknown, components are unconventional, concept is ‘alien,’ does not give people the chance to talk about the event to the extent that trauma therapies do”. Do you deny your clients the ability to speak about the trauma? What do you think best serves your client?

As indicated in the guidelines, some clients report preferring EMDR because, “they don’t have to expose themselves or talk about the details of their trauma out loud. (Not wanting to feel shamed, or embarrassed.)” Others “have heard it’s quick and efficient and prefer that.” Yet these issues and the factors that allow EMDR to achieve results comparable to CBT without homework and permit effective treatment on consecutive days are not addressed in the guidelines, which declare that EMDR is inferior to other psychotherapies.

APA states that the mechanism of change is not understood which reduces credibility of the treatment in the eyes of both patients and clinicians. We know better. Numerous randomized component analyses and physiological studies have explored this issue. The mechanism of change for EMDR therapy is as well understood for those who know the literature.

Panel Response to EMDR Comments

Most of the comments about EMDR raised concern that it was given a conditional (in the previous draft the panel used the term weak) recommendation, compared to inactive comparators instead of a strong recommendation. We first explain the reasoning behind our recommendation (also presented in Appendix D, Decision Table for EMDR Efficacy) and then address specific questions raised by comments about our EMDR recommendation.

In formulating the response to the collected comments on EMDR, members of the panel reviewed each of the assertions presented by Drs. Shapiro, Maxfield and Lee and in each instance, did not find the assertions to have merit. Many of the specific points had to do with aspects of the systematic review, such as how studies were identified, evaluated for inclusion or exclusion, etc. Panel members returned to the systematic review to evaluate these concerns and determined that they were in agreement with the RTI-UNC EPC's conclusions regarding study inclusion/ exclusion and evaluation of the studies. Given the length of this commentary, the panel opted to not include a point by point assessment of each concern but summarizes its review in the following response.

We followed a structured approach to making a recommendation for all interventions, including EMDR. We assessed: 1) The strength of evidence for critical and important outcomes, based on data from the systematic review that we used as our evidence base (Jonas et al., 2013); 2) The balance of benefits and harms, based on evidence from the systematic review and a supplemental search of the literature for harms and burdens; 3) Patient values and preferences, based on data from a recent systematic review on patient preferences for trauma treatment (Simiola et al, 2015); 4) Applicability to populations of interest.

Strength of evidence (SOE): The SOE ratings, from the systematic review, for the critical and important outcomes for EMDR, compared to inactive comparators were:

PTSD symptom reduction: Low SOE

Loss of PTSD diagnosis: Moderate SOE

Prevention / reduction of comorbid depression: Moderate SOE

Prevention / reduction of comorbid anxiety: Very low SOE

The systematic review that served as our evidence base included four trials that were rated medium or lower risk of bias in the assessment of EMDR compared to inactive controls: Hogberg et. al, 2007; Rothbaum et al., 1997; Rothbaum et al., 2005; Carlson et al., 1998 (Jonas et al, 2013; Table 18, p 66). (Three other trials compared EMDR to active comparators and were not used in the assessment of EMDR efficacy: van der Kolk et al, 2007; Nijdam et al., 2012; Taylor et al., 2003).

Based on those four included studies rated medium or lower risk of bias, the standardized mean difference (SMD) for EMDR, compared to inactive comparators (waitlist or usual care), for PTSD symptom reduction, was -1.08, 95% confidence interval (CI), -1.83 to -0.33 (Jonas et al., 2013, p 68). There was a large amount of heterogeneity in the findings across the four studies (I-squared = 70%), with the studies comparing EMDR to waitlist controls having a much larger effect size (SMD = -1.37) than the study comparing EMDR to usual care (SMD = -0.19). Based on the criteria used by all of the AHRQ-funded Evidence-based Practice Centers to assess strength of evidence (Owens, D.K., et al., 2009), the evidence for PTSD symptom reduction by EMDR compared to inactive comparators was rated low, because of inconsistency of findings (i.e., the range of effect sizes was broad) and imprecision (the confidence interval for the effect estimate was wide, with a range from a very large effect (-1.83) to a small effect (-0.33).

Balance of benefits and harms: Based on the magnitude of benefit of the critical and important outcomes, from the systematic review, and the magnitude of harms, from a supplemental search for harms and burdens that was conducted for all interventions, we concluded that benefits clearly outweighed harms / burdens for EMDR, compared to inactive comparators.

Patient values and preferences: In three studies that were identified in a systematic review of patient preferences for trauma treatment, EMDR ranked lowest among trauma treatment options that were presented to patients. However, due to low certainty about the specific comparison of EMDR to inactive comparators, patient preferences did not substantially factor into our recommendation.

Becker, C. B., Darius, E., & Schaumberg, K. (2007). An analog study of patient preferences for exposure versus alternative treatments for posttraumatic stress disorder. Behaviour Research and Therapy, 45, 2861-2873.

Becker, C. B., Meyer, G., Price, J. S., Graham, M. M., Arsena, A., Armstrong, D. A., & Ramon, E. (2009). Law enforcement preferences for PTSD treatment and crisis management alternatives. Behaviour Research and Therapy, 47, 245-253.

Tarrier, N., Liversidge, T., & Gregg, L. (2006). The acceptability and preference for the psychological treatment of PTSD. Behaviour Research and Therapy, 44, 1643-1656.

Applicability: There were no concerns about applicability of EMDR to specific populations or persons with specific types of trauma.

Overall Recommendation: We recommended EMDR, conditionally (weakly), compared to inactive comparators. The major factor that kept EMDR from being given a strong recommendation was the low strength of evidence for the critical outcome of PTSD symptom reduction. If EMDR had been given a strong recommendation, it would have been the only intervention for which a strong recommendation had been given for an intervention with less than at least moderate strength of evidence for the critical outcome of PTSD symptom reduction. All of the interventions that we recommended strongly had at least moderate strength of evidence for the critical outcome of PTSD symptom reduction and at least moderate strength of evidence for at least one important outcome (e.g., loss of diagnosis).

The systematic review that we used as the evidence base for our recommendations included articles published through May 2012. To assess the likelihood that our recommendations would remain unchanged based on more recently published studies, we conducted an updated search of trials published between May 2012 and June 2016 that would have met inclusion criteria in the systematic review.

As shown in Table 12, Appendix H, of the Guideline Appendices, we concluded that there was insufficient evidence to determine whether the weak recommendation for EMDR efficacy would be likely to change (to a strong recommendation) as a result of the identification of one new trial (van den Berg et al., 2015). The effect size for EMDR from the systematic review was large. In its original deliberations, we gave EMDR a weak recommendation rather than a strong recommendation, despite the large effect size for PTSD symptom reduction, because the strength of evidence (SOE) from the systematic review for PSTSD symptom reduction was rated as low. (The low SOE was due to imprecision (i.e., a confidence interval that was wide enough to permit clinically distinct conclusions) and inconsistency (i.e., large differences in the effect sizes from the included RCTs). The new trial identified in the search update process (van den Berg, et al., 2015) had a medium effect size and a sample size nearly equivalent to the sample size from all of the trials, together, included in the systematic review for EMDR. If a new meta-analysis were to be done, including the one new trial, the effect size would still be in the medium to large. However, as a result of essentially doubling the sample size (from 117 in the older trials to 225 in a meta-analysis including the older and the new trials), the confidence interval would be narrower and it is possible that the SOE might be upgraded from low to medium as a result.

However, because we did not do independent assessment of risk of bias of any trials that we identified through the updated search, it is unclear whether the new trial would be rated moderate or lower risk of bias and thus included in a future meta-analysis or whether it would be rated high risk of bias and excluded. Accordingly, we concluded that there was insufficient evidence to determine whether the weak recommendation for EMDR would be likely to change (to a strong recommendation) as a result of the new trial identified. Future systematic reviews will be able to resolve this issue and future guidelines, based on those systematic reviews, will help to resolve the issue of the strength of recommendation regarding EMDR efficacy for treatment of PTSD.

Response to specific issues

<u>EMDR therapists and/or proponents were not included on the panel</u>

No panel members were selected on the basis of their allegiance to specific therapies. Unlike previous APA panels, in which members were selected as representatives of particular constituencies, the members of the PTSD Treatment Guideline Development Panel were selected for their general expertise in the field of trauma and PTSD and their ability to assess and apply evidence fairly and free of conflict of interest. To avoid even the appearance of conflict of interest, APA did not select panel members who had developed specific psychotherapy treatments or who had staked claims to specific treatments. However, diversity of discipline and background were considered important; the panel included professionals from a variety of disciplines (psychology, social work, psychiatry, family medicine) and panel members were from diverse ethnic backgrounds. We are adding an appendix to the report that includes the biographies of the panel members.

Although experience with or use of specific interventions was not a criterion by which APA selected members for panel inclusion, several panel members have been trained in and have used EMDR in their clinical practices.

<u>Comment: Clinical experience has shown that EMDR works</u>

Some commenters reported that they had used EMDR in their own clinical practice and that they had seen it work.

Clinical experience is unfortunately a problematic indictor of what works and what doesn't. There are many treatments that were thought at one time to be beneficial but were later shown in randomized trials to be harmful. Likewise, there are treatments that were thought to be harmful but were later shown in randomized trials to be beneficial. Consistent with the recommendations from the IOM report, Clinical Practice Guidelines We Can Trust (IOM, 2011b) we used a systematic review of high-quality randomized trials as our primary evidence base for assessment of efficacy of interventions. For assessment of harms and burdens of interventions and for assessment of patient values and preferences, for which there was much less high-quality evidence available in the published literature, we included the input of clinician and patient panel members, though that evidence was accepted as having very low strength of evidence.

<u>Comment: Patient values and preferences erroneously or incompletely asserted</u>

One aspect of generating recommendations based on research evidence is to consider what is known about patient values and preferences. Unfortunately, in general for mental health treatment, the strongest conclusion about patient preferences is that patients want treatment rather than not receiving treatment. Very little systematic evidence is available regarding preferences for one type of treatment

over another. The quoted statement "Treatment is unknown…" comes from a member of the panel, describing his experience with individuals regarding EMDR and is noted in the appendices (Recommendation Worksheet Topic #7- Efficacy of EMDR). The quotes highlighted by Stephanie Baird reflect the impressions of clinicians on the panel. In both instances, the panel was aware that these are anecdotal experiences and not systematic evidence and did not substantially drive the recommendation. Additionally, the few studies on patient values and preferences for treatments for PTSD were reviewed but in the draft appendices, these articles are not referenced. This has been corrected and references for those studies included in the decision table.

Comment: The description of EMDR is not accurate

Some commenters stated that the description of EMDR in the Appendix is not accurate. We have utilized EMDRIA and other source documents to update the description of EMDR. The descriptions of all of the interventions that we assessed are intentionally brief with the expectation that those who wish to learn about the treatment will undertake appropriate training.

Comment: The current guideline's recommendations for EMDR are different from other guidelines

Some commenters objected to our statement that our conclusions are "largely consistent" with other guidelines. Those commenters noted that other guidelines (with the exception of the American Psychiatric Association Guideline) "put EMDR and CBT on the same level" while the APA Guideline gives EMDR a weak recommendation.

We do not believe that the evidence for CBT and EMDR are comparable. For the critical outcome of PTSD symptom reduction, the SMD (effect size) for CBT compared to inactive comparators (-1.36), measured with the gold standard CAPS was larger than the SMD for EMDR compared to inactive comparators (-1.08). The estimate was more precise, as indicated by the narrower 95% confidence interval [(-1.87 to -0.85) for CBT compared to (-1.83 to -.33) for EMDR]; in addition, the confidence interval for the CBT estimate includes only large effect sizes while the confidence interval for EMDR is compatible with a large effect size or a small effect size. Moreover, for CBT there was moderate SOE for the important outcomes of remission (no longer having symptoms), loss of PTSD diagnosis and prevention of comorbid depression while for EMDR there was moderate SOE for loss of PTSD diagnosis and prevention or reduction of comorbid depression.

We believe that the statement that our conclusions were "largely consistent" with other guidelines is correct. We also included a paragraph describing the differences between our recommendations and those of other guidelines; in that paragraph we reported the recommendations given for EMDR by other guidelines. We would also like to point out that, contrary to the statements from many commenters about EMDR, the American Psychiatric Association Guideline was not the only guideline that did not give EMDR its highest level of recommendation; the IOM Guideline did not give EMDR (or any psychotherapy other than exposure) any recommendation at all.

Comment: Exclusion criteria for the systematic review were "too strict"

Some commenters stated that the criteria used for inclusion of trials in the systematic review were "too strict", thereby eliminating evidence of the efficacy of EMDR. Like all systematic reviews, the RTI-UNC systematic review developed inclusion and exclusion criteria to determine which trials should be included. Those criteria are shown on page 10 of the systematic review.

We believe that those criteria were reasonable and did not inappropriately exclude trials that should have been included. The systematic review only included trials in which participants met full

diagnostic criteria for PTSD using clinical evaluation or a diagnostic interview. Trials were excluded from the systematic review if they only included participants exposed to trauma but did not have PTSD, if potential participants had partial / subthreshold PTSD, or if a screening test was the only method used for assessment of PTSD at the start of the trials. Those criteria are appropriate because they guaranteed that the included trials assessed interventions in a group that was homogeneous with respect to diagnosis of PTSD at baseline. There were no exclusion criteria for type of trauma, demographic characteristics, or geographic location.

Trials that met inclusion criteria but were rated high risk of bias were also excluded from the systematic review. Four trials (Johnson et al., 2006; Power et al., 2002; Marcus et al., 1997; Zimmerman et al., 2007) comparing EMDR to inactive comparators were identified but were excluded because of high risk of bias.

The criteria that were used in the systematic review by the RTI-UNC Evidence-based Practice Center to assess risk of bias are the same criteria used by all thirteen AHRQ-funded Evidence-based Practice Centers (Viswanathan et al., 2012). That approach is very similar to the methods used by the GRADE consortium (Guyatt et al., 2011) and the Cochrane Collaboration Higgins, Altman, & Sterne, 2011).

Risk of bias was based on the assessment of 12 distinct criteria (Appendix E, Jonas et al., 2013). High risk of bias ratings were assigned to studies that were believed to have a "fatal flaw" (i.e., one or more serious methodological problems), including the following:

1. *Inadequate method of randomization (e.g., alternating) and resulting baseline differences between groups with no subsequent approach to handle potential confounders*
2. *Attrition ≥40 percent or differential attrition ≥30 percent;*
3. *Attrition over 20% or differential attrition over 15% and inadequate handling of missing data (e.g., completers analysis)*
4. *Other combinations of multiple risk of bias concerns.*

The ratings for each of the 12 risk of bias items for all studies included in the systematic review and all studies excluded because of high risk of bias are shown in Appendix E of the systematic review (pages E2 – E27).

We believe that the criteria used to assess risk of bias were appropriate and not "too strict". First, as noted above, the criteria used by all of the AHRQ-funded Evidence-based Practice Centers are very similar to the criteria adopted by the GRADE consortium and the Cochrane Collaboration. Second, a chief advantage of using a risk of bias assessment that has been used to assess a wide variety of medical and mental health interventions, like the one used by all of the AHRQ-funded Evidence-based Practice Centers, rather than an ad hoc instrument developed just for PTSD treatment research, is that health professionals and the public can have the same degree of trust in the efficacy of interventions for PTSD as it has in the efficacy of other interventions assessed by the Evidence-based Practice Centers. Since 2001, the Evidence-based Practice Centers have produced more than 600 systematic reviews on screening, diagnosis and treatment of a wide range of medical and behavioral health topics. We believe it is reassuring to know that the evidence for assessing efficacy of treatments for PTSD is based on the same strong methodological standards to which the evidence for treatment of cardiovascular disease, asthma, depression and other common conditions were subjected.

