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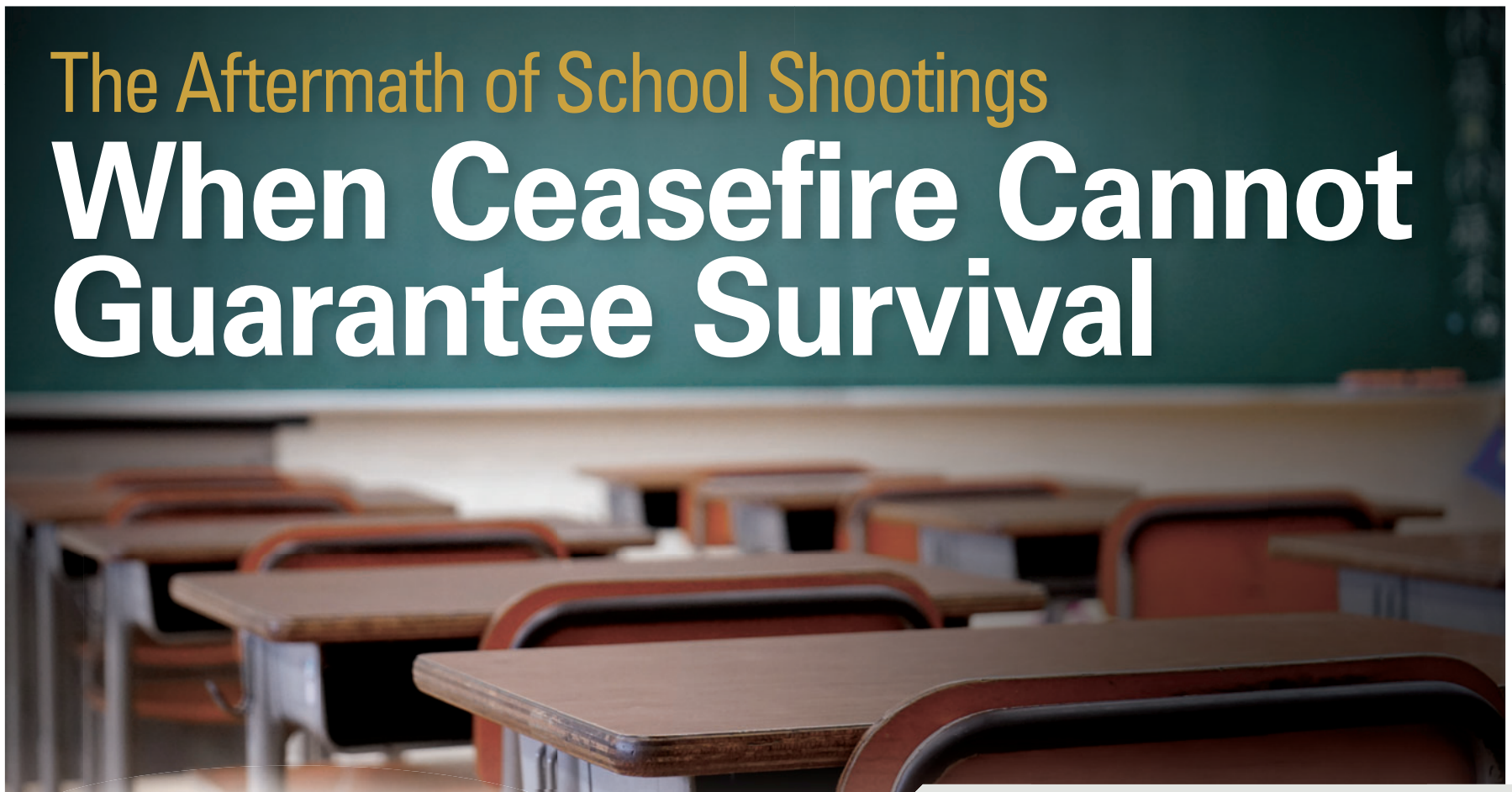

The Aftermath of School Shootings

When Ceasefire Cannot Guarantee Survival

» Phebe Tucker, MD and Eleanor Lastrapes, MD

The recent suicides of two teenaged survivors of the 2018 school shooting at Marjory Stoneman Douglas High School in Parkland, Florida and the father of a child killed in the 2012 Sandy Hook Elementary School shooting raise the question of the interplay and impact of survivor guilt, post-traumatic stress disorder, and traumatic bereavement among survivors and victims' loved ones after such traumatic events. Alarmingly, these three suicides occurred within a 10-day period. The mother of one shooting survivor who died by suicide shared publicly her daughter's PTSD and survivor guilt. The father of the young Columbine victim had struggled with prolonged grief over 6 years after his daughter's death, according to his wife. In addition, suicides have also occurred in the wake of the Columbine and Virginia Tech school shootings.

