AMERICAN PSYCHOLOGICAL ASSOCIATION

Date: June 2018

From: Society of Pediatric Psychology, American Psychological Association Division 54

To: Pediatrician Colleagues and Other Pediatric Medical Providers

Re: Summary of Research Findings Relevant to Pediatric Care

Following is a summary of published research findings in the Society of Pediatric Psychology peer reviewed journals (and several other journals featuring the work of pediatric psychologists/trainees). We believe this information may be helpful to your own practice, with citations provided for further information. Please contact me with feedback or questions. Sharon.Berry@ChildrensMN.org

Sharon Berry, PhD, ABPP

Trial of Amitriptyline, Topiramate, and Placebo for Pediatric Migraine.
Powers, S.W., Coffey, C.S., Chamberlin, L.A., Ecklund, D.J., Klingner, E.A., Yankey, J.W., Korbee, L.L., Porter, L.L., Hershey, A.D., CHAMP Investigators. (2017) *New England Journal of Medicine*, 2017 Jan 12; 376(2):115-124. Published online first, Oct 27, 2016 at NEJM.org.

This NIH-funded, multi-center, double-blind Phase 3 clinical trial (The Childhood and Adolescent Migraine Prevention trial [CHAMP Study]) examined the two most commonly prescribed prevention medications for pediatric migraine (amitriptyline and topiramate). The goal was to provide evidence for primary care providers and specialists about which may be the optimal first-line medication (with information about safety, dose, duration of care, and impact on headache days and disability). The trial was stopped early due to futility. Amitriptyline at a dose of 1 mg/kg/day and topiramate at a dose of 2 mg/kg/day were not found to be any more efficacious than placebo. In the primary analysis, the relative reduction of 50% or more in the number of headache days over a 28 day period was observed in 52% of the participants who received amitriptyline, 55% of those who received topiramate, and 61% of those who received placebo.

No differences were observed in any of the trial sensitivity analyses, on the analysis of absolute reduction in number of headache days, or the analysis in change in headache related disability. Both medications produced adverse events that were greater than placebo. Serious adverse events occurred in each medication group. Of note, relative to the very few other trials of prevention medications in youth with migraine, this study included a more real-world sample of children and adolescents. Prior trials often limited headache days to no more than 12 per month;

the CHAMP Study included baseline headache days from 4 to 28 per 28 day period (M of 11.4 +/- 6.1) and the sample characteristics are quite representative of the types of patients that are seen in practice. The authors concluded that there was a lack of a favorable risk to benefit profile to suggest use of these two therapies for prevention of migraine in pediatric and adolescent patients.

The Childhood and Adolescent Migraine Prevention (CHAMP) Study: "What do we do now?" Invited Guest Editorial.
Powers SW**,** Hershey AD, Coffey CS, CHAMP Study Group (2017) *Headache* Feb; 57:180-183).

An earlier trial (Powers, S.W., Kashikar-Zuck, S.M., Allen, J.R., LeCates, S.L., Slater, S.K., Zafar, M., Kabbouche, M.A., O'Brien, H.L., Shenk, C.E., Rausch, J.R., Hershey, A.D. (2013) Cognitive behavioral therapy plus amitriptyline for chronic migraine in children and adolescents: a randomized clinical trial. *JAMA,* 2013 Dec 25; 310(24):2622-30) focused on chronic migraine (15 or more headache days per month) and found that combining cognitive behavioral therapy with amitriptyline was superior to this medication plus education, and a recent Cochrane review (Eccleston C, Palermo TM, Williams A, et al. Psychological therapies for the management of chronic and recurrent pain in children and adolescents. *The Cochrane Library* 2014) provided strong evidence for cognitive behavioral therapy for pediatric headache. As a result of these recent pediatric migraine studies, our group at Cincinnati Children's Hospital is seeing a notable increase in referrals of youth with migraine for evidence-based cognitive behavioral therapy as a first line intervention for patients. It is likely that pediatricians, family practice physicians, neurologists, and adolescent medicine specialists – among other providers – will be seeking colleagues who can help youth and families by providing proven non-pharmacological therapy versus writing a prevention medicine prescription. Multidisciplinary care remains the standard for these patients, with recent evidence pointing toward the importance of early intervention with cognitive behavioral therapy.