

April 28, 2015

Representative Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington DC 20515-6115

Chairman Murphy-

Thank you for an opportunity to present to the sub-committee on March 26, 2015. I received your letter requesting a response to additional questions for the record. Below are my responses.

The Honorable Tim Murphy asked:

Question:

1. During your testimony you cited a long-term, 42-month follow-up study conducted in NIDA's Clinical Trial Network led by Dr. Roger Weiss.
 - a. This study relied on telephone interviews to find out if patients were still using illicit opioids, or in fact, were opioid-free. There were no drug tests administered. In the "Limitations" section of the study, the authors stated that relying only on telephone interviews "may have inflated rates of good outcomes" (p.7). Do you agree with the authors?

Response:

Yes, this is a limitation of the study; however urinalysis data also can have substantial limitations. Self-report has generally been shown in the research literature to have reasonable reliability and validity, there still could be bias towards inflating good outcomes. However, drug usage is not the only meaningful outcome of interest. Treatment engagement is a very important outcome measure also documented in the study and an outcome that is strongly associated with improved functioning and cost savings across multiple studies.

Question:

- b. Out of the original 653 participants in the study, 375 were enrolled to participate in this telephone interview follow-up study. Of those 375 that enrolled, 306 completed the 42-week telephone interview (less than half of the original sample). In the "Limitations" section of the study, the authors state that the results of the study "may not be generalizable." (p. 7) Do you agree with the authors?

Response:

There are actually two different issues: 1) representativeness of the follow up group relative to the whole group and 2) representativeness relative to a much larger, general population.

In terms of the first question:

Somewhat.

It is a limitation to not have everyone in the follow up study, but this was strongly related to the time since involvement in the original study. The group that did not participate in the follow up study was very similar to the participating group, so there is no indication the resulting data are biased with regards to representativeness of the subset to the larger study.

Regarding the second questions:

Yes.

The question of generalizability is a limitation of virtually every research study conducted unless it is a massive study, e.g. tens of thousands, across an enormous population. Every diligent researcher discusses the limitations of their study, in fact it is a requirement of research journals to discuss limitations.

The Honorable Larry Buschon asked:

Question:

1. What changes in Medicare and Medicaid policies are needed to expand access to medication-assisted treatment?

Response:

- Medicare should pay for medication assisted treatment including methadone provided by Opioid Treatment Programs.
- Medicaid should pay for buprenorphine and naltrexone dispensed in Opioid Treatment Programs. Dispensing fees, should be reimbursed so that those who require more frequent dosing/dispensing can receive their medication as needed whether it is once a month or three times per week.
- Medicaid coverage should continue while people are incarcerated so that they can be maintained or initiated on medication assisted treatment.
- Regulations should require inpatient programs (detoxes, residential, medical and psychiatric hospitals) to affiliate with programs offering methadone, buprenorphine and naltrexone to allow for direct admission upon transition from inpatient to outpatient settings. Inpatient to outpatient transitions of care are where patients often relapse and overdose.

Question:

2. Should access to medical therapy including methadone, vivitrol, and buprenorphine all be available at federally funded substance abuse clinics?

Response:

Sort of.

Medication assisted treatment with buprenorphine should be available at all federally funded substance abuse clinics serving opioid addicted person. However, given the pharmacology of methadone it should only be provided by federally and state approved opioid treatment programs. Given the limited evidence base for extended-release-naltrexone/Vivitrol it could be offered at substance abuse clinics, but should not be the only type of medication assisted treatment offered.

Methadone and buprenorphine have an excellent evidence base in terms of improving functionality, saving lives and being cost effective, see for example, *Medication-assisted treatment of opioid use disorder: review of the evidence and future directions*. By Hillary Connery in the *Harvard Review of Psychiatry* 2015 Mar-Apr;23(2):63-75. However, to date, extended-release-naltrexone/Vivitrol does not have a strong evidence base for opioid addiction; there are several ongoing clinical trials funded by the NIH/NIDA.

Residential treatment programs should be required to admit and maintain patients on medication assisted treatment, working with appropriate opioid treatment providers as necessary.

Per my discussions with many physicians and opioid treatment providers expert in medication assisted treatment, it is my opinion that Vivitrol should not be the only form of medication assisted treatment offered to opioid addicted persons whether it is a federally funded substance abuse clinic or a federally funded drug court or corrections facility. This is because: 1) the evidence base for the real world effectiveness Vivitrol for opioid use disorder is weak, 2) there is increased potential for overdoses during the transition onto and off of Vivitrol, and 3) we have two other effective medications. Offering patients multiple treatment options when they are available is good medicine. Just like we offer multiple possible anti-depressant medications to those with depression, it is appropriate to offer multiple effective medications for opioid use disorders, different people do well on different medications.

Lastly, given that opioid addiction is a chronic relapsing condition, patients should be allowed to be on medications as long as it is resulting in improved functioning.

Please contact me if I can provide any additional information.

Sincerely,



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