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Out of the Mouth of Babes: School Shooting Survivors Share Their Insights, Concerns

» Heidi Anne Duerr, MPH

Despite the outpouring of support, are survivors of mass shootings getting the care they really need?

In the days following the three suicides of school shooting survivors and in anticipation of the 20th anniversary of the Columbine shooting, Parkland and Columbine students took time to contemplate the attacks and how their lives have been affected. Both groups have been outspoken about the need for better approaches to assisting survivors in the days, weeks, months, and years following such tragedies.

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ISSUE HIGHLIGHTS

tablishing a reasonable time frame during which the work-relevant functional impairment can be expected to be reversed given the patient's full compliance with the recommended treatment.

By employing the tools of a Functional Assessment, psychiatrists can introduce a more objective standard that is needed in disability evaluations and prognosis for a return to work.

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ELECTROCONVULSIVE THERAPY

The FDA on ECT

Supporting a Vital Treatment

» Charles H. Kellner, MD

After many years of inaction, the FDA issued a final order on the classification of ECT devices in December, 2018.[1,2] The very good news is that the order allows for ongoing availability of ECT devices in the US; the slightly less good news is that the new list of "on label" indications for ECT is shorter than in the past. To understand the implications of the new order, let's review some of the background leading up to it, as well as the state of ECT in the US today.

Modern ECT allows virtually all patients who need this modality to be treated safely, effectively, and with a level of tolerability previously unheard of.

The FDA regulates medical devices as well as drugs. As you might imagine, some aspects of this regulation are straightforward and easy to understand, but some are complicated, arcane, and highly bureaucratic. (For a review of earlier FDA actions leading up to the recent order, please see https://www.psychiatrictimes.com/electroconvulsive-therapy/fda-advisory-panel-reclassification-ect-devices.) Medical devices are classified into three risk categories, with Class I considered the safest, Class III the riskiest.

Until now, ECT devices had been "grandfathered" into Class III for all indications, and the list of "cleared indications" was depression (unipolar and bipolar), schizophrenia, bipolar manic (and mixed) states, schizoaffective disorder, schizophreniform disorder, and catatonia. That list conforms well to the generally accepted uses of ECT in the US. The FDA needed to update the classification of all "grandfathered" devices, and the process (this is the complicated part) would require "premarket approval" for indications that would not be moved from Class III to Class II. Premarket approval typically requires new controlled clinical trials to demonstrate safety and efficacy, a requirement that would not be feasible, for both financial and ethical (the inappropriateness of subjecting very seriously ill psychiatric patients to placebos) reasons. Thus, it was crucial that some (at least one) of the previously "cleared indications" be moved to Class II, in order not to interrupt the availability of ECT devices for the US market.

The new ruling does just that: it moves two indications (depression and catatonia) into Class II, with "special controls." The "special controls" are a series of requirements regarding technical parameters of the devices, labeling about adverse effects, practitioner training, and a few aspects of clinical practice.

So, what are the implications of the FDA order reclassifying ECT devices for ECT practice in the US? Most importantly, the move of the depression indication into Class II insures that the majority of ECT patients will continue to be treated without any change in their care. The way the order is written for this indication (that the depression should be "a severe major depressive episode associated with major depressive disorder or bipolar disorder in patients aged 13 years and older who have treatment resistance or who require a rapid response due to the severity of their psychiatric or medical condition") mirrors closely clinical practice for the majority of patients referred for ECT in contemporary US practice.

The move of the indication "catatonia," to Class II is also very important, but applies to a much smaller subset of ECT patients, perhaps no more than 5%.[3,4] In my estimate, the two indications moved to Class II constitute 60% to 70% of current American ECT practice.

What about the other 30% to 40%? The FDA order makes it very clear that the FDA does not regulate clinical practice; they actually say this several times in the text accompanying the order: "FDA does not regulate the practice of medicine (see section 1006 of the FD&C Act [21 U.S.C. 396]). Diagnosis and treatment of patients are clinical decisions that fall within the practice of medicine." In other words, practitioners are free to continue to prescribe ECT for any patient, regardless of diagnosis, whom they feel would benefit from the treatment.

This is similar to the freedom to use a medication for an off-label indication. The fact that the FDA chose to leave schizophrenia, schizoaffective disorder, and mania in Class III is perplexing and disappointing. Globally, schizophrenia may be the leading indication for ECT, and the clinical and research evidence base supports ECT as safe and effective for this illness.[5-7]

One of the issues related to the FDA's consideration of reclassification of indications is that they have a bundled, unitary concept of "safety and effectiveness." Thus, their review panel may not have been convinced by the data for effectiveness of ECT in schizophrenia, but this has no bearing on safety. In fact, there is no reason to believe that the safety profile of ECT differs by psychiatric diagnosis.