<u>Comment: The statement in the report that the mechanism of change is not understood is incorrect</u>

Some commenters reported that a sentence in the decision table on the mechanism of change for treatment with EMDR was inaccurate.

The statement in question was: "Mechanism of change is not understood which reduces credibility of the treatment in the eyes of both patients and clinicians". This statement was generated by one of the clinicians on the panel as part of the discussion about patient values and preferences and we believe it represents the belief of some clinicians and researchers (Jeffries & Davis, 2013). As noted above, data on patient preferences and values did not factor into our recommendation for EMDR because of low certainty about the validity of those data.

References

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van den Berg, D. P., de Bont, P. A., van der Vleugel, B. M., de Roos, C., de Jongh, A., Van Minnen, A., et al. (2015). Prolonged exposure vs eye movement desensitization and reprocessing vs waiting list for posttraumatic stress disorder in patients with a psychotic disorder: A randomized clinical trial. JAMA Psychiatry, 72(3), 259-267

Comments on Prolonged Exposure v Exposure

Commenter: Sheila A.M. Rauch, PhD, ABPP: Sheila.a.m.rauch@emory.edu

Comment:

While all other established protocol therapies are mentioned by name, the treatment with the most RCTs (Prolonged Exposure) is not mentioned by name. This NEEDS to change. Calling it exposure therapy is not consistent with the other therapies. The guideline would be better to specifically mention the named interventions that meet the recommendation high bar (PE, CPT, CT, etc.). This needs to be changed throughout the guideline.

Be consistent in stating ALL named protocols that meet the evidence bar. Specifically, it is not just Exposure Therapy but also Prolonged Exposure.

Commenter: Peter Tuerk; tuerk@musc.edu

Comment:

No I concur with the other comments regarding the importance of identifying Prolonged Exposure specifically, rather than 'exposure therapy.' PE, as a protocol, has significant support in funded trails and effectiveness contexts. Besides missing an opportunity to capitalize on a standardized vs. a non-standardized recommendation, which holds merit in and of itself, the differences between PE and 'exposure therapy' in general are not academic. Namely, from the perspective of a PTSD specialty clinic director and EBT trainer in VA, DoD, and civilian contexts, the PE protocol sets a comparatively high standard for exposure dosing compared to typical therapist-directed exposures in general, also PE contains post-exposure processing. In other words, there are important content-oriented differences between PE and exposure therapy in general; the differences cannot just be assumed to superficially

procedural or only related to the timing or ordering of the "non-active" psychoeducation portions. While the wealth of information we have for PE across many treatment contexts might reflect well on other exposure therapies compared to non-exposure or supportive therapies, the PE evidence base does not support the equivalency of all exposure-oriented protocols, in fact, it is relatively silent on the matter. It is probably best for treatment guidelines to avoid reliance on inductive reasoning wherever possible, and given the comparatively large evidence based for PE, it is definitely possible in this case. Note, this is true even if most parties agree that the exposure component is the most important PE component; in human interaction and psychotherapy, the devil is in the details. If this were not the case, treatment fidelity would be unrelated to outcomes, which it is not. There may be a valid concern that using the specific name PE would be interpreted as excluding other treatments that include PE or are based on PE, such as protocoled treatments in virtual reality contexts, or duel treatments for PTSD and substance abuse, or PTSD and borderline personality disorder. This unintended consequence could be easily addressed with clarifying language if that were the intention and view point of the committee. I appreciate this portal and opportunity to comment.

Commenter: Yoshiharu Kim, joice21@yc4.so-net.ne.jp

Comment: No Misguiding recommendation of exposure therapy in general.(Please see the reason in the column below).

No Evidence shows the efficacy of the prolonged exposure therapy, not exposure therapy in general. But it is misinterpreted as if it supports the use of exposure therapy in general.(Please see the reason in the column below).

We appreciate your hard work for creating this draft of the guideline for PTSD treatment, but we are strongly afraid that it will create enormous backlash in the treatment of PTSD, in that it does not distinguish the prolonged exposure therapy (PE) from exposure therapy in general, while it clearly distinguishes the cognitive processing therapy (CPT) from cognitive therapy in general. This implicitly suggests that PE does not have advantage compared to exposure therapy in general, while it is far from the truth, because all the evidence the guideline cited for exposure therapy actually deal PE.

This is quite fatal in Japan, where PE has become to covered by the National Health Insurance System this spring and we are now rigorously disseminating it. The important background of the Japanese government's decision was, in addition to the studies and trainings in Japan, that PE has been always recommended by world famous treatment guidelines such as those issued by the National Academy of Science, the International Society for Traumatic Stress Studies, etc. If the guideline from the APA fails to acknowledge PE as the first line treatment of PTSD, then it risks that the government will reconsider the status of PE for the health insurance coverage. They may suspect there might be some reason that the APA has "withdrawn" PE from the recommendation and replaced it with other exposure therapies. This will be catastrophe to a number of patients who really benefit from this effective therapy in this country.

Exposure therapy is a generic term and has been employed to various types of mental disorders. It has been applied to trauma, since the 1st World War, but it created a bulk of failures. Babinski's electric shock therapy in France is notorious among them. It is only through PE that the element of exposure was scientifically integrated to produce reliable and sustainable benefit. I regret to say that APA's new guideline brings us one-century back, ignoring the piled-up evidence, verified clinical activities and voices from the clients, all strongly supporting PE. This is even more problematic when you distinguish CPT from cognitive therapy. Is there any specific reason that you avoided to use the term PE?

We strongly wish that the guideline shall use the specific terminology, prolonged exposure therapy, to refer specific treatment method and evidence accurately. We believe otherwise the guideline would not beneficial, either for therapists, researchers, or, most importantly, those who suffer from PTSD and need really effective treatment.

Commenter: Edna B. Foa; foa@mail.med.upenn.edu

Comment:

I was astonished to read the proposed American Psychological Association guidelines for PTSD and learn that the most studied treatment for PTSD, "Prolonged Exposure therapy" (PE) was not listed as a recommended treatment, and in fact was not mentioned throughout the document. Exposure therapy is included as a recommended treatment. However, exposure therapy is a general approach to therapy and does not refer to a specific treatment program. While there is no therapist manual called exposure therapy for PTSD, there is a widely known and used manual titled "Prolonged Exposure therapy" for PTSD that was published by Oxford University Press in 2007. Since 1995, 155 published reviewed papers had "Prolonged Exposure" in the title versus 38 papers that had "exposure therapy" in their title (many of which actually used PE according to the treatment description in the manuscript). In contrast to PE, a much less known and studied exposure therapy program called "Narrative Exposure therapy" (NET) is included in the guidelines.

Another general treatment approach is cognitive therapy, which includes several specific treatment programs such as "Cognitive Processing Therapy" (Resick et al., 2002), and "Cognitive Therapy" (Elhers et al. 2005). Surprisingly, these two specific cognitive therapy programs are listed in the guidelines, whereas "Prolonged Exposure" was not mentioned. There are serious negative consequences for omitting PE from the guidelines. First, it will cause confusion in the field about the distinction and relationship between a general approach to therapy (i.e., exposure therapy) and a specific manualized treatment program (i.e., PE). For example, the government in Japan recognized PE as the only reimbursable treatment for PTSD. Second, there has been widespread dissemination of PE, not of exposure therapy, within systems such as the VA and the DoD and around the world. As a result of this extensive dissemination, many thousands of therapists were trained and certified as PE therapists, and not as exposure therapists. If the APA does not acknowledge the existence of PE, a grave consequence will be that the thousands of PE therapists will be providing a treatment that is not recommended by the APA. The guidelines provided by the APA will have great influence, and the aim of these guidelines, presumably, is to provide accurate, clear, and specific recommendations to guide best practices in treating PTSD. Omitting the most studied treatment with the strongest evidence base of any PTSD treatment, runs counter to achieving this aim. I hope that the panel reconsiders the recommendations based on this feedback.

Commenter: Carmen McLean; mcleanca@mail.med.upenn.edu

Comment: It is odd that PE is omitted, since other specific PTSD programs are mentioned. The guidelines should clarify what the relationship is between exposure therapy (an umbrella term) and PE (specific program), and how the recommendations relate to each separately. Thanks.

Commenter: Mark Powers; mbpowers@utexas.edu

Comment 1: No There is a distinct omission of the most researched treatment for PTSD (Prolonged Exposure Therapy or PE). Instead, the guidelines use the umbrella term "exposure". However, this is not consistent with other named therapies such as Cognitive Therapy and Cognitive Processing Therapy (CPT). This is confusing and misleading. PE is a very specific manualized treatment. The guidelines should

mention PE specifically as there are meta-analyses and RCTs on this specific treatment. Also, the US and Canada are rolling out Prolonged Exposure Therapy, Cognitive Processing Therapy, and EMDR. Not, Exposure, CPT, and EMDR. The reason for this is that PE is not the same as "exposure therapy" in general.

Specifically break out PE from other exposure therapies.

Comment 2: The data reviewed is almost entirely from PE and not from generic exposure therapy. There are approximately 160 publications on PE and only about 35 on exposure.

Commenter: Sudie Back, PhD; backs@musc.edu

Comment 1:

No Evidence shows the efficacy of the prolonged exposure therapy, not exposure therapy in general. But it is misinterpreted as if it supports the use of exposure therapy in general.(Please see the reason in the column below).

Comment 2: I was very surprised to see that Prolonged Exposure (PE) is not included in these guidelines. PE is one of the most effective and evidence-based treatments available and I would highly encourage the committee to include PE as well as a reference to the PE manual by Foa, Hembree and Rothbaum. Otherwise, clinicians in the field may think that they are doing "exposure therapy" but they may not be. Clinicians often want and need a therapy manual to guide them. In the drafted guidelines, other manuals are included, such as CTP and Seeking Safety but not the PE manual? This is a big oversight and would weaken the validity of the guidelines if not addressed before publication.

I see that the term "exposure therapy" is used in some places and perhaps a lot of those studies include PE, but I would recommend making it as clear as possible and referring to the evidence of PE (not just a broad category of "exposure therapy" which could include all kinds of techniques). So, I think to improve the guidelines so they are most helpful to the field, the guidelines should include a specific review the PE literature, and include the PE manual so clinicians will know how to properly deliver PE and help their patients.

Thanks, in advance, for considering my comments and suggestions.

Panel Response:

The systematic review that served as the evidence base for our recommendations included trials of "prolonged exposure" (a branded therapy) as well as trials using other exposure protocols in the "exposure" category. RTI-UNC did not conduct separate analyses with only the prolonged exposure trials. The panel used the term exposure in its draft document but after reading the comments, it returned to the SR and reviewed the exposure condition used in the trials.

This is its analysis- In the SR, 15 studies of Exposure-Based Treatments were included (see pp. 42-45; see Table 13 on page 42 of the AHRQ report).

Only 5 studies were not specifically on PE. They are listed below:

- *Basoglu et al. 2007 – a study that examined a one-session behavioral treatment with disaster victims in Turkey. This study appears in some of the comparisons of exposure versus inactive*

controls for a few outcomes of interest – reduction in PTSD symptoms, preventing or reducing depression. In all cases, it was one of 8 studies (all the rest were based on PE), and like the PE studies it had a favorable outcome. If you look at the tables in Appendix F, starting on pages F-12 and F-13, you will see that the effects of intervention essentially remain the same even if this study is removed from consideration.

- *Gamito et al. 2010 – this was a study of only 10 individuals comparing virtual reality with imaginal exposure and a waitlist control among male combat victims in Portugal. I did not see it anywhere in any of the SR tables. It is a comparative study with too few participants to make any valid comparison.*

- *Bryant et al. 2003 – This is a "comparative" study that examined (prolonged) imaginal exposure versus cognitive restructuring. Conducted in Australia. It is likely a PE study as well. However, it was only included in the SR as a comparative study – for which there was too little evidence to draw any conclusions. See highlighted tables in Appendix F.*
- *Schnurr et al. 2003 – Like the above study, this was a "comparative" study of two types of group therapy, one involving an exposure in mixed trauma individuals. This was only included in the SR as a comparative study – for which there was too little evidence to draw any conclusions. See highlighted tables in Appendix F*
- *Tarrier et al. 1999 -- Finally, this was also a "comparative" study of imaginal exposure versus cognitive therapy for which there was too little evidence to draw any conclusions. See highlighted tables in Appendix F.*

In addition to the above, the SR also includes some evaluations that were based exclusively on PE studies. For example, only 5 trials looked at loss of PTSD diagnosis, and all of them were PE studies. All found support for a loss of diagnosis. See Appendix F.

Since we do not make strong recommendations about the comparative effectiveness of exposure relative to other active treatments (e.g., EMDR), it is less problematic that the few comparative studies in the SR included ones with exposure (but not specifically PE).

Therefore, the panel agrees, that it is appropriate to describe the intervention as Prolonged Exposure (and not simply exposure) and has made that change throughout the document.

Topiramate

Commenter: Charles W. Hoge, MD; Charles.w.hoge.civ@mail.mil

Comment:

Most importantly the suggestion to use topiramate should be deleted. EMDR (and probably also brief eclectic psychotherapy and NET) should be included in the "strong for" recommendation category for psychotherapy, rather that separated from CBT, CPT, cognitive and exposure therapies. The comparative effectiveness recommendation should be broadened to include all trauma-focused therapies, rather than highlighting only exposure and exposure plus cognitive restructuring.

Panel Response: *The panel did revisit its decision table on topiramate. It determined that in actuality, no recommendation could be made about topiramate. Please see the revised decision table in the appendices for documentation of its review. The guideline has been changed accordingly.*

Prazosin

Commenter: David Osser MD; david.osser@va.gov

Comment: Page 79. I think your group has missed the boat regarding psychopharm treatment where you omitted discussion of prazosin. Here's what you said:

Although some guidelines have recommended prazosin for nightmares, the panel did not make any recommendations for prazosin because the panel did not include nightmares as a critical or important outcome.

Wow. You couldn't be more wrong. Nightmares and disturbed awakenings without nightmare recollection are a horrible problem suffered by the vast majority of PTSD patients that I see in the VA and also from what I hear from clinicians in other practice settings. Also research indicates that the sleep abnormalities in PTSD may be the primary sign or symptom of this disorder. Prazosin is described by my patients as the "penicillin for ptsd". I didn't make that up. I have treated hundreds of veterans with it. The results can be amazing, and far better than you see with SSRIs. Also, it works for daytime symptoms as well especially after the sleep deprivation associated with the nightmares improves. The 4th placebo controlled study was in 2013 so it didn't make the initial cut in this review (and you do not even mention it in your review of newer developments to 2016), but was the largest of the 4 small RCTs, also gave the medication during the day in the AM, as well as at night. But ALL the studies showed reduction of general PTSD symptoms, not just nightmares, with effect sizes around 1.0 - far better than you get with SSRIs in their studies, where the effect sizes range from 0.1 to 0.4. Yes the prazosin studies were very small studies and all from one site. But...it works. Also, there is a new placebo controlled small trial of doxazosin showing efficacy. You've missed the opportunity to help a lot of PTSD sufferers. What a waste.

Commenter: Loretta Malta; lsmaltaphd@gmail.com

I am also unclear why evidence for Prazosin, which has shown efficacy for nightmares & other PTSD symptoms was not even mentioned.

