Evidence-based Medicine

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What to do?

I am writing an opinion piece on the management of psychosis in Parkinson's disease. My responsibility is, of course, to review the literature, and propose an algorithm. At risk of being immodest, I like to think I am an expert in this disorder, and have the experience to merit the status of providing an expert opinion. My problem was how to recommend a particular drug that I find very helpful in the face of three, well-performed, adequately powered clinical trials demonstrating a lack of statistically significant benefit. Evidence-based medicine is based on evidence, and the evidence indicates that the drug is not effective. In trials of this medication at much higher doses in a very different population, the drug had some adverse effects, and in meta-analyses, involving very large numbers of patients, the drug has a small but significant increased risk of mortality, large enough to require a "black box warning." So, we have a drug with "proven" lack of efficacy and a black box warning of increased mortality. While it sounds like an easy decision to state the data and not advise its use, the problem is that I've used the drug a lot, probably a lot more for this purpose than all but a few doctors in the world, and I find it to be quite effective.

As I got to the end of my essay and had to write my own advice, I checked some of the published recommendations by others. A recent review from a prominent and estimable European expert group reviewed the data and did not recommend using the drug. An earlier publication by an expert group in the U.S. noted the lack of "proven" benefit but stated that its members thought the drug helpful, not, however, recommending its use, something along the lines of, "despite evidence to the contrary, several members of our committee have found it helpful." (Not a real quote). Another European expert cited the risk, rather than the benefits, in advising against its use

In a quandary I decided I'd do my first Survey Monkey and sent out a single question, to be replied anonymously, asking if the recipient found this drug to be helpful and used it sometimes to treat PD psychosis. I chose 40 people, mostly neurologists, but a few psychiatrists as well, whom I regarded as experts in this area. The result was 19 responses, all in favor of the drug's use. Now, armed with a survey, I can write that I recommend this drug's use, despite evidence to the contrary, and that 19 experts, all of whom are familiar with the three negative studies, also believe the drug to be useful and safe enough to be recommended.

While I believe this was the correct approach, I cannot keep from thinking that for two thousand or more years, bloodletting was a "clearly" efficacious treatment for a number of disorders until falling out of favor, presumably not related to a placebo or active treatment-controlled research study. "Bloodletting vs. penicillin for the treatment of strep throat" would have been unlikely to gain IRB approval.

Evidence-based medicine is always limited by the subject population, either by design or by happenstance. If you study people with PD and bipolar disorder, you don't know if the treatment may also work for people with PD and anxiety. A recent study had inclusion criteria that allowed demented people into the study, but the mean score for the subjects indicated that few, if any, were demented. Since the study drug will be used primarily in PD patients with dementia, what can be deduced? Perhaps more problematic is the heavy reliance on "intention to treat" trials, in which subjects are included in the outcome assessment once they sign an informed consent document and are assigned to a treatment arm, whether they get the treatment or not. A person becomes a "subject" once the informed consent is signed. The subject becomes a data-contributor once randomized to a treatment arm. How useful is an anticoagulant in reducing stroke in atrial fibrillation patients if half the subjects drop out in the first few days because of

side effects and the ones who tolerate the medication have fewer strokes? By one analysis, the standard intention to treat, the medication may not be statistically significant, whereas the "per protocol" analysis, which only assesses those who had the intervention, shows a significant benefit. Different interpretations for the final outcome obviously differ considerably. There are always limitations for evidence-based interpretations in the "real world" of the clinic.

We are all influenced by our last few patients. Our decision making should not be based on this, however, and surveys of experts may well have led to continuation of bloodletting, continued use of hormone replacement therapy for post-menopausal women, skull surgery for Bell's palsy, and the extra-cranial intracranial bypass surgery for carotid occlusion to prevent stroke. We doctors, like everyone else, come to believe that what we do must be correct, since everyone else does it too. There is a wonderful fable by James Thurber, in *The Thirteen Clocks.* A character describes how he started a rumor, a complete fabrication, that gold had been discovered someplace, which precipitated a mass exodus of people to mine the gold. The person telling the story reports that he, too, joined the exodus. "Everyone else went, so I figured there must be something to it."

I don't see how to resolve this problem, which will continue to dog clinicians forever. ❖

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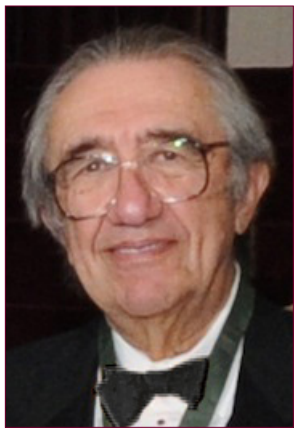
Civil commitment laws for substance abuse treatment: An acceptable option?

HERBERT RAKATANSKY, MD

A recent story in the Providence Journal describes a "life saving" intervention on an unconscious passenger in a car. The driver stopped a passing police vehicle and the passenger was given 4 doses of Narcan. He was sent to a hospital ER where he was treated and released.



Our society currently is ravaged by a disease with a peculiar characteristic. Only 10% of those afflicted receive appropriate treatment. And fully 90% of the untreated (about 17 million adults) think they do not need any treatment in spite of the fact that for many the disease is fatal.