Overall, the FDA order allows patients who need and want ECT, as well as practitioners who perform it, to breathe a sigh of relief. ECT will continue to be an important, albeit small, part of the psychiatric armamentarium landscape. From speaking with fellow ECT practitioners around the country, it is apparent that ECT use is increasing. The ongoing enthusiasm for transcranial magnetic stimulation and ketamine (intravenous or intranasal) has done little to decrease the demand and need for ECT; indeed, many of the patients whom we see in ECT consultation have tried those newer treatments but the treatments have failed.[8]

The psychiatric community has a responsibility to support and promote treatments that are in the best interests of our patients, those treatments with a track record of safety and effectiveness. ECT certainly fits that bill. But organized psychiatry has always been a tad, or more, ambivalent about supporting ECT. Amazingly, there is no official path to training in ECT, there is no board certification, and it is unclear if the next generation of ECT practitioners

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READ MORE For a review of earlier FDA actions leading up to the recent order, please see **https://www.psychiatrictimes.com/electroconvulsive-therapy/fda-advisory-panel-reclassification-ect-devices**

Pharmacogenomics

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portant psychiatric topic of pharmacogenomics. Despite this, only four genes (*CYP2D6*, *CYP2C19*, *HLA-B*15:02*, and *HLA-A*31:01*) have been vetted as clinically actionable by the two organizations that were established to monitor and curate the pharmacogenomic literature. Curiously, there are numerous laboratories that market pharmacogenetic tests, as well as "gene panels," that have not yet reached a level of evidence base to inform meaningful clinical decisions on medication choices. The savvy clinician should continue to monitor the pharmacogenomics literature and utilize the constantly updated CPIC and International Society of Psychiatric Genetics websites to remain appraised of the additions of new genes as they cross the evidence-based threshold.

References

1. Yoshida K, Muller DJ. Using pharmacogenetics in making treatment decisions for schizophrenia. *Psychiatric Times*. 36(3):19-21.
2. Zeier Z, Carpenter LL, Kalin NH, et al. Clinical implementation of pharmacogenetic decision support tools for antidepressant drug prescribing. *Am J Psychiatry*. 2018;175:873-886.
3. Nurnberger Jl Jr, Austin J, Berrettini WH, et al. What should a psychiatrist know about genetics? Review and recommendations from the Residency Education Committee of the International Society of Psychiatric Genetics. *J Clin Psychiatry*. 2019;80:17nr12046.
4. Zubenko GS, Sommer BR, Cohen BM. On the marketing and use of pharmacogenetic tests for psychiatric treatment. *JAMA Psychiatry*. 2018;75:769-770.
5. Rosenblat JD, Lee Y, McIntyre RS. Does pharmacogenomic testing improve clinical outcomes for major depressive disorder? A systematic review of clinical trials and cost-effectiveness studies. *J Clin Psychiatry*. 2017;78:720-729.
6. Singh AB, Bousman CA. Antidepressant pharmacogenetics. *Am J Psychiatry*. 2017;174:417-418.
7. Preskorn SH. Genetic and related laboratory tests in psychiatry: What mental health practitioners need to know. *Curr Psychiatry*. 2016;15:19-22.
8. Rosenblat JD, Lee Y, Mansur RB, et al. Letter to the editor: Inadequate evidence to support improved patient outcomes with combinatorial pharmacogenomics. *J Psych Res*. 2018;107:136-137.
9. Goldberg JF. Do you order pharmacogenetic testing? Why? *J Clin Psychiatry*. 2017;78:1155-1156.
10. US Food and Drug Administration. The FDA Warns Against the Use of Many Genetic Tests With Unapproved Claims to Predict Patient Response to Specific Medications. https://www.fda.gov/medical-devices/safety-communications/fda-warns-against-use-many-genetic-tests-unapproved-claims-predict-patient-response-specific. Accessed May 13, 2019.
11. Mortimer O, Lindstrom B, Laurell H, et al. Dextromethorphan: polymorphic serum pattern of the O-demethylated and didemethylated metabolites in man. *Br J Clin Pharma*. 1989;27:223-227.
12. PharmGKB. https://www.pharmgkb.org. Accessed May 13, 2019.
13. Clinical Pharmacogenetics Implementation Consortium. https://cpicpgx.org. Accessed May 13, 2019.
14. Hicks JK, Bishop JR, Sangkuhl K, et al. Clinical Pharmacogenetics Implementation Consortium (CPIC) Guideline for *CYP2D6* and *CYP2C19* genotypes and dosing of selective serotonin reuptake inhibitors. *Clin Pharmacol Ther*. 2015;98:127-34.
15. International Society of Psychiatric Genetics. Genetic Testing Statement. https://ispg.net/genetic-testing-statement. Accessed May 13, 2019. ❐

FDA on ECT

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will be large enough for the need. In a country with 49,000 psychiatrists, it is estimated that fewer than 1000 actually practice ECT.