Panel Response: *Many outcomes are important considerations in determining what interventions to utilize in the treatment of PTSD. As part of the guideline development process, the panel considered numerous outcomes relevant but in the process of reviewing the evidence, as part of the process for developing recommendations, the panel identified two critical outcomes (PTSD symptom reduction and serious adverse events) on which to evaluate all studies. Specific reduction of nightmares was not one of the identified outcomes and studies were not identified for review on the basis of that outcome.*

EFT/ Energy Psychology

Many individuals commented on the lack of a recommendation for EFT and energy psychology. Most comments were a variation on one comment and one individual did include the following instructions with his/her comment:
Then use the indented italicized text as a basis for your own words and sentiment. Or write something completely original. It will be far less effective if everyone copies these words exactly. Make your comment unique. Use only part of what is written below. Add some of your own language. At a minimum, swap out a few words or sentences.

Commenter: Several commenters "filled in the blanks" and submitted this comment.

Comment: As a coach who has worked _8__ years with patients with PTSD, I was deeply disturbed to discover that APA's Div 56 guidelines on treating PTSD focused almost exclusively on medications and CBT but did not include anything on energy psychology approaches (such as Emotional Freedom Techniques and/or Thought Field Therapy). I have used these exposure-based somatic psychotherapies for the last _8___ years with tremendous success and minimal adverse effects.

There have been over 8 RCTs on EFT or TFT and PTSD in the last 5 years. It is absurd that these were not included in the review. TFT has been evaluated by the National Registry of Evidence-based Practices and Procedures (NREPP) as having demonstrated "effective outcomes" in trauma treatment. EFT is currently under review by NREPP and has even stronger evidence.

This Guideline appears to be heavily biased toward CBT. Why is the American Psychological Association even focusing on medication at all? I do not understand how the Guideline can make reference to two approaches that are not well known (NET and SS) and not include EFT or TFT, that have been used by thousands of therapists on thousands of patients.

Perhaps the panel erroneously considered EFT and TFT as "complementary and alternative approaches". This would not be correct. EFT and TFT are exposure-based psychotherapies that combine exposure and cognitive restructuring with somatic stimulation. Both are very similar in process and structure to EMDR, which was included for review in these guidelines. These approaches appear to work better, with fewer treatment and with less adverse reactions, than many CBT approaches such as prolonged exposure and medication.

Please review the EFT and TFT literature, and based on that review, recommend them as effective treatments for PTSD.

We believe Dr. Schwarz organized individuals to respond to the call for comments. In addition, on behalf of the Association for Comprehensive Energy Psychology, Dr. Schwarz submitted a comment.

Commenter: Robert Schwarz, PsyD; acep_ed@energypsych.org

The following is our entire response not geared to the specific questions on this form:

Thank you for the opportunity to review the draft of the "Clinical Practice Guideline for the Treatment of Posttraumatic Stress Disorder (PTSD) in Adults." We at the Association for Comprehensive Energy Psychology have several significant concerns.

In the RTI-UNC review, the section entitled "Treatment Strategies for PTSD" states: "The following psychological treatments were included: brief eclectic psychotherapy; CBT, such as CPT, CT, CR,

exposure-based therapies, and coping skills therapies; EMDR; hypnosis or hypnotherapy; interpersonal therapy; and psychodynamic therapy." The section does not explain how these treatments were included, nor how other therapies were excluded.

The review further states: "We manually searched reference lists of pertinent reviews, included trials, and background articles on this topic to look for any relevant citations that our searches might have missed…"

Among the "relevant citations" that your searches "might have missed" are acupressure assisted exposure therapies such as Emotional Freedom Techniques (EFT) and Thought Field Therapy (TFT) that are part of the family of approaches collectively known as Energy Psychology (EP). EP methods have been demonstrated, in both research and clinical practice, to be effective evidence-based approaches with few adverse reactions and high applicability.

We are deeply concerned that the panel has not included the significant literature on EFT and TFT. It is our position that this lack of inclusion appears to be due to a significant error in understanding and/or to various processes that have led to selection bias. We ask that these studies be included in the research and in the Guideline. Our argument follows:

The original literature review did not reference 3 citations in the literature as of 2012: two studies on TFT, one review in a major APA journal, the review of general psychology. That said, this review is already four years old. As this guideline is likely to shape the field of trauma treatment for the next 5 to 10 years, it is important that it be based on the latest data, and not on a review that is both incomplete and already out of date.

The CPG does state that an additional review of the literature was done from May 2012 to June of 2016. But it stated that the panel concluded that none of the recommendations were likely to change.

The latest and more rigorous research on acupressure assisted exposure therapies has been published in the last four years. A recent (Nov 2016) literature search of PubMed, PsycInfo, and the Cochrane Library for 'PTSD' and 'Post Traumatic Stress Disorder' retrieved 11 references for EFT treatment for PTSD, and 6 references for TFT treatment for PTSD. In this group of 17 references there are 8 randomized control trials on these approaches in the treatment of trauma or PTSD. Furthermore, a recent meta-analysis of RCTs investigating EFT treatment of PTSD found a strong aggregate effect size and is scheduled for publication inJanuary, 2017 : http://www.explorejournal.com/article/S1550-8307(16)30160-4/abstract

In addition, TFT has been evaluated by the National Repertory of Evidence-based Practices and Procedures (NREPP) as having demonstrated "effective outcomes" in trauma treatment (among other conditions). This finding has been available since February of 2016. EFT has been under review by NREPP for the last two years and a finding is expected soon.

So the question remains; why did the panel not review the substantial amount of research on EFT and TFT? There is far more research on these methods than there is for Narrative Exposure Therapy or Seeking Safety, and the panel did include these methods. In reviewing the CPG closely we have found 2 potential issues that may account for why the significant results of 12 clinical trials have not been included in the review of the research or the CPG.

1) Perhaps the panel erroneously considered EFT and TFT as "complementary and alternative

approaches". If so, this assumption must be corrected. EFT and TFT are exposure-based psychotherapies that combine exposure and cognitive restructuring with somatic stimulation. EFT and TFT are very similar in process and structure to EMDR, which was included for review in these guidelines. The main difference between these approaches is that EMDR uses bilateral stimulation whereas EFT and TFT utilize somatic stimulation of acupressure points.

2) On page 16, lines 11 and 12 of the guideline, it states: "Studies that did not require a formal diagnosis of PTSD for participant inclusion were not included in the RTI-UNC Systematic Review." Perhaps the EFT and TFT trials were not included because of this requirement.

This requirement eliminates the overwhelming majority of research studies on PTSD! It skews your evidence base via inclusion of the small minority of studies that fulfill this requirement. Whether or not it was the panel's intent, the effect was that virtually all of the studies on energy psychology approaches with PTSD were excluded. In other words, an entire class of treatments that show highly significant results were wholly eliminated from consideration as if they do not exist. This is bias by definition

The EFT and TFT trials did include well-recognized and validated assessments such as the CAPS, PCL-M, Trauma Symptom Inventory (TSI), Hospital Anxiety & Depression Scale, the Modified Post Traumatic Stress Disorder Scale (MPSS), and the Symptom Assessment-45. It can be argued that validated questionnaire measures of PTSD symptoms are more reliable that a psychiatrist's diagnosis. It should be pointed out that the NIH ceased using DSM diagnoses three years ago

We certainly understand the need for scientific rigor and the validation of evidence based treatments. We believe that while diagnoses may be important (to researchers, physicians and psychologists!), patient-centered assessment of symptom reductions are what is most important to our patients. The effect of an exclusive allegiance to methods that can 'prove' PTSD diagnosis and meet very stringent methodological criteria while ignoring research studies that do not, will result in discouraging clinical innovation and prevent many who are suffering from receiving effective assistance.

Finally, the guidelines state that the panel considered four factors as it drafted recommendations: 1) overall strength of the evidence; 2) the balance of benefits vs. harms/burdens; 3) patient values and preferences; and 4) applicability. ?

EFT and TFT excel on all of these factors. In addition to the 11 clinical trials published prior to June 2016, numerous reports document EFT's and TFT's applicability and effectiveness following real-world calamities such as in Rwanda, Kosovo, Haiti, Iraq, and New Orleans. EFT and TFT have excellent benefit-to-harm ratios. They are far gentler than approaches such as prolonged exposure, which have significant drop out rates largely due to the discomfort that patients feel.

With regard to patient values: the Guideline's recommendations focus almost exclusively on cognitive approaches while excluding somatic approaches. This does not respect the values of patients who do not respond well to cognitive–only approaches. Again this shows a strong bias towards one form of treatment and actually disregards the latest findings in neuroscience and trauma-informed care that point to the importance of body-oriented approaches.

The CPG mentions four factors in drafting its recommendations, the last one being 'applicability.' Appendix B of the CPG lists dose ranges for different therapies, including 1-30 for exposure, 4-16 for CBT, 12-17 for CPT, and 16 for Brief Eclectic with session durations of 60-120 minutes. Both research and

clinical experience with EFT and TFT have shown significant reductions in PTSD symptoms in 4-6 sessions, with a session duration of 60 minutes or less.

We respectfully submit that the guidelines are deficient in not reviewing the significant amount of research on EFT and TFT, all of which have documented evidence for efficacy with PTSD, with medium to large effect sizes. It is our opinion that, based on a review of the literature, these approaches are at the very least equivalent in effectiveness to EMDR.

More importantly, the current guidelines do not mention these approaches at all, as if they do not even exist. This amounts to a significant degree of bias favoring cognitive approaches and completely disregarding somatic approaches. The effect of such exclusion will be to dissuade research and dissemination of clinically effective tools that have been documented to help thousands of people.

We request that that the panel review the available literature on EFT and TFT and adopt guidelines informed by that review.

In addition to adding EFT and TFT to the list of recommended treatments, we believe that the CPG, as written, creates a significant barrier to innovation by not even mentioning the possibility of promising and innovative approaches to treating trauma. Borrowing from the field of economics, it appears that the CPG is focusing on “trailing indicators” rather than on “leading indicators”. PTSD treatment has hardly reached an optimal level of effectiveness as measured by success rates, speed and ease of delivery.

We recommend that the CPG include a new section on "Emerging Interventions for the Treatment of PTSD" that describes treatments with promising research that may not yet meet the methodological standards set by the panel.

We appreciate that the panel is seeking to make its process transparent and to provide opportunities to correct deficiencies or errors. We thank you for your consideration. A thoughtful response to our concerns will be appreciated.

Commenter: Robert Pasahow; affiliates600@aol.com

Comment: You are not considering energy psychology which is an exposure therapy very similar to EMDR in structure. The only difference is that energy psychology uses acupressure stimulation be tapping and EMDR uses eye movements.

I am an APA member Martin Seligman was my supervising research professor in my undergraduate school.> I have published in APA journals.

Commenter: Kristin Miller; krijohnmill@gmail.com

Comment: Thought Field Therapy is now evidenced based treatment Post Traumatic Stress and is much less invasive and difficult for the client to engage in with the same or better results as EMDR. Exposure Therapy as shown to traumatize individuals and Cognitive Behavioral Treatment does not help with emotional regulation issues and desensitization from the trauma.

Commenter: Suzanne M. Connolly; smc@suzanneconnolly.com

Comment: I am shocked by the absence of any inclusion of the research on Thought Field Therapy(TFT). How was this overlooked? I have. Been using this technique for 20 years with PTSD and getting

consistently good results, as good, and even slightly better than the results I get using EMDR. I used EMDR for several years after training with Francine Shapiro, and was quite surprised that TFT worked equally as well in even a shorter period of time. There are several good research articles on using TFT with PTSD. I was PI on two RCT's using TFT in Rwanda with victims of genocide. Both were published in peer reviewed journals. A cardiologist from the UK and his team adjusted the. RCT slightly using different test instruments but acheived equally good results in Uganda. In Rwanda the International Red Cross has TFT tents where during the genocide memoraials they bring traumatized participants to receive TFT treatments from the Rwandan TFT facilitators. What gives that TFT is not getting used more in the U.S. ?

Commenter: Lorna Minewiser, PhD; lornaminewiser@gmail.com

Comment 1: In Energy Psychology there have been 47 randomized controlled trials as of 2016, with 3 meta-analysis showing strong support for Energy Psychology. An additional meta-analysis of studies of EFT for PTSD was published October 24, 2016 showed a weighted Cohen's-D of 2.96. Included in the meta-analysis are studies that compared EFT to CBT and to EMDR.

In 2016 TFT was validated by NREPP as an evidenced based treatment and EFT is currently under review by NREPP and NICE.

Comment 2: The review of research from 2012 to 2016 should have included alternative therapies, especially Energy Psychology Techniques such as Emotional Freedom Technique (EFT) and Thought Field Therapy (TFT), as there has been additional research published since 2013.

Commenter: David Feinstein, Ph.D.; df777@earthlink.net

Comment: This otherwise superb document fails to mention one of the most promising treatments for PTSD. Protocols that combine cognitive restructuring and exposure treatments with tapping on acupuncture points look strange, but they are effective. Disaster response teams are using them increasingly, with strong anecdotal support having come from New Orleans, Sandy Hook, Haiti, Kosovo, and Rwanda, among other areas where natural or human-made disasters have affected entire communities. Delivered in various formats -- with Emotional Freedom Techniques (EFT) and Thought Field Therapy (TFT) being the most well-known -- a recent meta-analysis of 7 clinical trials treating PTSD with EFT protocols found strong effect sizes. http://www.explorejournal.com/article/S1550-8307(16)30160-4/abstract

Not including these approaches (collectively know as "Energy Psychology") is a serious omission from the Guidelines.

Panel Response:

The search terms "PTSD," "post-traumatic stress disorder," "psychotherapy" and "randomized clinical trial" were used to search multiple databases to identify relevant research. All identified studies were then evaluated for inclusion or exclusion in the systematic review following best practices.

As noted in Table 3, p 11 of the systematic review that served as the evidence base for this report, randomized trials of the following psychological treatments were eligible for inclusion in the systematic review:

- *Brief eclectic psychotherapy*
- *Cognitive-behavioral therapy*

• *Cognitive restructuring*

• *Cognitive processing therapy*

• *Exposure-based therapies*

• *Coping skills therapy*

• *Stress inoculation training*

•*Relaxation*

• *Eye movement desensitization and reprocessing*

• *Hypnosis or hypnotherapy*

• *Interpersonal therapy*

• *Psychodynamic therapy*

The decision regarding what treatments to include was made by the RTI-UNC systematic review team with input from both "key informants" and "technical experts." Other psychotherapies and alternative and complementary treatments were not included in the search. EFT/ TFT/ Energy psychology was not identified as a psychotherapy to be included in the systematic review.

One randomized trial that included EFT as a comparator to EMDR was identified but was excluded from analysis due to high risk of bias ratings.

Because the panel did not review the evidence, the panel cannot render any recommendation about these interventions. Any future iterations of this guideline will rely on new systematic reviews which may include evaluation of the evidence base for energy psychology.

