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Response to Dr. Fiscella: Transparency and Debate are Essential to Improve Guidelines and Measures

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Our paper was intended to facilitate transparency and stimulate discussion about the hundreds of debatable decisions that we made while specifying quality measures for the American Society of Addiction Medicine's (ASAM) Standards of Care. We were therefore pleased to read Dr. Fiscella's thoughtful letter. We agree with his overall summary of the evidence and support continued debate by ASAM members and other stakeholders on at least three questions.

What criteria should be used to recommend a medication in clinical practice guidelines and subsequent quality measures?

The ASAM OUD guideline used FDA approval as the criterion for inclusion¹. The quality measure panel required for inclusion at least one of the following criteria: 1) FDA approval for the indication; 2) Effectiveness for the indication supported by high-quality meta-analysis. These decision rules are debatable and should be debated. The “1 or 2” approach sets a minimum bar and captures medications with different effectiveness profiles and other characteristics. Requiring both criteria be met (“1 and 2”) might eliminate naltrexone for OUD due to weak meta-analytic support (and disulfiram and topiramate for AUD for different reasons). Perhaps medications that meet Criteria 2 could be first line and those that only meet Criteria 1 could be second line and/or be recommended with conditions. Our hope is that ASAM members and other stakeholders continue to discuss the benefits and risks of these and other alternatives.

How should the current evidence be translated into ASAM OUD

Guidelines?

Developing professional standards often involves using imperfect science filtered through diverse clinical experience and stakeholders perspectives to arrive at guidance that helps improve practice but does not produce unintended consequences. Dr. Fiscella has made a reasoned and concise proposal for summarizing current evidence into concrete standards: “Evidence...supports recommendations for methadone and buprenorphine as first line drugs for OUD under most circumstances. Naltrexone should be reserved for highly motivated, supervised patients.” The current ASAM guidelines cite the same facts and recommendations but do not take the step of distinguishing first line and other medications. A possible downside of Dr. Fiscella's proposal is that some patients who are less motivated or not supervised might prefer or benefit from naltrexone, but might not receive it under more prescriptive guidelines and measures. A downside to being less prescriptive is that clinicians and patients might not appreciate the underlying science. We hope in the next revision of the guidelines, discussion will focus on the benefits and potential pitfalls of distinguishing methadone and buprenorphine as first line drugs for OUD, and carefully specifying the condition under which naltrexone should be considered.

How should quality measure developers proceed when data are not available to operationalize relevant concepts?

Let us assume that only patients with high motivation and the potential for supervised administration should receive naltrexone for OUD. No data exist to operationalize these concepts. Thus, we are again stuck with unsatisfying choices, all with attendant risks and benefits. We can give credit for giving naltrexone or not, but we have no way of assessing motivation or capacity for supervision. Each choice has benefits and risks. Especially given that overall access to medications for OUD is a bigger quality problem, at least in our pilot data, than over-prescribing of naltrexone, the current quality measure is focused on access, rather than other domains of prescribing quality such as choice of medication or persistence.

Acknowledgments

We thank Dr. Fiscella for stimulating thought and conversation. Our profession should be committed to making these decisions in an atmosphere of transparency and open debate.

References

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