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# Miscommunication, Misclassification, and Missed Opportunities in Adolescent OUD Care

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Hadland et al. should be commended for their timely national evaluation of opioid use disorder (OUD) care among Medicaid-enrolled youth. Their cascade of care findings are striking: only 50.7% of youth-initiated treatment within 14 days of diagnosis, 32.9% engaged in care, and just 15.2% received medications for OUD (MOUD) [1]. Most concerning, only 6.6% of adolescents received MOUD, compared with 51.2% of young adults. These data underscore the profound risks adolescents face in a fentanyl-dominated drug supply. The authors' overall conclusions are sound, though a few points merit clarification.

First, the study groups individuals aged 13 to 25 years under broad labels such as "youths," "adolescents and young adults," or "adolescents younger than 18 years." This practice is inconsistent with regulatory definitions that govern pediatric drug development. As we recently summarized all major drug regulatory agencies define adolescents as individuals aged 12 to 17 years [2] and various documents rely on this demarcation [3-6]. This age range is used in prescribing information to delineate adolescent indications, stratify safety and efficacy data, and structure pediatric labeling [2].

Combining adolescents with young adults may increase sample size, but it obscures age-specific outcomes and perpetuates the evidence gaps that limit adolescent access to MOUD. The absence of an adolescent indication remains the elephant in the room, shaping clinician hesitancy, fear of adverse regulatory sanctions, family reticence, guideline development and research priorities. It also contributes to reimbursement limitations, and prior authorization delays.

Second, Hadland et al. state that buprenorphine is approved by the FDA "for individuals aged 16 years and older." This widely repeated claim is incorrect. No buprenorphine product carries an FDA indication for treating OUD in adolescents [2]. Since approval in 2002, transmucosal buprenorphine prescribing information (PI), also referred to as the "label," has stated that these products are "used to treat adults addicted to opioid..." [7]. However, until 2018, the labeling information also noted that "safety and effectiveness … in patients below age 16 have not been established," which may have been misunderstood by some as approval from age 16 onwards [8]. In 2011, the age 16 wording was removed from the Full Prescribing Information (FPI) [8].

However, this information was inadvertently retained in the Highlights of Prescribing Information (HPI) even though language in the HPI is supposed to be sourced entirely from the FPI [9]. Nonetheless, this inconsistency was eventually corrected with the February 2, 2018 label, when the statement "safety and effectiveness ... in patients below the age of 16 have not been established" was removed in its entirety [10]. Many influential sources continue to repeat the erroneous claim, including a recent review by Ball et al. [11-15]. Accurate regulatory framing is essential, as misstatements about adolescent indications for controlled substances are precisely the barriers Hadland et al.'s work has long documented.

The undertreatment described by Hadland et al. is not benign; it produces predictable and preventable harms, including overdose, death, and the entrenchment of chronic opioid addiction during adolescence. Two decades of evidence reveal a clear and persistent pattern: youth with OUD are the population least likely to be offered MOUD, least likely to maintain treatment, and most likely to be routed into nonpharmacologic care, including psychosocial interventions and short-term detoxification, even though they bear the greatest overdose burden and have the most to gain from timely medication initiation. Surveys of addiction treatment staff further illustrate this gradient: enthusiasm for MOUD declines sharply for adolescents aged 16 to 17 [16].

A clearer regulatory foundation, coupled with recognition of these epistemic dynamics, would enhance the impact of Hadland et al.'s analysis and help ensure that adolescents receive evidence-based MOUD.

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