Other interventions

EEG Biofeedback

Commenter: Kirtley Thornton, PhD; ket@chp-neurotherapy.com

Comment: The draft had no mention of the use of EEG biofeedback for PTSD, yet there is sufficient literature to justify discussing this approach.

see below, but there are many more that should be reviewed

Peniston has done a number of research studies on this problem

Anxiety Associated With Post Traumatic Stress

Disorder—The Role of Quantitative Electroencephalograph

in Diagnosis and in Guiding

Neurofeedback Training to Remediate the Anxiety

Jonathan E. Walker, MD

Biofeedback

Volume 37, Issue 2, pp. 67–70

Commenter: Edward Hunter; ehunter@kumc.edu

Comment: This form is way too much trouble for a busy clinician to take the time to fill out. Here's my rant which the group can decide which sections it goes into:

This is an excellent example of how a document can be produced that overlooks real world clinical practice, and obfuscates terms through concrete thinking. For example, the document says that there is no evidence for the use of relaxation in PTSD, whereas relaxation is a module of PE therapy (which it says works!). Furthermore, what is called “brief eclectic therapy” (which supposedly has little evidence of working) involves imaginal exposure and reprocessing trauma, which is the same general idea as CPT and to some extent PE (which they say works!) Further, what they call “narrative exposure therapy” (which supposedly has little evidence) is what is generally done in CPT (but one supposedly one works and the other doesn’t!). It’s the idea that there are pure forms of these treatments which are lockstep. We have little idea of why these treatments really work- maybe there are some underlying principles, but those are what need to be considered- not names of treatments.

Commenter: Nickolas Frost; ndfrost@wisc.edu

Comment: As others have mentioned, the scope of the evidence reviewed is significantly limited. Present Centered Therapy - a non-exposure based treatment for PTSD is not reviewed despite having strong empirical evidence for its efficacy (Frost, Laska & Wampold, 2014). It is unclear as to why this particular treatment is all together omitted from the document since it is listed as an evidence-based treatment by Division 12 of the American Psychological Association.

Commenter: Vivian Dent; drvivdent@att.ent

Comment:

No, I find these recommendations appalling. When someone like Bessel van der Kolk has written a book as comprehensive and important as The Body Keeps the Score (not to mention the many great works that preceded it), it's absurd for the APA to cautiously recommend or completely ignore all of the treatment modalities he advocates--not to mention giving a strong recommendation for exposure therapy, whose long-term effects are not looking good. No mention of somatic approaches. No mention of approaches (like IFS) that target dissociation. No neurofeedback, or mention of it. No mention of any of the group approaches he's found helpful No one prominent on the panel to represent any of these approaches. Ridiculous.

Commenter: Elaine Ducharme; elaine.ducharme@yahoo.com

Comment: comments re relaxation and seeking safety.....

So many trauma patients need to figure out how to deal with their own over activated nervous systems. I really think this was not addressed properly. Not relaxation alone. But the client's ability to self soothe and stay safe before any treatment begins needs to be assessed and dealt with. I see this as a serious flaw in this work. It is much clearer in other guidelines, such as those developed by the Australian Centre for Post traumatic Mental Health.

Commenter: Nathan D. Tomcik; nathan.tomcik@va.gov

Comment: Considering that many states are proclaiming cannabis to be a treatment for PTSD, I think it would be extremely useful to include a critical review regarding cannabis as a treatment for PTSD, with a recommendation that it is not currently a treatment for PTSD and more research is needed in this area.

Multimodal interventions

Commenter: Jerry Wesch; jerrywesch@yahoo.com

Comment: I an a senior Clinical Psychologist. I dealt with military PTSD from 1970-74 (USAF Active Duty) and from 2007-2015 (DOD Civ at Fort Hood, TX, directing the PTSD Program). I have strong opinions about military PTSD treatment. We developed a comprehensive program that took 12 soldiers every 3 weeks in a day treatment program with 6 weeks of outpatient individualized follow-up.

The protocol included aggressive behavioral health treatments (individual and group) and a variety of CAM modalities (Acupuncture, Massage, Reflexology, Reiki, Yoga and Meditation), in a structured, phased integrative protocol. We also used EFT and EMDR. Our outcomes were excellent with all measures significant (p<.001) The results were published. "PTSD Integrative Treatment, Energy Psychology 7:2, Nov 2015, 33-44."

No mention of such multi-modal integrated programs is offered.

Panel Response:

The article by Frost, Laska and Wampold was not included in the systematic review for two reasons. First, the studies included in the systematic review were published after May 24, 2012, the date of the final search. Second, the Frost, Laska and Wampold article is a meta-analysis; the systematic review included only randomized trials, not meta-analyses.

Many interventions are being used to treat PTSD; many clinicians use "parts" of interventions in their approach to treatment. This guideline was focused on identifying the efficacy of treatments, specifically for an identified set of psychological treatments (based on expert consultation at the start of the search for articles to include in the review) and pharmacological treatments. Other interventions were not included in the systematic review. It is beyond the scope of the panel to independently conduct a review regarding cannabis, EEG or other treatments for PTSD. Future iterations of this guideline may include a larger range of interventions or may include a discussion regarding how to sequence treatment strategies in the treatment of individuals with PTSD.

The panel limited its focus and scope to psychological and pharmacological treatments for PTSD. To that end, it utilized an independent systematic review conducted by RTI-UNC that addressed the following key questions: KQ 1: What is the comparative effectiveness of different psychological treatments for adults diagnosed with PTSD? KQ 2: What is the comparative effectiveness of different pharmacological treatments for adults diagnosed with PTSD? KQ 3: What is the comparative effectiveness of different psychological treatments versus pharmacological treatments for adults diagnosed with PTSD? KQ 4: How do combinations of psychological treatments and pharmacological treatments (e.g., CBT plus paroxetine) compare with either one alone (i.e., one psychological or one pharmacological treatment)? KQ 5: Are any of the treatment approaches for PTSD more effective than other approaches for victims of particular types of trauma? KQ 6: What adverse effects are associated with treatments for adults diagnosed with PTSD?

Panel members appreciate the innovative work occurring in the field and encourage careful assessment and evaluation of treatments. As previously noted, in many areas of health care, assumed efficacious

interventions have not always been demonstrated to "work" when properly evaluated but at the same time emerging treatments continue to arise and proper evaluation of these is necessary. Without strong research, though, the panel is unable to render recommendations.

Commenter: Greg Garavanian; GGaravanian@hotmail.com

Comment: No It is 2016 and these recommendations are not current and do not reflect what we have learned about trauma since the invention of the MRI. The important work of researchers and practitioners such as Bessel van der Kolk, Peter Levine, Pat Ogden, and Stephen Porges have not been considered/represented. Exposure therapy and Cognitive Therapy? I can't help but think that politics has had a hand in these recommendations. I am disappointed in the APA.

Panel Response:

The panel limited its focus and scope to psychological and pharmacological treatments for PTSD. To that end, it utilized an independent systematic review conducted by RTI-UNC that was completed in 2012 to draft its recommendations. An updated literatures search was performed specific to the treatments recommended on the basis of the 2012 literature to determine whether any subsequently published research might alter the panel's recommendations. The panel did not conduct a full updated search of all relevant literature and recognizes that some emerging interventions may not be included in its recommendations. Additionally, the panel notes that there are important gaps in the literature and hopes the research base continues to evolve so as to improve knowledge and ultimately care for individuals with PTSD. To form the panel, the call for nominations was distributed widely and individuals who were not strongly identified with any one particular treatment approach were selected in order to reduce potential or actual intellectual conflicts of interest. Many researchers and clinicians have made important contributions to the literature and panel members are familiar with, and referenced the work of many during the drafting of the document.

Somatic Psychotherapy

Jennifer C. Franklin, PhD drfranklin@opendoortherapy.com

I have not had the time to read through this entire document, but reading through it and skimming through some, it appears to omit even the mere mention of such somatic psychotherapeutic methods as Somatic Experiencing. Somatic Experiencing along with other somatic psychotherapeutic methods are methods that are challenging if not impossible to study using purely quantitative methods because they are so tailored to each individual's specific experience of PTSD and the nature of the specific traumatic events that led to the PTSD symptoms. It should be stated in the limitations of this important and highly influential report that many practitioners across the world treat PTSD using methods that were unable to be included in your study because qualitative research methods were not utilized or because there are no studies that met the criteria for inclusion in your report.

Group Psychology

Commenter: Dr. Suzanne B. Phillips; suephil@optonline.net

Comment: No Whether you are a clinician who has witnessed the impact of group intervention after a terrorist attack like 9/11 or a natural disaster like Hurricane Sandy, a psychologist who has researched the impact of a trauma focused groups vs. present centered groups in a VA setting, or a female patient suffering from metastatic breast cancer with clinically significant anxiety, depression and traumatic stress symptoms who has found relief from Supportive-Expressive Group Therapy (Clinical Intervention

Trial, Arch Gen Psychiatry. 2001;58(5):494-501.), it is inconceivable to imagine that the American Psychological Association would completely eliminate group intervention (psychodynamic, CBT, Trauma Focused, Supportive, Present Centered, Stress Management etc.) as an effective modality to mediate PTSD.
As a psychologist, member of APA for over thirty years and Certified Group Therapist with an ABPP in Group Psychology, I have spent years offering training and services in the aftermath of traumatic events (terrorism, shootings, murders, rape) and natural disasters. We know that trauma assaults and creates fear, helplessness, loss, isolation and shame. It leaves us without words or a sense of emotional or physical safety. The use of a group as a modality (with many effective protocols) offers a network of connection, reduces isolation, normalizes stress responses, reduces stigma, allows for a return of agency, allows for the narrating of loss and trauma, etc. The very nature of this modality serves as a container that fosters regulation of traumatic impact and grief.
A Google Scholar search lists 24,200 sources when searching the question of investigating effectiveness of Group Interventions for PTSD. The failure to consider any of these underscores the gap in scope and dismissal of results that reflect the effective use of different types of Group Treatment in addressing PTSD.

Commenter: Les R. Greene, PhD; lesrgreen@peoplepc.com

Comment: We, the co-chairs of the Science to Service Task Force of the American Group Psychotherapy Association, appreciate the opportunity to offer our thoughts and reactions to the APA draft guidelines for ptsd treatment. The primary impetus for our comment is our critique that the guidelines fail to sufficiently delineate differential and unique effects of different treatment modalities, such as individual versus group therapies. Regarding group psychotherapy for ptsd, there is clearly a growing data base derived from the RCT investigations. In a recent meta-analytic review of these studies [Sloan, D., Feinstein, B., Gallagher, M. Beck, J., & Keane, T (2013) Efficacy of group treatment for posttraumatic stress disorder symptoms: A Meta-analysis. Psychological Trauma, 5, 176 183], the authors conclude that "group treatments are associated with significant pre- to posttreatment reduction in PTSD symptom severity." They further conclude that superiority of group treatment is clearly established relative to waitlist or treatment-as-usual conditions. While they also assert that no superiority is seen in comparison to other active treatment conditions, this conclusion, when stated differently, means that group treatments are essentially equivalent to other active treatment conditions in terms of showing positive effects. When coupled with the obvious fact that group treatments are more cost effective, the superiority of group interventions can be asserted. A number of additional RCT studies have appeared in the literature since this meta-analysis that further substantiate the effectiveness of group treatments for ptsd:

Castillo, D. T., Chee, C. L., Nason, E., Keller, J., C'de Baca, J., Qualls, C., Fallon, S. K., Haaland, K. Y., Miller, M. W., & Keane, T. M. (2016) Group-delivered cognitive/exposure therapy for PTSD in women veterans: A randomized controlled trial. Psychological Trauma: Theory, Research, Practice, and Policy, 8, 404-412.

Resick, P. A., Wachen, J., Mintz, J., Young-McCaughan, S., Roache, J.D., Borah, A. M., Borah, E. V., Dondanville, K. A., Hembree, E. A., Litz, B. T., & Peterson, A. L. (2015) A randomized clinical trial of group cognitive processing therapy compared with group present-centered therapy for PTSD among active duty military personnel. Journal of Consulting and Clinical Psychology, 83, 1058-1068.

Ford, J. D., Chang, R., Levine, J., & Zhang, W. (2013) Randomized clinical trial comparing affect regulation and supportive group therapies for victimization-related PTSD with incarcerated women. Behavior

Therapy, 44, 262-276.

Beyond this amassing data base about the effectiveness of group therapies for ptsd, clinical expertise, as reflected in the abundance of material on the group treatment of ptsd that is readily available at the website of the American Group Psychotherapy Association, convincingly underscores the therapeutic power of groups and thus corroborates the mounting empirical evidence. For example, the highly acclaimed Group Interventions for Treatment of Psychological Trauma published by the American Group Psychotherapy Association, a series of clinical reports developed from the extensive clinical experience of expert group psychotherapists dealing with victims of natural and manmade disasters, attests to the effectiveness of group approaches for dealing with trauma and ptsd, effectiveness stemming not only from specific technical interventions but from the unique power of groups to evoke ameliorative feelings of cohesion and universality. We would hope that ideas accrued from the clinical wisdom and insights reflected in these materials would be better represented in the guidelines you are proposing.

As clinicians and researchers who are dedicated to the integration of science and practice, our primary concern with the document as it currently reads is the imbalance in inputs from these two domains and sources of knowledge. While we certainly applaud the effort to explicate what we currently know about the psychotherapeutic treatment of ptsd, we find the overvaluing of RCT findings and the relative neglect of clinical expertise unnecessarily shortsighted, an imbalance that seems limiting in terms of clarifying our understanding of the complex questions of what works, for whom, under what conditions and how. The listing of brand name therapies derived primarily, if not exclusively, from RCT data fails to shed any meaningful light on what the active ingredients are that actually make a difference, a well-known limitation of RCT methodology. Thus, for example, stating authoritatively that CPT works fails to recognize the significant attrition rates that plague most of these RCT studies, fails to explore or understand what optimizes treatment for any particular patient, and fails to understand the mediating factors that underlie therapeutic change. The gaps in the research listed on pages 91-96 of the current draft underscores how much more we don't know, based strictly on research, in comparison to what we think we know, suggesting what perhaps is a prematurity and narrowness of this document. Relatedly, the document fails to substantially take into account an earlier APA statement that incorporates clinical expertise as a basis for making judgments about what works; to state it more directly, this set of draft guidelines seems to unnecessarily minimize input via clinical expertise, as reflected in a reference list that is composed almost entirely of research studies.

We hope you find our feedback helpful in your subsequent revisions of this important document. Please feel free to call upon us, if you think we can be of further help, particular in the area of group therapeutic approaches to the treatment of ptsd.

Philip Flores, PhD, ABPP, CGP, LFAGPA
Les R. Greene, PhD, CGP, LFAGPA
Rebecca MacNair-Semands, PhD, CGP, FAGPA
Co-Chairs
Science to Service Task Force
American Group Psychotherapy Association

Commenter: Janice Morris; drjanmorris@swbell.net

Comment: No APA has neglected to include in these guidelines any reference to group treatment. The American Group Psychotherapy Association, whose membership overlaps significantly with APA, has

well-documented, well-researched methods and guidelines for working with PTSD in group settings. To omit reference to the wealth of experience and information available to clinicians and the public about the efficacy of group treatment is a glaring oversight. In addition, there is no reference to psychodynamic approaches, which are well-documented to be effective in the treatment of PTSD.

Panel Response:

As previously noted, a variety of psychotherapeutic interventions were identified for evaluation in the systematic review. Group psychology was not identified as a distinct intervention but was understood to be a modality of care. The review team did not provide analyses of the efficacy of interventions delivered in individual or group format.