Modern ECT allows virtually all patients who need this modality to be treated safely, effectively, and with a level of tolerability previously unheard of. The proper understanding and contextualization of the (largely transient) cognitive effects of ECT suggests that exaggerated concerns about this adverse effect should not interfere with the appropriate prescription of a potentially life-saving treatment.

We believe that the adverse cognitive effects of ECT should be considered a tolerability and not a safety issue. In medicine, safety refers to the risk of physical injury or death. To elevate cognitive adverse effects to this level perpetuates the stigma surrounding ECT.

The most apt analogy to properly contextualize the seriousness of depressive illness weighed against the risks of ECT is cancer and chemotherapy. Many cancers are lethal, life-threatening illnesses for which treatments (surgery, chemotherapy, and radiation) carry considerable risks. Patients rarely categorically refuse cancer treatments because of concerns about adverse effects, yet this happens frequently with ECT. Our contention is that refusing ECT because of concerns about memory loss is equivalent to refusing cancer chemotherapy because of concerns about hair loss.

These effects are unpleasant and upsetting, but not worth risking one's life over. Just as the side-effects of chemotherapy abate, so too do those of ECT; most of the hair grows back, most of the memories return, and the patient's life is saved.[9]

The FDA order removes what was a potentially dark cloud on the horizon of ECT. It continues to be the responsibility of our field to train an adequate number of ECT practitioners and to counter unsubstantiated attacks by the anti-psychiatry movement through education and ongoing contributions to the research evidence base for ECT.

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References

1. Food and Drug Administration. Neurological Devices; Reclassification of Electroconvulsive Therapy Devices; Effective Date of Requirement for Premarket Approval for Electroconvulsive Therapy Devices for Certain Specified Intended Uses. Final order. *Fed Regist*. 2018;83:66103-66124.
2. McDonald WM, Weiner RD, Fochtmann LJ, McCall WV. The FDA and ECT. *J ECT*. 2016;32:75-77.
3. Fink M, Kellner CH, McCall WV. Optimizing ECT technique in treating catatonia. *J ECT*. 2016;32:149-150.
4. Fink M. Rediscovering catatonia: the biography of a treatable syndrome. *Acta Psychiatr Scand Suppl*. 2013;(441):1-47.
5. Leiknes KA, Jarosh-von Schweder L, Høie B. Contemporary use and practice of electroconvulsive therapy worldwide. *Brain Behav*. 2012;2:283-344.
6. Grover S, Sahoo S, Rabha A, Koirala R. ECT in schizophrenia: a review of the evidence. *Acta Neuropsychiatr*. 2018 Dec 3:1-13.
7. Sanghani SN, Petrides G, Kellner CH. Electroconvulsive therapy (ECT) in schizophrenia: a review of recent literature. *Curr Opin Psychiatry*. 2018;31:213-222.
8. Kellner CH, Greenberg RM, Ahle GM, Liebman LS. Electroconvulsive therapy is a standard treatment; ketamine is not (yet). *Am J Psychiatry*. 2014;171:796.
9. Kellner CH, Farber KG. Electroconvulsive therapy and cognition: a salutary reappraisal. *Acta Psychiatr Scand*. 2016;134:459-460. ❐

Islamophobia

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socio-ecological model to describe vulnerability and resilience to Islamophobia and its resulting psychosocial problems. In such context, community engagement strategies, "a bottom-up approach," seeks and finds self-sustainability, growing social support, and overall positive results. Rich and transparent principles will have to face, however, strong logistic demands: providing community members with the opportunity to advocate for their needs and participate in the design of sensitive interventions is easier said than done. Experience shows that critics of this approach will quickly label these efforts as "socialist" infiltrations, and conservative sectors may very well impede the provision of financial and human resources. Yet, it describes encouraging results from several ongoing projects in California. Whether this can reach other parts of the country and the world where Islamophobia and related conditions (fed by authoritarianism, oppression, rejection, demagoguery, and/or hatred) dominate, remains a challenging reality.

In short, this book represents a laudable initial effort to study a social phenomenon of somberly complex characteristics. It is multidisciplinary and, as such, recognizes the strong bio-psycho-socio-cultural-spiritual basis of Islamophobia. It presents a solid historical background about Islam, analyzes the different doctrine-based perspectives on the psychological/mental nature of Islamophobia, exhibits artistic illustrations, and succeeds in describing clinical outcomes. Among its few setbacks one can mention is a mild trend toward conceptual repetitiousness, some lack of precision in diagnostic and therapeutic proposals, some theoretical excesses and polemic political pronouncements, and a small number of editing typos. The 20 items listed in the Editors' Conclusions, however, show concrete evidence of a job well done.

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