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Subcutaneous Buprenorphine Extended-Release Use Among Pregnant and Postpartum Women

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We read with interest the case series from Cleary et al in the November 2020 issue that details patient experiences when transitioning to extended-release injectable buprenorphine (Sublocade) while pregnant (n=2) or postpartum (n=1).¹ We are concerned that the authors recommend against extended-release injectable buprenorphine in this population based on experiences of three patients who reported euphoria and withdrawal after one injection.¹

While the pharmacokinetics of extended-release injectable buprenorphine during pregnancy and postpartum are not well understood, in the general population, steady state is not reached until month 4 through 6 (Sublocade [buprenorphine extended-release] [package insert]. Burlington, MA: Indivior Inc.; Feb 2020) and withdrawal symptoms described in month 1 are not unexpected. In our clinical experience where we successfully transitioned eight postpartum nonlactating women to extended-release injectable buprenorphine, more than half benefitted from initial sublingual supplementation and some required loading doses beyond month 2. (Peckham AM, Kehoe LG, Gray JR, Wakeman SE. Real-world outcomes with extended-release buprenorphine (XR-BUP) in a low threshold Bridge clinic. Poster presented at: The American Society of Addiction Medicine 51st Annual Conference; April 2020; Converted to virtual format due to COVID-19. Poster available at: <https://www.eventscribe.com/2020/posters/ASAM/SplitViewer.asp?PID=NzE0Mjc5MDc2MDA>. Full manuscript accepted by Journal of Addiction Medicine, publication forthcoming.) This is consistent with pharmacokinetic data demonstrating fluctuating serum levels in the general population.² These treatment plan modifications are patient-centered and are not treatment failures.

Furthermore, the authors failed to mention that the excipient in extended-release injectable buprenorphine, N-methyl-2-pyrrolidone, has produced teratogenic effects in animal studies at similar doses (Sublocade [buprenorphine extended-release] [package insert]. Burlington, MA: Indivior Inc.; Feb 2020). Perhaps this is less relevant to the two women enrolled after the first trimester; however, it is very relevant to the readership given that many pregnancies are unplanned.

There is an ongoing clinical trial examining the safety, efficacy, and pharmacokinetics of an alternative N-methyl-2-pyrrolidone-free, extended-release buprenorphine in pregnant and postpartum women.³ While awaiting the results from this trial, we strongly encourage clinicians to engage in shared decision making with their patients and are wary of a recommendation against this option based on the negative experiences of three patients.

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