Treatment other than Individuals/ Target of Treatment

Commenter: Dr. Suzanne B. Phillips; suephil@optonline.net

The guidelines are also a concern in terms of the limitation of only addressing individual patients with a Diagnosis of PTSD. We live in a world that has been punctuated by terrorism, violence, school shootings, political and racial unrest. Why would APA at this time, limit its consideration of guidelines to address PTSD to one possibility - the single practitioner with the diagnosed client? Group programs that have been utilized by the American Group Psychotherapy Association across the time line of trauma from acute stage to Anniversary Events offer options in the wake of terrorist attacks, natural disasters, and violence. Such programs can make possible the availability of Group Psychological First Aid, Large Group Psycho-education, Family Programs etc. that in the aftermath of traumatic events mediate the impact and degree of PTSD and provide a stepping point for higher levels of treatment and care. Why are such programs not being considered? Why are they not part of the scope of interventions that impact the treatment of PTSD?
A recent article published in American Psychologist (Blanco A., Blanco, R., & Diaz, D, 2016, Vol.71, No.3, 187-198.) is entitled " Social (Dis) Order and Psychosocial Trauma: Look Earlier, Look Outside and Look Beyond the Persons." It's consideration of intentional collective violence shouts out to us that our treatment of trauma must extend beyond the office and single patient. With reference to human rights violations, peritraumatic factors as life threat rooted in political or social belonging as suffered by millions of people in Latin America and elsewhere, the authors suggest that the main targets of therapeutic intervention must be " to help victims restore the network of social and emotional ties destroyed by collective violence."
" There was a general agreement that the group and community setting is the best place for achieving these goals."

Panel Response:

The commenter describes important issues confronting society and in so doing, raises an important question regarding the nature of these guidelines. The intent and scope of these guidelines is identifying which treatments are efficacious for treating the health condition of PTSD. Preventing the onset of PTSD, promoting the resilience of communities that experience trauma and other adverse events, supporting families that have experienced disaster are all worthwhile activities but beyond the scope of these guidelines.

Whole body/ Neuroscience

Commenter: Sarah M Thome, LSCSW, LLC; sarah.m.thome@gmail.com

Comment: No I feel it would be helpful to discuss the whole person impact that trauma has on an individual. Mentally, emotionally, and physically. There is room for all types of therapy to promote healing, but the body-centered therapies such as EMDR, Somatic Experiencing, etc. also address the trauma locked into the nervous system and how that impacts the body. They are biologically based, not just psychologically based, such as CBT.

Commenter: Jennifer Turner; yoginijenn@mac.com

Comment: No It appears to be a very limited approach to treatment of trauma, that heavily favors CBT oriented approach, which may be effective for single incident trauma's, but are quite ineffective in a constellation of traumatic experiences. I am curious to know why this would cognitive approaches would be so heavily favored given all that we currently know from recent neuroscience findings in how trauma impacts the brain and body.

Commenter: Janina Fisher; DrJJFisher@aol.com

Comment: These guidelines should reflect not only efficacy research but also the neuroscience research of the last 20 years that establishes the biological basis for PTSD, demonstrates that de-sensitization to narrative memory is different from resolution of implicit trauma-related memories, and addresses changes at a brain and body level.

Commenter: Jane Statlander-Slote; drbjanes@gmail.com

Comment: Generally, it's clear that the APA has lost its intellectual mind. It must no longer understand how important neuroscience is to the understanding of the brain and trauma. The brain is not just "mentality". It is not just logic and reason. It works much more complexly. The brain doesn't just respond to "cognitive" directives as in CBT. The problem of trauma and PTSD is images, feelings, sounds, etc.

It's beyond me how the APA can say thing.

Panel Response: *Panel members share commenters enthusiasm for developments in various areas such as neuroscience that have provided new insights into the basis and development of PTSD. However, the intent of this guideline is to review the evidence and recommend treatments that are efficacious for PTSD and not to review a wide range of other topics.*

Brand name psychotherapy/ process factors

Commenter: Roger Brooke, PhD, ABPP; brooke@duq.edu

Comment: No I do not have time for a literature review of evidence supporting the following comments, but I trust my readers are aware of it, or easily can find it. Brand name for effective treatments is a poor predictor of the processes in effective treatment. Experienced psychotherapists of different traditions might practice in ways more similar to each other than experienced and novice practitioners in the same tradition. There is a lot of overlap in the process factors found in effective CBT and psychodynamic psychotherapies, for instance. I do recall a study in Psychotherapy Research by Ablon and Jones (1998), which found that the CBT therapists who were effective were those whose treatments also met a significant number of psychodynamic descriptors of treatment, and that those CBT treatments what

stuck more closely to the manual were not effective. Wampold and others have reported a growing body of evidence that adherence to a manual is negatively correlated with outcome. (Would you choose for yourself a therapist who had a reputation for sticking strictly to a manual?) Much better to say what process factors seem to be effective.

Commenter: Cynthia Eckert-McCoy; cyndy@threerivers.kscoxmail.com

Comment: As a Licensed Specialist Clinical Social Worker in Kansas, I have never been attracted to CBT treatment. After 30 years of formal training and practice with Bowen Theory and 15 years of formal training and practice with EMDR Therapy, I make the following comments. 1. Research has shown that any approach can be useful if the clinician has a solid therapeutic relationship with clients and is competent in the use of her/his chosen approach. 2. A consistent observation is that psychology has overvalued the use of CBT, in any of it's forms. What makes it necessary to proclaim that CBT is the "best?" 3. EMDR Therapy for recent and chronic PTSD and especially with Complex PTSD and Serial PTSD, e.g., DID, with it's advanced protocols, can hasten improvements in understanding of and functioning in the internal world of the client, as well as the external world of family and other relationships. 4. CBT does not embrace as thoroughly as EMDR Therapy (and as thoroughly as Bowen Family Systems - a biological theory of human behavior) the new knowledge base that have come out of affective neuroscience. 5. Others will comment better than I on the details of the EMDR Therapy research proclaiming effective use of the approach for PTSD and other disorders of extreme stress

Commenter: Charles Glazier, LICSW; charles@thewaytobetter.com

Comment: The evidence that was reviewed leaves out more of clinical practice than it includes. Including the basic fact, which is that across modalities and approaches, the main variables have to do with therapist factors, and therapist factors improve with experience and training irrespective of approach.

Panel response: *The recommendations for psychotherapy presume that the person delivering the intervention is attentive to matters such as developing a respectful therapeutic relationship. However, teaching individuals the basis of effective clinical relationships is not the purpose of this guideline but rather to identify which interventions, presumably delivered in the context of an ongoing, respectful, professional relationship, demonstrate efficacious outcomes.*

Applicability

Commenter: Elaine Ducharme; elaine.ducharme@yahoo.com

Comment:

More or less. I am concerned that lack of data from clients limits the results.

Generalizability

Commenter: Loretta Malta; lsmaltaphd@gmail.com

Comment: Yes For the most part. However, there is little discussion of actual findings of generalizability across subtypes of groups, other than to convey that there was insufficient evidence. See comments below.

Applicability

Commenter: Dr. Joseph Graca; joseph@rekindleyoursoul.com

Comment: Yes. The guidelines fail to report on the research of the "real world " application of these therapies that temper the strong recommendations given. For reference see; Psychotherapy for Military-Related PTSD; A Review of Randomized Clinical Trials JAMA. 2015;314 (5):489-500.Maria M. Steenkamp, PhD; Brett T. Litz, PhD; Charles W. Hoge, MD; Charles R. Marmar,MD. They reviewed many of the same research studies examined in the APA report and concluded; "In military and veteran populations, trials of the first-line trauma-focused interventions CPT and prolonged exposure have shown clinically meaningful improvements for many patients with PTSD. However, nonresponse rates have been high, many patients continue to have symptoms, and trauma-focused interventions show marginally superior results compared with active control conditions. "

Commenter: Leah Cochrane; leahcochrane@icloud.com

Comment: One issue remains a strong concern for me, and I felt its importance was not appreciated in the draft. Specifically, the issue of generalizability and the heterogeneity of subgroups as stated here:

I am speaking as a psychotherapist with 15 years experience, including certification in working with returning vets with PTSD, MST and TBI. I predominately use Cognitive Processing and less frequently EMDR for those with a diagnosis of PTSD. I work in a pro bono situation as well with vets with PTSD who have not been able to conform to the behavior required of them in order to receive treatment at the VA or at Vet Centers. Let me repeat: Their symptoms prevent them from being able to receive the only treatment that is available to them. There are a lot of these men and women. It is from this perspective that I make my comments.

The systematic review concluded that there was insufficient evidence “to determine whether the findings are applicable to all those with PTSD or whether they are applicable only to certain groups” "and insufficient evidence about whether there were subgroup effects. Thus panel members did not reach consensus about the generalizability of the systematic review’s findings ... Some panel members think that lack of generalizability to all subgroups should be assumed in the face of insufficient evidence about generalizability. Others on the panel believe that, in the face of insufficient evidence about generalizability or strong theoretical rationale to suggest treatment effect heterogeneity, generalizability to most subgroups should be assumed. Panel members agree however that examination of treatment effect heterogeneity with diverse samples should be prioritized for future research. "

The call for future research, while welcome, does little to overcome the real issue underneath the learned opinions, that is, that the subgroups, while diverse, may very well exclude or underrepresent those who are most at risk for your "critical issues" since one of the key characteristics of those with severe PTSD (and MST and TBI) is their unwillingness to expose themselves to further risk (even if the risk is low) or to cope with the vulnerability of seeking treatment through normal channels. It is traumatized veterans who are largely represented in this category, I believe, but it could include other groups I'm not aware of. Additionally, as mentioned in the discussion, it is beyond the scope of the review to determine which treatments might benefit which patients. I believe these two issues, 1) lack of generalizability and heterogeneity of subgroups, and 2) which treatment is best for which patient are of critical importance and should be given more emphasis and exposition so that practitioners make no assumptions about treatments that "should work" or should work "for everyone."

Panel Response:

The research that was considered as part of the systematic review was generally efficacy studies or studies that establish that a treatment works. Relatively few studies examine how well the treatment works in real world settings (effectiveness studies.) However, the panel did review the demographic characteristics of the participating patients in the studies and noted that there was a fairly broad range of precipitating traumas (e.g. domestic abuse, sexual assault, combat, refugees) and that there was not evidence to suggest that treatment outcomes would vary based on presenting concerns or demographic characteristics. More effectiveness studies would be useful of course.

Additionally, two community members participated in the initial framing of the guideline, including agreeing on the critical outcomes for consideration, and one community member participated throughout the entire evidence review and guideline writing. While one or two people cannot speak for all individuals with PTSD, both have extensive experience working with individuals with PTSD as do many of the clinicians on the panel. To the extent possible, they strove to present the diversity of client experience. When possible, data from published studies were also reviewed to understand patients' values and preferences in regards to treatment.

The panel wholeheartedly endorses greater involvement of individuals with PTSD in research study design and presentation in order to better capture their experience and the outcomes of greatest importance to those seeking care.

Gaps in research and evidence

Commenter: Michael C. Freed, PhD, EMT-B; mfreed@cbhw.org

Comment: We recognize the importance of these APA guidelines for PTSD treatment, and we offer specific suggestions in the sections below.

At a high level, to be maximally helpful for providers and patients in routine care arrangements, the guidelines could be significantly improved by drawing attention to evidence and gaps related to a) the performance of evidence-based interventions in routine care settings, b) findings on practice setting and procedure modifications associated with desired outcomes when research-based treatments are implemented in routine care settings, and c) engaging and retaining patients in evidence-based care as well as matching patients with care, balancing patient preference and likelihood of good outcomes.

These suggestions would help contextualize findings from a thoughtful evidence review into information for clinicians, who will be the users of these guidelines. In recent years, the fields of mental health services research and implementation science have taught us much about the utility of Clinical Practice Guidelines (CPGs) and the need for them to fit within a larger context to best effect practice change.

However, as described in more detail below, we believe that additional review criteria (distinguishing efficacy, effectiveness/pragmatic, and implementation trial research) would be of importance to the audience.

We also believe that the APA recommendation could encompass a broader evidence base to include necessary service delivery practices (screening and response to treatment) and evidence-supported treatment delivery models such as collaborative care.

Commenter: Tammy Barnes (on behalf of the Committee on Rural Health); tbarnes@apa.org

Comment: If it is to be an aspirational guideline, it would be helpful to have a broader approach. Barriers to accessing the preferred treatment are not addressed in the guideline. These could possibly be met through telehealth options, integrated care or collaboration for financial or transportation support

Recommendations:

Add to the Gaps in Literature section p. 91-92 e.g., to include intergenerational trauma.

Highlight challenges to providing services such as accessibility, costs, limited number of providers in rural/remote areas.

CRH provides this suggestion in respect to its mission of "...[a]dvocating to ensure availability of behavioral health for rural and remote populations and the parity of behavioral care with physical health services;and...[e]ncouraging collaborative and interprofessional models of care..."

Commenter: Leah Cochrane; leahcochrane@icloud.com

Comment: Following from the statement above, you could further address the two issues I brought up [1) lack of generalizability and heterogeneity of subgroups, and 2) which treatment is best for which patient]. If the research falls short in these areas, in what way does it do so, and what effects might this have? Is there some other way to understand the effects of what we don't know in this area? Have there been past situations that mirror the current one from which some direction might be drawn? This is a position paper, not just a literature review or meta-analysis, so in my opinion it would be with scope to delve into the problem, as it were, of these two issues.

Panel Response: *In psychotherapy research, "what works for whom" is the question that has been asked for decades, however that is not the question of these guidelines. The panel appreciates the commenters' inquiry and believes that clinical practice guidelines are one tool to aid the clinician in determining what interventions to offer to any given individual. Of course, more research to guide that process would be welcome but at this point, such specificity is limited in the psychotherapy research.*

The comments regarding contextualizing the recommendations are helpful and will be utilized as dissemination and implementation of these recommendations proceeds.

Selecting treatment/ implementation

Several commenters raised questions regarding application of the guidelines- selecting treatments, necessary training of providers, how to implement treatments in various treatments settings. While the recommendations and accompanying text provide minimal direction in this regard, APA plans for disseminating and implementing the guidelines will address some of these concerns.

Commenter: Julian Ford; jford@uchc.edu

Comment: A clearer statement of the extreme degree of individual variability in response to all PTSD psychotherapies, and of the need for much better evidence regarding the crucial clinical choice of matching therapy to the individual client (based on client preferences as well as RCT evidence) is needed. Evidence of limited and variable utilization of one-size-fits-all manualized PTSD therapy models

should be cited to counterbalance the misleading impression that any of the "strong" evidence models will be suitable and must be provided ethically to any adult with PTSD. It also should be stated emphatically that therapist variation in the application of any PTSD therapy model is not sufficiently researched and may have effects on "common factors" such as the therapeutic relationship and client motivation/expectancies which also have not been sufficiently researched and may be as important to retention and positive treatment response as the technical model of therapy.

Commenter: Committee on International Relations in Psychology (CIRP); sleverty@apa.org

Comment: The Committee on International Relations in Psychology (CIRP) appreciates the extensive work done in compiling the report of the APA Clinical Practice Guideline for the Treatment of PTSD in Adults. CIRP is concerned about the absence of an emphasis regarding cultural factors that relate to the psychotherapies/ interventions and medications used in the treatment of PTSD that would effectively respond to culturally diverse populations inclusive of international clientele. Culture and Diversity Competence is minimally addressed on page 75 and 76 of the Clinical Practice Guideline for the Treatment of Posttraumatic Stress Disorder (PTSD) in Adults from the Guideline Development Panel (GDP) for PTSD Treatment. The section on cultural diversity is less than one page in length. The last sentence in this section summarized related issues to cultural competence noting, “These are important components of the therapeutic relationship and context that support treatment but are beyond the purview of this document”. CIRP would strongly recommend that a comprehensive review of cultural diversity in relationship to the psychotherapies/interventions of PTSD and variance in medication based on cultural differences is within the purview of this report and a critical component that should be included throughout the document in order to ensure culturally responsive treatment and guidelines. Subsequently CIRP would strongly recommend that the report be revised to include substantive attention to cultural differences and cultural competencies.