Of course we are talking about addiction, highlighted by the opioid crisis layered over the historical rate of alcoholism and other drug addictions. I cannot think of another disease in which the afflicted know they are ill but do not believe they need medical care. (Some healthy people think they do not need vaccines.)

Generally, a competent adult can refuse any and all treatment for any disease. There are a few exceptions. Persons attempting suicide routinely are held for several days of treatment. Persons with certain infectious diseases may be forcibly isolated, if not treated (remember Ebola?). Persons with mental illnesses who do not have the capacity to understand their illness and/or are dangerous to themselves or others are a separate issue.

In 2015 civil commitment laws (no crime committed) for treatment of adults with addiction existed in 32 states plus Washington D.C. (there may be more now). The length and type of treatment and utilization of this approach varies. Some states use civil commitment more frequently (MA over 4500 cases/yr.) than others (Texas 23 cases/yr.). Rhode Island has a law, but it is almost never invoked. Imminent danger to self or others is required in RI. The case reported above seems to be as close a brush with imminent harm as one could come! Also, in RI, only a family member may petition the court for civil commitment.

Even in states that try to address addiction by civil commitment there are barriers. There may be no treatment facilities available to treat. And if facilities are available there may be no money to pay. Insurance may not cover the treatment and it is not clear whether a person receiving "unwanted" court-mandated treatment could be forced to pay the bill. Patients may be sent to prison programs if no other facility is available.

But even if all of the difficulties in access disappeared we must ask whether undesired treatment works. In one study, civil commitment was requested for 28 persons with addiction. The court granted the request in only 7. After treatment and release, 6 persons relapsed promptly. In another group (in Florida) the rate of successful treatment was the same for voluntary and involuntary patients (treatment non-participation resulted in contempt of court and jail). However, post discharge follow-up data was not obtained.

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A survey of American Psychiatric Association members revealed "only 22% supported involuntary commitment for alcohol; or drug abuse treatment."

Additionally there are risks. Patients who have been abstinent during treatment have less tolerance and thus are more likely to overdose. And patients who have been civilly committed at the request of their family may be resentful and angry with their family. This reaction may sever trusting relationships and impair emotional and other support, making the addicts' situation even worse than before.

Physician Health Programs (PHP) have been described as "mandatory treatment." But that is not true. A court does not order the treatment and the regulatory authority (licensing board) does not force treatment. Successful

treatment is a condition of continued ability to practice medicine. This is a patient safety issue. The doctor is free to refuse treatment and pursue another occupation. PHP treatment is a strict regimen and is uniquely highly successful; 70–90% of those enrolled do well for over 5 years.

The successful treatment of addiction, of course, requires state-of-the-art facilities and approaches, including medically assisted treatment (MAT – drugs that block opioid receptors), group and individual therapy, etc.

But there must be an underlying motive for the patient to get into and stay in treatment. The motivation that inspires doctors and others to enter long-term therapy is the desire to not lose some central core value or desire. We know what it is for most doctors. Doctors, almost uniformly, value their ability to practice so highly that they will "stay the course" in an intensive 3–5 year treatment program. But for many others the power of the addiction is greater than their strongest core value.

For all patients it is critically important to determine if there is any such core value and work with the patient to help them understand that continued use of drugs ultimately would deny them this core. This knowledge alone does not cure addiction but is the best motivating force to stay in treatment.

But even if civil commitment along with forced treatment works, should doctors administer it? For example, Vivitrol, an opioid receptor blocker could be administered by injection over the patient's objection.

An adult patient with the capacity to understand the proposed treatment and make decisions has an absolute right to reject any medical treatment for any disease. A Jehovah's Witness may refuse blood products even if death is the consequence.

Even if the patient is a criminal and a court orders treatment, the AMA Code of Medical Ethics requires the treating physician to adhere to a 3-step process. An independent expert must confirm the medical diagnosis. The proposed treatment must conform to nationally accepted standards and, most importantly, an independent physician must verify informed consent. Patients ordered by a court to have treatment during civil commitment must have the same protections. Doctors must not participate in treatment of an adult capacitated patient without freely given informed consent.

Is consent truly voluntary when it is obtained as the alternative to prolonged confinement, when such confinement is not punishment for a crime or necessary to protect the safety of the patient or others? Occasionally persons will ask to be civilly committed as a means of getting motivation for a full course of treatment. These cases have obviously given informed consent. But for the others, does the choice given to the addict of treatment or confinement (in the absence of a crime) place the doctor in the position of being a partner of the government in the forced granting of the consent?

The patient described above who was saved by the police and discharged from the ER has little chance of sustained recovery. We need to do better.

Many simultaneous approaches are necessary:

We need to avoid unnecessary exposure to opioids in medical practice. Progress has started in this area.

Sources of illegal supplies of drugs must be reduced. Long-term results have not been encouraging. (The profits are too great.)

MAT reduces the craving and markedly increases the success rate and should be considered in all cases. New drugs that act directly on the brain (even possibly preventing opioid addiction in some cases) offer significant hope.

We need to focus on the core value(s) that might motivate the patient to engage in treatment.

More and better facilities and trained treatment personnel are required. But this requires adequate funding that our society has not seen fit to provide.

In my opinion, civil commitment with forced treatment is not an acceptable option. Doctors should participate in treatment only if there is voluntary informed consent. ❖

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