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Submission For The Record of CNS Response

Hearing on 11/19/2014: Legislative Hearing

Submission for the Record

House Committee on Veterans Affairs, Subcommittee on Health

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In July, we asked that the Committee take note of the growing role of predictive analytics in reducing harm from mental health medications chosen by trial and error. Our news today is very positive, and it is our belief that HR 5059 may accelerate adoption of such innovations.

Suicide Prevention — the best place to start is to avoid the wrong medications

In mental health, the elephant in the room is that standard treatments don't work very well, and evidence for them has deteriorated substantially since the medications were first approved. Since each medication used to treat mental disorders carries an FDA "black-box warning" for suicidality, reducing trial and error treatment is a military imperative.

Predictive analytics — in the form of PEER Interactive — have significantly reduced trial and error in multiple clinical trials. Results of the Walter Reed PEER Trial became clear in the first 10% of trial enrollment, as shared with Congress in April. Statistically significant results have been reported for physicians who followed PEER recommendations vs. physicians who did not follow PEER, including:

- 75% greater improvement in Suicidality scores
- 144% greater improvement in Depression scores
- 139% greater improvement in Post-Traumatic Stress Disorder (PTSD) scores
- 43% more patients remained in treatment, with more than 50% improvement in treatment efficiency

As every PEER trial has demonstrated, **doctors with more information achieve better outcomes.** From a budget standpoint, we can no longer afford trial and error prescribing of medications as our dominant treatment, with costs that are 4 times higher than effective first-line treatment. And the human costs of trial and error therapy, for veterans and their families, are intolerable.

Preventable medical error — the problem

In July, the parents of Clay Hunt and Daniel Somers gave us stories that were hard to hear: they spoke of treatment delays, trial and error pharmacotherapy, and inexplicable differences in treatment between facilities. Still, VHA faces challenges in improving access, because:

- VHA cannot hire clinicians fast enough - only 681 residents enter the specialty each year
- Clinicians in private practice cannot fill the gap - only 13% have capacity (per RAND)
- Current treatments are not effective enough to prevent dropouts

Comment on HR 5059
- We ask the Subcommittee to be cognizant of the severe supply limitations in Psychiatry, which impacts hiring and retention of mental health professionals.
- We recommend that VHA prioritize research on physician extending technologies, like PEER, which can multiply the reach of VHA's current pool of Psychiatrists.

The Military response to preventable error

In September 2014, Defense Secretary Hagel committed to "system-wide improvements in quality and safety", with a mandate to reduce preventable error across the board and to achieve results that are not just average, or above average, but the best in class. The review was prompted by internal reports and a New York Times series finding widespread evidence of preventable error.

By the end of the year, each military hospital must have metrics in place to track quality improvement. Army Surgeon General Patricia Horoho articulated some of the principles behind this system-wide commitment to reducing preventable error:

- Take corrective action immediately — at the point of care
- Ensure transparency and accountability
- Use outcome data to improve the quality of treatments

The Army Surgeon General's leadership is welcome, and we believe the hard lessons of its adoption path can be useful for the VHA in the course of its transformation under Sec. McDonald.

Comment on HR 5059
- Performance Metrics and Annual Independent Review are critically important components of 5059 — the only way to drive out fear of reporting and address root causes.
- Standards of evidence - VHA must set clear and transparent standards for evidence of superiority, so new innovations can be rapidly tested and adopted.
- Need to improve on VHA's ability to rapidly execute public-private partnerships.

Emerging Technology Improves the Odds

Physicians in the 1990s made a surprising discovery: if they could match known medication outcomes to a standard test of electrophysiology, they could target medications directly to patients who would be more likely to respond to a particular agent. Even better, they could avoid the wrong medications. Just like most other specialties, where doctors use tests like x-rays, blood tests, or bone scans to guide their choice of treatment. The database, which now exceeds 37,000 clinical endpoints for 10,000 unique patients, is called PEER (Psychiatric EEG Evaluation Registry).

PEER is an outcome registry and recommendation engine based on machine-learning, so outcomes in this trial can make future generations of the PEER Report more predictive and useful to physicians. This same approach was pioneered by pediatric oncologists beginning in the 1970s, when cancer registries allowed physicians to better match treatments to patient phenotypes, driving cure rates for childhood cancers approaching 90% today.

The Walter Reed PEER Trial

The Walter Reed PEER Trial is designed to follow up to 1,600 soldiers under a public-private partnership with Walter Reed National Military Medical Center. First interim results focused on 150 evaluable subjects who were treated for up to six months at Walter Reed National Military Medical Center and Fort Belvoir Community Hospital, two of the nation's largest psychiatric treatment centers for active military members.

The findings have been peer-reviewed for publication in Neuropsychiatric Disease and Treatment, the journal of the International Neuropsychiatric Association. Each of the interim trial results above were statistically significant, and were consistent with multiple prior studies of PEER technology. Accordingly, the FY15 Defense Appropriations Bill calls for expansion of this approach:

> **Prescription Effectiveness of Psychotropic Medications…**
> *The Committee understands that this research is currently taking place at Walter Reed NMMC and Ft Belvoir Community Hospital and encourages its expansion to additional sites as preliminary findings have shown promising early results.*

Cumulative evidence
While the evidence base for antidepressants has worsened in recent years, the evidence base for quantitative EEG biomarkers has grown: there are now 98 controlled trials of EEG-medication response prediction, representing 6,025 subjects. Most were independent studies of similar technologies or sub-components of PEER, with 6 controlled studies sponsored by CNS Response

Conclusion

Improving medication performance for our veterans is a problem that neuroscience can answer, that can improve lives today. We support passage of HR 5059, to help the VHA accelerate adoption of the best evidenced-based psychiatric care that our country has to offer.