Commenter: Policy and Planning Board

Comment: Guidance on how culture issues are considered when selecting treatments.

Commenter: Barbara Gormley; BGormley@govst.edu

Comment: My concern is that people will perceive these guidelines as applying to anyone with exposure to a traumatic event, without reading the fine print. There is some language that only symptoms rising to the level of PTSD are addressed by the systematic review, but I think this should be stressed at the beginning of the list of recommended therapies. The document acknowledges that there is insufficient evidence regarding therapies that work with women, people of color, and other marginalized groups, but again, it is not stressed in the list of recommended therapies that these guidelines may be more appropriate for white men than for others. Complex trauma and the potential need for studies of the effectiveness of psychodynamic interventions in such cases is not addressed. In summary, the limited application of these guidelines to simple trauma rising to the level of PTSD where traditional (not marginalized) populations are involved is not sufficiently stated for users.

Dr. Jane Storrie *jstorrie@svapsych.ca*

Yes it does, but it is disappointing that the Guidelines do not speak to some important issues that have been addressed variably by existing Guidelines (for example, necessary training requirements for clinicians doing trauma work). It was also a little disappointing that the Committee was unable to take a stronger position on certain issues, such as the use of specific modalities for different populations, efficacy of psychotherapy vs pharmacotherapy, etc.

Commenter: Steven Baerg, LCSW; srbaerg@yahoo.com

Comment: It could be made more genuinely helpful by including all treatment options that have significant evidence for effectiveness, not just the currently popular versions and the highly promoted ones. It could help clarify the choice of therapy significantly by offering suggestions for making decisions about the best match between client and therapeutic approach considering the wider variety of choices discussed.

Commenter: Andrew M. Bezooyen; andrew@community-solutions.ca

Comment: The most relevant information for me as a practicing clinician is "what intervention is best indicated by the research for this particular client, dealing with this particular symptoms, at this time of the client's life?"

The draft document does not make this information readily available. It would be helpful to see the evidence that verbally based cognitive therapies are effective for adults of normal intelligence, but that strategies like EMDR are effective with children who have less verbal processing capacity, or to know how various strategies can be sequenced to achieve maximum benefit (for example, begin with relaxation training, as the client develops ability to self regulate, apply EMDR and then move to more cognitively based strategies)

Commenter: Michael C. Freed, PhD, EMT-B; mfreed@cbhw.org

Comment: It would be helpful if there was a section which described how these APA guidelines complement those developed by the Dept. of Veterans Affairs and the Dept. of Defense (aka, VA/DoD CPGs for PTSD). The VA/DoD CPGs for PTSD (soon-to-be-updated 2010 version) rate evidence of psychotherapies and medications for PTSD, like these APA guidelines do. However, the VA/DoD CPGs go further. For example, there is language which contextualizes these treatments within the VA and DoD healthcare settings. And there are accompanying documents (e.g., pocket guide and implementation guide) to help providers and clinic leaders institute practice change.

We suggest that APA consider adding similar language and documents. While differences across health systems exist, many mental health service delivery challenges are similar, and helping provider address those challenges would be of benefit to the military, veteran, and community populations in need of high quality PTSD treatments.

The guideline scope could be expanded to include those key procedures utilized in the treatment studies reviewed for these guidelines. For example, appropriate screening, diagnosis, ongoing symptom monitoring (e.g., measurement-based care), and treatment fidelity monitoring are essential to help ensure these interventions are implemented as intended and used with the correctly diagnosed population.

The literature is replete with examples where efficacious treatments (i.e., treatments tested under tightly controlled conditions) drift considerably and in a multitude of ways when attempted to be implemented in 'real-world' practice settings. When this happens, quality of care becomes questionable and outcomes can suffer.

Because efficacious PTSD treatments are highly specialized, we suggest that these APA guidelines

recommend use of those processes and procedures to help ensure efficacious treatments are effectively delivered.

We suggest adding data from epidemiological and clinical epidemiological studies demonstrating the pathways into care and service utilization for a target population of people with PTSD.

There are a series of papers from the National Comorbidity Survey-Revised, other epidemiological studies, and reports from the Institute of Medicine which call attention to the fact that many people with PTSD are not identified as having unmet needs. Of those who find their way into care, many have difficulty accessing high quality care, and many fall out of care (i.e., dropout).

Clinical practice guidelines play an important role: they advise providers about what high quality PTSD care could be delivered. Given that bringing that high quality care to scale remains a challenge, the guidelines would ideally speak to these data both as part of the justification and as part of the recommendations for PTSD treatment and management.

Horace Benefield *mikeb-oakleaf@sbcglobal.net*

A recommended additional resource in terms of proper use of the guide by practitioners is a mandatory program of pre-education and certification by all authorized users of the guide. Practitioners would be trained in the use of the guide and certified that they bring the requisite set of skills to perform credible PTSD diagnoses, evidence-based treatments/therapies within the context of the post-traumatic disorder and DSM-5. For example, skills and training in applying clinician diagnosis and treatment /therapies to various multicultural people.

Jamie Zabukovec *zabuk@aol.com*

when information regarding all treatment options available is not regularly provided to all patients, with a fair, equal and balanced explanation (without bias) in presenting the information? That certainly applies to those facilities and treatment providers who only provide information regarding CPT and PE to clients, using EMDR as a back-up only if CPT and/or PE fail, or do not provide equal, objective information regarding all of the available treatments when discussing treatment options with clients. Exploring why patients prefer particular treatments could provide invaluable information in understanding treatment effectiveness. For example, some patients with PTSD prefer to avoid things that remind them of the trauma, and subsequently would avoid treatment that would have them access aspects of the trauma.

Commenter: Ricky Greenwald; rg@childtrauma.com

Comment: Process & Method, first paragraph. The listed criteria were appropriate as far as they went, but two very important criteria were omitted.

1. Acceptability to clients and to therapists is a key consideration, because a "good" treatment that no one will do is not of much use. See (for example): Najavits, L. M. (2015). The problem of dropout from “gold standard” PTSD therapies. F1000Prime Reports, 7, 43. DOI: 10.12703/P7-43

2. Treatment efficiency is also important, because a more efficient treatment will use fewer resources, achieve results more quickly, and have fewer dropouts.

Omission of these, especially of #1, will lead to an important-sounding document that may not actually be relevant to clinical practice. And that will therefore not serve the function for which it was intended. So much work, for nothing.

Inclusion of these will lead to a re-ranking of recommended treatments, with EMDR likely coming out on top, because it is more useful in actual clinical practice. At least, as per my own meta-analysis of direct comparisons, which is in preparation.

Commenter: Janina Fisher; DrJJFisher@aol.com

Comment: The Trauma Symptoms Inventory by John Briere is an important resource for therapists working with trauma because it elicits symptom detail rarely volunteered by clients and helps to establish treatment priorities. Based on the treatment priorities (i.e., severity of different clusters of symptoms), the clinician can be advised on how to tailor the treatment to the specific individual. For example, CBT exposure is contraindicated for unstable, self-harming, suicidal or addicted clients, whereas CBT cognitive restructuring might be helpful as would be stabilizing EMDR techniques.

Commenter: Janina Fisher; DrJJFisher@aol.com

Comment: Describe the subject groups that are being compared (i.e., what conditions, symptoms, co-morbidities were excluded) more fully so that therapists can compare their clients with the subjects studied.

Tie the recommendations for treatment not just to the efficacy research but also to the signs and symptoms being treated in typical clients. Include the issue of the effects of trauma on the brain and body.

What treatments for which patients?

Commenter: Carolynn R. Campbell, MSW RSW; carolynn@campbellrsw.com

Comment: Which treatments work best for which patients? In other words, do patient characteristics or type of trauma modify treatment effects?

Commenter: Policy and Planning Board

Comment: P&P looks forward to the ultimate implementation of these guidelines and believes that might include possible flow charts to assist clinical decision making for front line clinicians. This might include guidance on how culture issues are considered when selected treatments.

Panel Response:

As previously noted, the question of what treatment for which patient is a very important clinical question for which there is relatively little guidance in the empirical literature. That underscores the importance of quality training of clinicians and the value of clinical judgment and shared decision making in developing treatment plans. While beyond the scope of the guidelines, improving our understanding of the acceptability of various treatments for PTSD for different populations will be helpful.

APA recently approved Guidelines on Trauma Competencies for Education and Training [Retrieved from: http://www.apa.org/ed/resources/trauma-competencies-training.pdf] which provide much guidance and will be important in the implementation of these treatment recommendations.

While the panel does not plan to detail issues specific to implementation in the final document, as APA prepares materials for this purpose, these points will be considered. The panel did review its Discussion and Considerations for Treatment Implementation with these comments in mind in order to provide some introduction to the important issues raised by the commenters above.

Appendices

Commenter: William Benson, PsyD; wwbenson1@gmail.com

Comment: Definition of CBT, CPT, EXP, etc. In terms of trials of CBT for PTSD, how was CBT defined? Must it be trauma-focused? How does it differ from CPT and Exposure therapy. Also is the term Exposure Therapy more broad than Prolonged Exposure? How is it defined? Having a section to define these terms would be very helpful.

Panel Response: *A description of each treatment can be found in Appendix A and a description of other terms can be found in Appendix E. The panel struggled with how much text to include in the guideline document and how much to include in appendices. CBT was operationalized somewhat differently in each of the trials included in the review but a general description of CBT is provided in the Appendix. The definitions have been revised for the final document. Those who wish to become competent in delivering CBT for treatment of PTSD are encouraged to participate in additional training (and materials and resources will be provided as part of the dissemination process for this guideline.)*

Additionally, exposure is the broad term that includes prolonged exposure. The systematic review that formed the basis for the evidence review for this document evaluated all exposure based trials together and did not separate prolonged exposure from other exposure interventions in the analyses; hence the panel used the umbrella term "exposure" in the draft document. However, the panel reviewed the included studies and concluded that all but one or two were studies of prolonged exposure and in determined that the evidence supporting prolonged exposure alone was as strong if not stronger than the evidence from all exposure based interventions. In the final version of the document, the panel has used the term "prolonged exposure."

Diversity Language

Commenter: APA Committee on Sexual Orientation and Gender Diversity

Comment: CSOGD is supportive of these guidelines and we appreciate the clarity and analysis of treatment of PTSD provided in the document. We do suggest that "gender identity and gender expression" is added throughout the document where lists of diversity dimensions are enumerated, including, but not limited to, the lists on p. 49, line 9 and p. 75, line 21. In addition, we also recommend following the style that NIH has adopted of using the term "gender and sexual minorities" when referring to the LGBT communities, so as to be inclusive of other gender and sexual identities beyond LGBT, including, but not limited to, the lists on p. 83, line 20; p. 84, line 2; p.86, line 1; and p. 92, line 16. Thank you for the opportunity to comment.

Panel Response: *The panel used the recommended phrases as appropriate in the revised document. However, the change was not warranted in some of the instances identified by CSOGD as the document*

was referring to specific analyses that were conducted with specific subpopulations. Not all diversity dimensions were subjected to subgroup analyses.

Detailed Comments on Document

The panel was grateful to receive section by section and line by line comments from several individuals, including a staff person at the American Psychiatric Association. These comments addressed both substantive and organizational issues and were carefully reviewed and the document was changed as appropriate.

American Psychiatric Association

Commenter: Jennifer Medicus; jmedicus@psych.org

Comment: Overall, this is a very detailed well-written document that clearly involved a great deal of thought and hard work on the part of the panel and the APA staff. However, the overall utility of the guideline for clinicians is unclear due to the constraints of the GRADE approach. As the authors point out, PTSD is a complex condition that is often associated with comorbid disorders and can result from many different types and durations of trauma. In addition, as noted in the document, there are many aspects of the therapeutic relationship that are likely to be critical to treatment outcomes yet are not readily studied in a randomized fashion. Other key aspects of PTSD treatment could be studied in more detail, but have not. The authors do a good job of discussing these complexities and gaps in the evidence but clinicians may still wish for more detailed recommendations to address these challenges in a way that will be most helpful to patients.

Guideline recommendations are increasingly being used to develop quality improvement measures or treatment authorization policies. Clinicians, patients, and families are also becoming increasingly aware of guidelines and seek out information that will help them making decisions about treatment approaches. For all of these reasons, it would be helpful to describe specific aspects of implementing these recommendations (e.g. fidelity to manualized approaches, training requirements for these strategies, geographic and other factors influencing availability of recommended approaches, strategies to use if trained therapists are unavailable).

Panel Response: *The panel appreciates the positive feedback. Some of the suggestions will likely be part of the guidance developed as part of the dissemination and implementation (D & I) effort and therefore will not be directly included in the guideline document. The panel absolutely agrees that clinicians, patients and families need information to help them make decisions about treatment approaches and APA is already developing accompanying material for this purpose.*

Comment: It would also be helpful to give more detailed descriptions of the recommended psychotherapeutic modalities. For example, brief eclectic therapy and EMDR have several components and the category for CBT is described as having "interventions using aspects of CBT that do not fit neatly into the other CBT categories" without providing other specifics. As far as possible, it would be useful to know which components of these therapies are effective and necessary among the broad range of techniques included.

Panel Response: *The descriptions of the treatments have been revised. The panel kept the description in the text relatively brief but will expand on these descriptions in the D & I material made available to the public.*

Comment: In copy-editing the document, it would be important to use someone with experience in proofreading documents that include pharmacotherapies and medical terminology. Although there is significant overlap with the psychological literature, familiarity with these topics can be important in identifying errors that are not typically captured by embedded spell-checking. As one example, the appendix spells "divalproex" incorrectly as "divaloproex" in several locations.

Panel Response: *Thank you for noting this. Thorough copy-editing is occurring before finalization.*

Comment: This section includes several recommendations that are based on the comparative effectiveness data but were not included in the summary of recommendations at the beginning of the document (p. 8). These comparative effectiveness statements do not seem helpful as they only address a few of the possible comparisons and provide no information about other, equally plausible comparisons.

Cognitive restructuring is not included as a specific treatment in the efficacy related recommendations, although it is presumably a component of some of the cognitive or cognitive behavioral therapies. However, this makes the recommendation comparing “exposure” to “exposure plus cognitive restructuring” unclear. If choosing among the recommended therapies, cognitive restructuring alone would not be considered. Also, because the data suggest comparable loss of PTSD diagnosis with exposure alone or exposure plus cognitive restructuring, it seems unnecessary to even consider adding the cognitive restructuring component to the treatment. The meaning of a "strong for" recommendation also may be confusing to clinicians when neither treatment is recommended in favor of the other.

The recommendations comparing “CBT” to “relaxation” and “exposure therapy” to “relaxation” are also not helpful as relaxation is not one of the recommended or suggested treatments. Similarly, “Seeking Safety” is not a recommended or suggested treatment so a statement comparing it to an active control is not very informative either.

The comparison of sertraline to venlafaxine ER lets clinicians know that there is no reason to prefer one over the other, but this does not allow one to prioritize the use of specific medications in other respects. As above, the meaning of a "strong for" recommendation also may be confusing to clinicians when neither treatment is recommended in favor of the other. The footnote attempts to clarify this information but does not make the statements any more helpful to clinicians.

p. 8 lines 7-11 In discussing the recommendations, there are several interventions -- seeking safety, relaxation, and risperidone – highlighted as having insufficient evidence. It's not clear why these particular treatments were singled out in these statements given the large number of other psychological and pharmacotherapeutic treatments that are available or have been used in PTSD. Therefore, these particular statements don't seem very helpful or informative. It may actually be more confusing than useful to mention these treatments as part of a formal recommendation statement.

