

Statement of CSAM Principles

RE: Evidence-Based Medicine

CSAM members receive multiple inquiries from the news media seeking information about addiction treatment. If you are contacted, you may, of course, speak freely as an individual physician; however, if you include your CSAM membership in your response or bio, we ask that you provide the following position of the society.

CSAM's mission is:

To advance the treatment of alcoholism and other addictions through education of physicians, physicians-in-training, and other health professionals. Additionally, the Society promotes research, prevention, and implementation of evidence-based treatment.

Evidence-Based Treatment:

Although our organization has never served the function of evaluating or policing specific treatments or treatment providers, we do stand for excellence in the scientific rationale underlying addiction treatment. The two most fundamental principles guiding CSAM are our commitment to

1. Evidence-based medicine (EBM) and
2. A Public Health approach to the treatment of addiction that combines concern for both the health of the individual and the safety of the general public.

A closer look at what evidence-based medicine means is helpful. The term first appeared in the medical literature in 1992 (G. Guyatt et al, *JAMA* 268:2420-5) as an evolving approach to the teaching of medicine. EBM offers a tested scientific point of view that references applied clinical research when filtered through standards of evidence designed to minimize bias by the use of strong statistical designs.

Several frameworks have been advanced for evaluating the level of credibility of research findings. A simple framework, recommended by the US Government Agency for Health Care Policy and Research, has three levels:

- A. Requires a least one randomized controlled trial (RCT) as part of the evidence
- B. Requires well-controlled clinical studies, but no RCT
- C. Requires clinical experience of respected authorities

Other frameworks make finer distinctions among different levels of evidence (e.g., Oxford Centre for EBM Levels of Evidence), but the thrust of each is the same. The “gold standard” for credibility is met by randomized, double-blind, placebo-controlled trials, with multi-site studies being preferred to single-site studies. The unique advantage of randomization is that it enables researchers to evaluate whether the intervention (or

product) itself, as opposed to other factors, causes any observed benefit. RCTs are the only method capable of eliminating bias. Less reliable are controlled studies without randomization. Single group “pre-post” studies, for example, run the risk of attributing improvement to an intervention when the improvement would have happened without the intervention.

Still less reliable are “open label” studies in which there is no placebo and patients know the treatment they are receiving. Prospective longitudinal studies are more highly rated than retrospective. The least reliable evidence comes from patient testimonials, case reports, and even expert opinion because of placebo effects and biases inherent in expectations. In contrast to traditional medical practice, evidence-based medicine has downgraded the power of ad hoc clinical experience. When “experts” also have a professional or financial stake in the success of any treatment that they are promoting, anecdotal evidence loses validity.

Although randomized controlled studies remain the gold standard for EBM, they must be well designed and implemented. The following OMB criteria defined a well-designed and implemented RCT (www.whitehouse.gov/omb/part/2004_program_eval.pdf):

1. The study should clearly describe the intervention.
2. The study should use placebo controls if participants’ beliefs that they are receiving an intervention may plausibly affect their outcomes.
3. The random assignment process should include safeguards to ensure it is not compromised.
4. The study should provide data showing that, prior to the intervention, the intervention and control groups do not differ systematically.
5. The study should use valid outcome measures – i.e., that accurately measure the true outcomes that the intervention is designed to affect.
6. The study should have low overall attrition, with no differential between controls and intervention groups.
7. The study should use an intention-to-treat approach.
8. The study should preferably obtain data on long-term outcomes.
9. Power analyses should assure that sample sizes are adequate.
10. All outcomes should be reported, not only positive effects.

Evidence-based medicine does have limitations. Not all research conclusions make it into the literature, which often obscures negative results. Some forms of treatment do not permit placebo controls for ethical or practical reasons (i.e., sham treatment). Expense can limit research. Lack of evidence and lack of benefit are not the same. Results that apply to populations may not apply to a single individual. The generalizing of results from one population to other populations is often in question (i.e., from a population of

men to one of women). Slavish adherence to EBM could promote a "cookbook" approach to medicine. The more complex problems are poor subjects for RCT research.

CSAM supports the longstanding authority of physicians to do "off-label prescribing," that is to try previously approved medications for new indications. However, under such circumstances their patients should be thoughtfully informed that the prescription is an off-label trial.

CSAM has concerns whenever the marketing for a new product or treatment protocol gets ahead of the evidence for both its safety and efficacy. While not every form of treatment can be researched with protocols that meet the gold standard for credible evidence, CSAM supports the principle that those products and protocols that can be researched at high levels of evidence-credibility should be, before their benefits are promoted and adopted as proven forms of treatment.

CSAM's endorsement of evidence-based medicine leads us to support the position expressed by Nora Volkow, Director of NIDA, regarding any addiction treatment that lacks sufficient evidence of its efficacy and safety:

...it has become extraordinarily important for us to provide objective evidence of the effectiveness of treatment interventions....Do I support the utilization of treatments that are not evidence-based? No, I do not.

In the field of drug addiction, it has been very, very difficult to change the culture to accept drug addiction as a disease and as you know, we are treated differently in that private insurances do not cover the treatment. Why? Because they say drug addiction treatment does not work.

And so it has become extraordinarily important for us to provide objective evidence of the effectiveness of treatment interventions. And it is harmful to the field to promote any treatment without that evidence, because it serves to... propagate the sense that treatment does not work."

CSAM recommends that physicians use caution when recommending unproven treatments for substance abuse.