Panel Response: *The commenter provides helpful feedback on the usability of the recommendations as presented in the report. The panel chose to review all interventions, and comparisons of interventions, if there was at least low quality evidence in the systematic review. However, as noted, this means that*

sometimes a statement is made about an intervention without further clarification and perhaps making the statement less useful to clinicians or patients. The panel chooses to keep the structure for this report but anticipates that how the recommendations are presented in D & I materials will better clarify some of the issues noted above.

Comment: p. 10 lines 23-25 Conflicts of interest are noted to be reviewed and managed, however the method for managing significant COIs is not well-delineated, either here or on page 32. At the end of the document (p. 100 line 25), it states that COI forms are available on request. In the interest of transparency, it would be important to have, at minimum, a printed disclosure similar to those found in typical journal publications. It would be preferable to list all potential COIs along with the specific steps that were taken to mitigate financial COIs.

Panel Response: *Additional content has been added to the main portion of the document to describe the process. A member by member disclosure statement has also been added to the appendices.*

Comment: p. 11 lines 17-19 The document states that the panel was unable to recommend psychotherapy over pharmacotherapy, which suggests that the strength of the recommendations for these two approaches should be comparable. This contrasts with the fact that psychotherapy is given a strong recommendation whereas medications are given a weaker recommendation.

Panel Response: *A statement has been added to clarify why the panel made few recommendations regarding comparisons between treatments nor made recommendations for one group of treatments over another on the basis of strength of evidence alone.*

p. 12 lines 23 The information on patient preferences is very important to include enhancing the patient-centered nature of care as well as in fulfilling key steps in the GRADE process. However, it is not clear whether the professionals' reflections on patient preferences might be affected by the greater proportion of psychologists on the panel. For example, individuals receiving treatment from a psychologist may be more inclined to view psychotherapy as a first choice as compared to patients seen by physicians. Depending on how the consumer panelists were selected, their views of treatment options may or may not be generalizable to other patients with PTSD.

Panel Response: *This is a good point and now noted in the document.*

Comment: p. 13 line 16 The beginning of the document includes an explanation on using the term "patient" instead of "client", however, some portions of the document (such as this section) still use the word "client."

Panel Response: *That has been corrected. Thank you for noting it.*

Comment: p. 13 lines 7-11 The section titled informed consent includes many important elements that are part of shared decision-making with the patient. Review of the pluses and minuses of various treatment options and incorporation of patient preferences are important parts of the process before initiating treatment, which are well described in the section on pp. 72 to 73 of the document. However, written documents are mentioned in this section implying that a signed consent is needed or typical when this is not generally the case. It would be important to clarify that informing patients about available treatment options and engaging in shared decision making does not imply the need for formal written consent for every treatment related discussion.

Panel Response: *Written informed consent is quite common for some of the disciplines represented on the panel but recognizes that it is not for all providers, nor is it necessary. That section has been modified.*

Comment: p. 41 lines 13-17 This section of the document does a good job of describing one of the limitations of the GRADE method. If any of the "critical" outcomes are identified as having insufficient or low evidence, then the overall strength of evidence must also be insufficient or low evidence (even if one of the critical outcomes had moderate or high strength of evidence). Virtually all data on adverse effects/harms are, at best, low strength of evidence. Furthermore, harms (e.g., mortality) will typically be at least one of the critical outcomes. As a result, the aggregate/global strength of evidence will typically be low/insufficient.

p. 43 lines 24-25 In this discussion of the results of the EMDR meta-analysis, the authors do a good job of explaining why it was unable to rate the magnitude of benefit for EMDR compared to inactive controls. Based on this discussion and the fact that the p value was non-significant, it is unclear why the panel suggested that EMDR be used. In terms of balancing benefits and harms of treatment, EMDR research has not typically examined harms. Thus, it is not clear how there is sufficient information to suggest use of EMDR at the same level with even the most efficacious medications.

Panel Response: *The section referenced is a description of how different values and confidence intervals for specific outcomes lead to different decisions (in one example, the point estimate was near zero and the confidence interval included zero; in the other example, the point estimate was moderate and far from the null value although the confidence interval contained the null value). It was not intended as a full explanation of how the panel arrived at its recommendation for EMDR; in fact, the panel reviewed multiple clinical outcomes from the efficacy studies for magnitude of benefit before arriving at an overall determination of EMDR's effect on critical and important outcomes.*

Comment: Table 5 The title of the table changes, which is not the usual convention for a table name. We would recommend changing the overall title and have sections within the table for each of the three areas or have separate tables. We would also suggest changing the wording of these section titles (e.g., Efficacy of Psychological Intervention Compared to No Intervention, Efficacy of Pharmacological Intervention Compared to No Intervention).

Table 5 The efficacy related statements in the table include the phrasing "compared to no intervention". This appropriately describes the comparator groups in the studies that support the recommendation, but is different than the wording used elsewhere in the guideline, which do not include this additional phrasing. In addition, from the standpoint of the clinical utility of recommendations, a decision has presumably already been made for some sort of treatment so the comparison to no intervention has already been made implicitly.

Table 5 The evidence in favor of offering topiramate compared to no intervention does not seem comparable to that for the other suggested medications. Although all medication trials are listed as having a serious risk of bias in the evidence profile tables and some of the trials of the SSRIs and venlafaxine have a wide confidence interval, the total number of subjects in the topiramate trials is much less than in the SSRI/SNRI trials. In addition, two of the topiramate trials had very wide confidence intervals that overlapped zero (albeit barely). It is not clear that this data warrants a rating of a moderate strength of evidence. Also, in weighing the balance of benefits and harms, Appendix D p. 266 notes that several trials were excluded due to high attrition. However, in at least one of those trials, there was differentially elevated attrition in the topiramate group related to adverse effects. Excluding

this trial, at least for considering harms, would seem to bias the final conclusions in favor of topiramate use.

Panel Response: *The panel appreciated the feedback and re-visited this particular decision table, ultimately modifying its recommendation.*

Comment: p. 76 Psychodynamic psychotherapy is included as a potential treatment for PTSD in the VA/DoD Clinical Practice Guidelines for PTSD and the ISTSS Clinical Practice Guidelines for PTSD. However, it is not included in this guideline or even discussed in the context of other guidelines' statements. We realize that the research supportive of psychodynamic treatments was excluded because of the threshold set for acceptable evidence in this review. Nevertheless, it would be important to mention psychodynamically informed therapy in this section as well as in the section on evidence gaps that need additional research.

Panel Response: *Please see more detailed response about psychodynamic psychotherapy as a potential treatment for PTSD. Some panel members have been trained in the psychodynamic/ analytic tradition and appreciate that approach to care. The panel did make some changes to the document, particularly in terms of discussing future research and gaps in literature.*

Comment: p. 79 line 3 We recommend spelling out American Psychiatric Association here. Otherwise, some readers may assume this is a typographical error and believe that it refers to the American Psychological Association.

Panel Response: *Done.*

Comment: p. 79 line 10 The current wording implies that the VA guideline rated topiramate as "ineffective or harmful", but only benzodiazepines were rated as harmful and topiramate was rated as ineffective in the VA/DoD guideline. It would be helpful to change the wording of the sentence to reflect these distinctions. It also states that the current recommendation was based on the strength of new evidence since publication of the VA/DoD guideline, but only the Yeh et al. study (2011) was subsequent to the VA/DoD guideline.

Panel Response: *Excellent point, the document has been changed.*

Comment: p. 80 line 17 This discussion comparing the psychotherapy and pharmacotherapy data is particularly well done, however these two issues are of such critical importance that they should also be addressed in the Executive Summary given the panel's differential recommendations regarding psychotherapy versus medications.

Panel Response: *Thank you, a brief note of this issue has been added to the Executive Summary.*

Comment: p. 87 line 16-20 The discussion does a good job of emphasizing the need for appropriate training to be able to deliver psychotherapies with high fidelity in order to achieve responses that are comparable to those seen in clinical trials. It may be helpful to point out that this is much less of an issue for medications, although successful outcomes will still depend on the many other aspects of a positive therapeutic relationship. If there is a lack of access to clinicians with appropriate training in the recommended psychotherapies, use of one of the suggested medications may be preferable.

Panel Response: *These are important points and ones that will be further amplified in the materials for D & I.*

Comment: p. 88 line 5 Here and elsewhere in the document the phrases "substance abuse", "substance abuse disorders", "substance dependence" and related terms are used. It would be preferable to substitute these phrases with "substance use" or "substance use disorders" (as appropriate) throughout the document for consistency with DSM-5 terminology.

Panel Response: *The panel appreciates that the terminology has changed with the publication of DSM-5 but decided that in some instances older terminology was appropriate (as decisions to include or exclude participants were based on diagnoses from DSM-IV) or that substance abuse conveyed the understood meaning of "problematic substance use." However, the panel did change to "substance use disorders" in many instances.*

Comment: p. 90 lines 20-24 As noted previously, it is not clear whether the preference for psychotherapy relative to medications would have been different depending on the panel composition.

Panel Response: *While it is possible that a different panel composition would have generated different recommendations, the panel followed a transparent process for decision making and "stands by" its assessment of the evidence. It is worthwhile to note that "*An open question is whether patient preference for specific treatment varies by treating provider such that patients choose professionals able to provide preferred treatment or identify a treatment as preferred on the basis of what the provider is able to offer." (text added page 17)

Comment: p. 93 line 1 Although the word "suicidality" is in common use, it can cause confusion among readers because it refers to a wide range of suicide-related ideas and behaviors. Individuals with suicide-related ideas and behaviors are at varying degrees of increased risk of suicide and have overlapping, but not identical, clinical and epidemiologic features as individuals who die by suicide. At times, individuals with non-suicidal self-injury are included in this generic description and also have significant differences in their characteristics from those who die by suicide. To avoid ambiguity, we suggest avoiding the general term "suicidality" and using more specific language (e.g., suicidal ideation, suicide attempts, suicide) whenever possible. In this particular context, we would suggest substituting the word "suicidality" with "significant risk for suicide".

Panel Response: *The panel has modified the document to be more precise in meaning.*

Comment: p. 93 lines 7-12 It would be important to include more studies that focus on the treatment of specific symptoms that are especially problematic for individuals with PTSD such as nightmares. Even if overall symptom scores are not sufficiently reduced to have a statistically significant effect, improvements in specific distressing symptoms may still improve functional outcomes and quality of life.

Panel Response: *The panel agrees that this is important and hopes it will be addressed in future updates. One challenge is that data is rarely reported on important outcomes such as functioning and quality of life.*

Comment: p. 93 lines 13 All effective medications have adverse events associated with them. Those medications purported to have no potential side effects, often have no effects at all. Anything with the "power" to alter a biological process has the inherent risk of unintended consequences. If psychotherapy has similar "power" it is hard to believe it does not have a similar downside. Clinically, it is doubtful if any experienced practitioner has not had some patients who have expressed negative consequences from a given psychotherapy experience.

Panel Response: *The panel agrees that it is important for psychotherapy research to begin to systematically document any adverse effects of treatment.*

Comment: p. 95 lines The discussion of the potential impact of researcher allegiances is a good one, but It may also be worth mentioning the possible impact of funding source on clinical trial design and findings. Although the potential impact of pharmaceutical funding is mentioned elsewhere, it may be useful to discuss it here as well or consolidate the discussion in one place.

Panel Response: *The panel agrees and has noted this in its discussion.*

Detailed comments for whole document

Commenter: Lisa Najavits; najavits@bu.edu

Comment:

Below are comments on the document, keyed to page numbers and line numbers (the former listed first and the latter after the "/" forward slash).

• Provide a glossary and mention it in the Executive Summary.

Panel Response: *An Appendix of Key Terms is included.*
• How often will the guidelines be updated and what will the process be? This should be stated.

Panel Response: *The panel does not know what the update process will be but knows that the document will be reviewed and updated no later than 5 years post- completion (2022).*

• Pg 10, 17-19 and 49/6-17 Although diverse in the variables named, the PTSD literature is historically known for having excluded many vulnerable populations, and the literature is not diverse with regard to inclusion of substance use disorder (SUD, especially severe cases), serious mental illness such as psychosis, homeless, incarcerated, cognitively impaired, violent and/or suicidal, current domestic violence, personality disorders such as antisocial and borderline, etc. These vulnerabilities are extremely important in clinical practice and can and should impact how clinicians choose treatments for PTSD. There is insufficient evidence on how many of the recommended treatments perform in the context of such vulnerabilities and this issue should not be ignored—it has serious real-world implications. Pg 11 lines 10-13 are far too strongly worded given this concern. This has been a long-standing issue in the field of PTSD treatment and this document, from an ethical and clinically responsible standpoint, should name it explictly. Pg 11 lines 24-25 are not explicit, for example, with regard to these subpopulations. So too pg 12 1-16, and pg 13 22-26. The term “diversity” should also be defined as it appears to be used primarily with regard to age, ethnicity and other sociodemographic variables but not with regard to the vulnerability of the samples.

Panel Response: *The complexity of treating PTSD is further described in the revised executive summary, including a brief discussion of the particular issues experienced by vulnerable populations. This is addressed in later sections of the document as well.*

• Pg 14 1-11 is good.
• The term "trauma-focused" is not defined on first use and it should be. Moreover, it's a problematic

term—sometimes meaning "any treatment intended to address trauma" and other times meaning "exposure-based" models. On 23-24 / 23-1 the definition provided is not accurate. For example, Seeking Safety directly addresses “thoughts and feelings” about the traumatic event, but does not address memories of it.
• Pg 16 11: ‘subthreshold’ should be clarified; does this mean studies were omitted if they included both PTSD and subthreshold (all had to have full-blown PTSD?), or that if they had only subthreshold they were excluded?
• 23 /9-11 The correct term is ‘substance use disorder’, not ‘substance abuse’

Panel Response: *The panel attempted to provide additional clarity and updated its use of terms as noted in the above examples.*

• 25 / 9 and 26/7-15: the focus on benefits vs harms is a great goal, but in absence of attention to the earlier point about vulnerable subpopulations, this document does not achieve an adequate focus on harms. I did see mention about generalizability and the split on the panel in relation to that (12/ 1-18) but the most conservative, ethical approach is to side with those in the panel who do not believe it is appropriate to generalize. This is the ‘first do no harm” approach. Especially concerning is the logic stated on 26/9-11: because there’s insufficient evidence with regard to harms, then there is no change to the conclusions about recommendations of treatments. This should be reversed: because of insufficient evidence, there should be caution about applying treatments that have not yet had sufficient evidence with vulnerable populations. Simply stating that there’s a research gap is not adequate— the stated goal of this document is to impact practice, which impacts real people and real lives, and insufficient evidence with regard to harms is grounds for caution.

Panel Response: *This is an inherent tension in clinical research and one that has had much debate within the field of psychology. Members of the panel discussed this in detail and absolutely agree that “do no harm” is an ethical imperative but also believe if treatments must be demonstrated efficacious with all relevant subpopulations, the harm of not treating may be greater than the harm of utilizing an intervention without demonstrated efficacy for a particular group. Clinicians naturally should document their treatment decisions and monitor care and adjust treatment accordingly if evidence of harm emerges.*

• Adding to the above point, a major omission are two criteria that were not part of the rating system yet should be in this systematic review: the complexity of the patient population and workforce capacity. For example, Seeking Safety has been studied on samples that are more complex. The only complexity variable I could locate in this document was PTSD severity, but that is not the most important one with regard to real-world concerns of clinicians. Issues such as suicidality, violence, etc. (per the list earlier in these comments) are more salient as these more directly impact clinical care. Someone with severe PTSD but who is non-violent, not suicidal, and not dependent on substances will be easier to treat than the reverse (mild PTSD but with the presence of those other issues).

Panel Response: *These are important clinical and empirical questions yet unfortunately little systematic data exists that comprehensively addresses these concerns. For these reasons it is important to note that this a guideline and does not supersede clinical judgment and decision making. Additionally, some of these issues will be addressed in the materials that are developed for Dissemination and Implementation. (D & I).*

• Table 5: the recommendation column needs a footnote or greater clarity in wording. I understand that it’s addressing RCTs that compared treatments to “no intervention”, but as written many clinicians

will read this table to mean "Use Treatment X no matter what." Without contextualizing such stark recommendations with regard to patient severity, such a meaning can have serious iatrogenic effects. The concept of 'first do no harm' really needs to be mentioned in this document. There are many anecdotal reports of iatrogenesis (e.g., see the book by Morris, The Evil Hours) and even if there is insufficient evidence from a methodology perspective, such issues do need to be stated and discussed so that clinicians will implement their clinical judgment—not a knee-jerk implementation of treatments across their caseloads.

Panel Response: *Again, these are important clinical and empirical questions yet unfortunately little systematic data exists that comprehensively addresses these concerns. For these reasons it is important to note that this a guideline and does not supersede clinical judgment and decision making. Additionally, some of these issues will be addressed in the materials that are developed for Dissemination and Implementation. (D & I).*

• Dropout is mentioned ["attrition"] but for clinicians use the term "dropout" is more clearcut (avoiding jargon would be good).

Panel Response: *The panel decided to retain the term in the document to be consistent with the research base but will use dropout in materials developed for D&I.*

• 37/12-16: this appears to be a very ill-conceived choice at odds with the rest of the methodology. Substance abuse treatments should not be considered active controls for PTSD as they were never developed for PTSD.

Panel Response: *A footnote has been added to clarify that this was a control condition only when a treatment for PTSD was evaluated with a population of individuals with co-morbid PTSD and substance use and the "control" was a substance abuse treatment.*

• 53/ #4: "No evidence that raises concern…". The Foa et al. trial on PE for comorbid PTSD /SUD would appear to raise a concern about applicability as it found no evidence for greater improvement on PTSD compared to a non-PTSD comparison treatment.

Panel Response: *The panel disagrees with the commenter and notes that its statement was derived from a collective evaluation of the evidence and not a particular trial.*

• Clarify early on in the document (and the Exec Summary) whether the panel focused on results at the end of treatment (the strongest timepoint for internal validity) or focused on baseline through followup. Also clarify early on whether intent-to-treat analyses were the focus (they seem to be, but it would be good to make this explicit).

• Unclear wording: 53/ "in some patients" makes the meaning of this bullet point unclear.

Panel Response: *Greater explanation is in the decision table (Appendix D). The panel opted not to add more detail to an already detailed table.*

• It's great to see the document focus clearly on COI and the inclusion of people with lived experience with PTSD.

Panel Response: *Thank you!*

• 60/footnote 19: Error / mischaracterization of Zlotnick et al. as having an active control. The control was TAU, as stated in the article. The provision of SUD treatment was part of the prison setting; it was not a manualized, specific treatment; there was no fidelity evaluation of it; and no citation of a model was provided in the article. All or most trials of PTSD/SUD patients allow patients to attend SUD 12-step groups and sometimes other treatments for SUD such as drug counseling and case management.

Panel Response: *This characterization was made by the RTI review team. The panel recognizes it may be imperfect.*

• 72-73/16-5: A very problematic point. This gives no guidance to patients nor clinicians about iatrogenesis, and it makes the assumption that "feeling worse" is simply part of the trajectory toward getting better—but that is not accurate. Sometimes "feeling worse" is on the trajectory toward suicide or other harm. This needs to be written in a responsible, balanced way.

Panel Response: *Some additional text was added to the document to note that "feeling worse" could be the trajectory and warrants discussion.*

• The only mention of the stage-based approach to PTSD treatment is early on as an aside about Australian treatment guidelines. Yet the majority of U.S. PTSD experts endorse a stage-based approach (Cloitre et al., 2011). For clinicians, the stage-based approach should be described and the various models that were reviewed should be placed into the stages.

Panel Response: *The panel added some brief material about the stage-based approach but felt this should be very limited in this particular document as that was not a focus of its review. It may however be included in more of the D&I materials.*

• 77/12 Seeking Safety is listed as Level A per the 2009 ISTSS treatment guidelines [http://www.istss.org/ISTSS_Main/media/Documents/ISTSS_g18.pdf] but is not listed here as such.

Panel Response: *This has been corrected.*

• 82: some of these weaknesses need to be noted in the Exec Summary. Many readers won't get to pg 82.

Panel Response: *The panel struggled with how much material should be included in an Executive Summary but in response to several commenters some additional material has been added. The panel has tried to stick closely to the evidence it reviewed however, particular when making any conclusions about treatments.*

• 83/21: 'co-existing conditions' should be clarified—any one? or specific ones? Given the exclusions in most PTSD trials (e.g., of people with SUD) it is challenging to understand how this was addressed. Moreover, it should be "co-occurring diagnoses" unless you're referring to other broader conditions such as homelessness, poverty, etc.

• 86/1-3: add to this the many other exclusions (see earlier in this document).
• 88: It's important to include greater SUD expertise in this section. The opioid crisis, the expansion of marijuana legalization, and the many other SUD public health issues make SUD (given its prominence in co-occurring with PTSD) a major issue that should not be addressed so lightly. Page 88 shows a lack of any mention, much less attention, to extremely important issues such as severity of SUD, which directly impacts which PTSD treatments should/should not be recommended for co-occurring SUD. There is no historical mention of why SUD patients have been excluded from the majority of PTSD trials (the reason is based on clinical and published anecdotal observation of dropout and/or worsening of SUD and/or other symptoms in the context of PTSD treatment). There is no mention of how when a PTSD treatment has been tested in PTSD/SUD samples it has always been adapted for SUD and/or conducted in the context of strong SUD treatment. There is no mention of the handful of RCTs on exposure-based PTSD treatments that have been applied/adapted for PTSD/SUD and found no benefit over much less intensive models. There is no mention of the fact that most clinicians lack training in SUD. There is no mention of the workforce and cultural differences between SUD and mental health domains. Finally, the inconsistent language with regard to SUD is an indication of lack of expertise; the language is easily correctable but the expertise is still sorely needed. Page 88 needs substantial rewriting.

Panel Response: *The panel modified the document in several places to reflect the important points above. It is clear that PTSD is complicated, particularly when considering issues related to substance use disorders, gaps in the research literature and other issues noted throughout the document and identified by commenters.*

• 91/19-20: the phrase "is strong" does not appear accurate. The PTSD RCT literature has been limited by numerous exclusions (see earlier) and lack of representation of real-world clinicians and settings. The term "is strong" should be modified directly by those caveats as otherwise it is misleading. More accurate would be: "is strong but within a context of numerous exclusions of vulnerable PTSD samples; the use of highly trained clinicians with advanced degrees that do not represent the typical workforce in community settings; and lack of attention to some other clinically-relevant phenomena (such as how many prior rounds of PTSD treatment the patient has already had, and how much treatment they obtained during the followup treatment that was provided in the study." Etc.

Panel Response: *The panel appreciates the many caveats identified by the commenter but disagrees with adding the proposed language to the document.*

• 92/26-3. This should be mentioned in the Exec Summary. Moreover, no mention is made anywhere of violent PTSD patients—only self-harm is mentioned. Violence is a major exclusion as well in most PTSD trials.

Panel Response: *The panel agrees that violence towards others is an important consideration and acknowledges that it can be an exclusion criteria in PTSD trials. The panel has added some appropriate language in various places in the document.*

• 95-96/24-2: "end of treatment" and "cessation of treatment" are the same thing (cessation means "end"). This needs to be reworded or clarified.

Panel Response: *Thank you for noting this; it has been clarified.*

• 97/6: numerous other research recommendations should be made: cost should be addressed (cost of the treatment, training clinicians in it, etc.). Also some PTSD trials have paid participants to attend

sessions (not simply to fill out questionnaires at assessments); this should be routinely reported. Personality disorders should be assessed.

Panel Response: *The panel agrees that the research recommendations could be extensive and has somewhat expanded its discussion. However, it has not created an exhaustive list of recommendations for future research and instead has focused on those points it believes are most important to advance clinical decision making or are most likely to be widely adopted in research practices at the current time and thus will yield more systematic findings across studies.*

• 98/9-10: Again it states that harm/adverse events were addressed but elsewhere in the midst of the long document it says that most studies don't report on this. Here too greater transparency and accurate wording is needed: "Although we attempted to address harms/adverse events, most studies did not report on that, and thus we cannot come to clear conclusions on this issue."

Panel Response: *The panel disagrees that this is an appropriate statement to add to the document. It is true that the data on harms/ adverse events is not of the same quality as the data on clinical outcomes, thus making it more challenging to draw strong conclusions about this matter but some evidence exists that can inform overall decision making related to the balance of benefits to possible harms/ burdens that is important for selection of treatments.*

Appendix
• 3/Imagery rehearsal therapy was not designed specifically for PTSD/SUD, to my knowledge.

Panel Response: *The original definition is how the treatment was described in the systematic review but a more accurate description of the treatment is now included in the appendix.*

• Regarding preferences for treatments see below (it's a study of clinicians' preferences and includes numerous models covered in the APA document).

http://www.treatment-innovations.org/uploads/2/5/5/5/25555853/2011_key_inform_txs_pa_jart.pdf

• 456/ the timing of '25 sessions' listed and the 'settings' comment based on that are inaccurate. Various trials, such as Hien et al. 2009 and Hien et al. 2015 used a partial dose (12 sessions). Also the model does not require 25 sessions, per the book and writings on the model.

Panel Response: *The panel attempted to identify and correct inaccuracies as noted by the commenter.*

Overall the document sets out with ambitious, laudable goals and reflects enormous effort. The end result is exceptional in its focus on methodology, but very weak in its real-world implications regarding important clinical topics that will-- and should-- directly impact clinicians' choice of treatments (e.g., complexity of clients, iatrogenesis, dropout, etc.). Although these issues are named and it is correctly stated that there is not enough research on these topics in the PTSD literature, the conclusions of the Exec Summary and the tables (Treatment X is 'strongly recommended', etc.) do not adequately reflect the limitations of the literature with regard to these issues. The PTSD literature is young and needs much greater real-world research and to prematurely use language like "proven" treatments, "strongly recommend" etc. without immediate caveats does a disservice to patients and clinicians in those real-world settings. The strong focus on removing COI and the inclusion of community clinicians and patients is excellent, but in the end, the tone of this document overwhelmingly appears to reflect the academic panel (and the original RTI document). I think it is not acceptable to draw such major

conclusions given the serious gaps in the research. Greater humility in the conclusions is warranted given the long list of limitations in the literature. The document identifies many of those gaps toward the end of the document, but this does not temper its strong wording earlier in the Exec Summary and the Tables.

Panel Response: *The panel appreciates the comprehensive review and detailed comments. The panel believes that the document has been improved as a result of attending to these careful comments. The panel also recognizes the concerns and limitations identified in the above paragraph. It hopes that the revision has addressed some of these concerns and expects that others will be addressed in the materials utilized for D&I.*

Committee on Early Career Psychologists Tyson Bailey; tdbaileypsyd@gmail.com

• The focus on evidence base was well done and adds a unique element over other practice guidelines that have been produced. However, we have concerns about how many studies were left out based on the criteria.
• The use of actual and potential harm in the analysis is an exciting and important development.
• The common factors section is insufficient given the importance in therapy. We are glad to see it addressed, but believe the section could benefit from more content and a further discussion, particularly for clients who have experienced trauma.
• The culture and diversity section is incredibly basic given the richness of the literature in this area. Particularly since issues of intersecting identities are a common reason individuals have experiences that lead to posttraumatic presentations (e.g., gay bashing), it is critical that these issues are more fully addressed. We strongly recommend increasing this section to highlight the importance of thinking about these issues within treatment.
• There appears to be limited discussion of the fact that the strict criteria created a database of only RCTs. There is a significant amount of research being done in non-academic or institutional settings that cannot obtain the same level of funding, and therefore, cannot run the same rigor of studies. While this issue is somewhat addressed in the justification and summary sections, it raises concerns that the selection criteria created a bias in the data set toward studies that have more funding.
o This appears particularly likely with EMDR, as the findings of this committee are at odds with all other published guidelines and a long history of research.
• Regarding the first recommendation, cognitive behavioral therapy is a broad construct that has many variations. The committee might consider outlining active ingredients of cognitive behavioral therapy that are thought to influence PTSD symptoms, so as to provide consumers of the guidelines with more direction regarding the essential components of CBT for PTSD.
• The authors are encouraged to clarify what is meant by "exposure" in recommendation #4 (e.g., imaginal, in-vivo). Is one alone sufficient or are both types of exposure necessary to result in "medium to large magnitude benefit"?
• The authors state that a recommendation cannot be made regarding choosing between Seeking Safety and active controls due to insufficient evidence. The committee might consider reporting evidence for controls that performed as well as trauma-focused therapies in reducing PTSD symptoms (e.g., Present Centered Therapy in Schnurr, P. P., Friedman, M. J., Foy, D. W., Shea, M. T., Hsieh, F. Y., Lavori, P. W., ... & Bernardy, N. C. (2003). Randomized trial of trauma-focused group therapy for posttraumatic stress disorder: Results from a Department of Veterans Affairs cooperative study. Archives of General Psychiatry, 60(5), 481-489. and Classen, C. C., Palesh, O. G., Cavanaugh, C. E., Koopman, C., Kaupp, J. W., Kraemer, H. C., ... & Spiegel, D. (2011). A comparison of trauma-focused and

present-focused group therapy for survivors of childhood sexual abuse: A randomized controlled trial. Psychological Trauma: Theory, Research, Practice, and Policy, 3(1), 84-93.).
• We appreciate the authors highlighting gaps in the literature and encouraging future research investigating potential moderators of treatment outcomes, particularly gender differences, cultural differences, and chronic/complex PTSD.

Panel Response: *The panel appreciates the review of the Committee on Early Career Psychologists. Many of the points raised by CECP have been addressed elsewhere in this document (such as selection of research). However, the panel did want to respond to the comments on common factors and culture and diversity. As CECP members alluded, these are areas rich in theory in research in the psychological literature. However, the panel does not believe that these guidelines are a review paper for these issues. This is another rich area of inquiry that will likely be referenced in the dissemination and implementation aspect of the initiative. The panel's scope has been on addressing the question of what is the evidence base for the efficacy of psychological and pharmacological treatments for PTSD, an area that has been fraught with some controversy in and of itself. It is evident that much more research is warranted and the panel looks forward to the continued growth of the field. The panel also anticipates that APA and its partners, such as Division 56, will develop some of the resources suggested by the comments above in its efforts to improve the treatment of PTSD.*

Once again, the panel thanks the almost 900 individuals who took the time to review the guideline and provide feedback. All comments were read and were used to improve the final document. The panel believes this is a strong foundation to base continued work on the development and implementation of treatments for PTSD.