RADARS® SYSTEM

Researched Abuse, Diversion and Addiction-Related Surveillance System

Fourth Quarter 2013 Technical Report

Impact of Tamper Resistant Formulations on Rates of Abuse of Schedule II Opioids

Key Points:

1. In the first year following transition to tamper resistant formulations of Opana® ER and OxyContin®, all Schedule II opioids rates, adjusted for both population and prescriptions, declined relative to the years prior to introduction of the reformulations.
2. There were 467 fewer intentional abuse cases in the RADARS® System Poison Center Program in the year following reformuation of both Opana ER and OxyContin than in the year before reformulation of Opana and after reformuation of OxyContin.
3. Introduction of tamper resistant formulations coincided with reductions in abuse exposure mentions of Schedule II prescription opioids reported to RADARS System Poison Centers.

Background

Recent studies demonstrate that the introduction of OxyContin® Extended Release (ER) reformulation in August 2010 was followed by reduction in the abuse of OxyContin (1, 2, 3). However, increases in the abuse of other prescription opioids following the introduction of ORF also were noted (2, 3). These findings raised concerns that while tamper resistant formulations may reduce abuse of a specific product, individuals who abuse these products may transition to other opioids. Therefore, the impact of these reformulations on the overall problem of prescription opioid abuse is unclear. This study sought to investigate the change in rates of abuse of all Schedule II opioids intended for the treatment of pain and tracked by the RADARS® System following the introduction of crush resistant Opana® ER and reformulated OxyContin.

Methods

Quarterly rates of intentional abuse exposure mentions from 3rd quarter 2009 through 2nd quarter 2013 were calculated for four drug groups: OxyContin, Opana ER, Schedule II opioids excluding OxyContin and Opana ER (IR and unidentified oxycodone, IR and unidentified oxymorphone, fentanyl, hydromorphone, morphine, and methadone tablets) and Schedule II opioids (other Schedule II opioids plus OxyContin and Opana ER). Unadjusted and prescription- and population-adjusted mention counts for Schedule II opioids were compared across three time periods: 1 year pre-OxyContin reformulation and pre-Opana ER reformulation (2009Q3 to 2010Q2), 1 year post-OxyContin reformulation and pre-Opana ER reformulation (2011Q1 through 2011Q4) and 1 year post-OxyContin reformulation and post-Opana ER reformulation (2012Q3 through 2013Q2). Transition periods (noted in grey in Figure 1) were excluded from the analysis. Comparisons were conducted using Poisson Regression.

Results

An increase in Opana ER intentional abuse rates following the reformulation of OxyContin in 2010 is evident (Figure 1). Declines in intentional abuse rates of Opana ER and OxyContin following the introduction of both reformulations also can be observed. Figure 2 presents both the total number of intentional abuse exposure mentions and the average population rates over the three time periods of interest. The proportion of all Schedule II opioid mentions and the average population rate that is accounted for by Opana ER, OxyContin and other Schedule II opioids is displayed. In the year after both reformulations were introduced, there were 473 fewer intentional abuse exposure mentions of all Schedule II opioids than in the year following reformulation of OxyContin but before reformulation of Opana ER. Results from the Poisson regression analysis indicate that the population rate of all Schedule II opioids showed a nonsignificant increase (3%, 95% CI: -5% to 12%, p=0.487) from the year pre-OxyContin reformulation and pre-Opana ER reformulation to the year post-OxyContin reformulation and pre-Opana ER reformulation. However, in the year post-OxyContin reformulation and post-Opana ER reformulation, intentional abuse exposure population rates were 18% (95% CI: 11% to 25%, p<0.001) lower than in the year pre-OxyContin reformulation and post-Opana ER reformulation. Results were similar when adjusting for number of prescriptions filled, with intentional abuse exposure prescription rates showing a 22% (95% CI: 13% to 29%, p<0.001) decline in the year post-OxyContin reformulation and post-Opana ER reformulation relative to the year pre-OxyContin reformulation and post-Opana ER reformulation.

Figure 1: The RADARS® System Poison Center Program Rates of Intentional Abuse Exposure Mentions by Year/Quarter and Drug, from 2009Q3 through 2013Q2

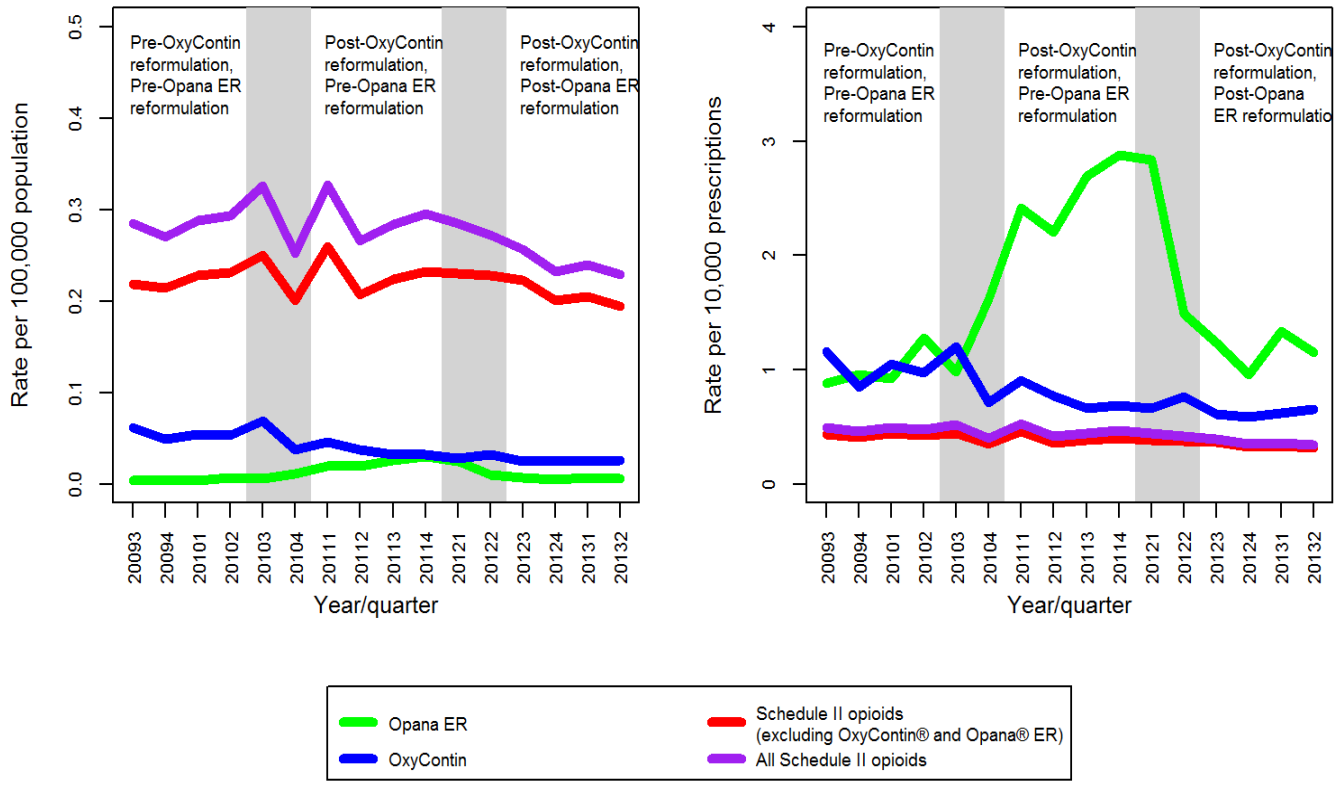
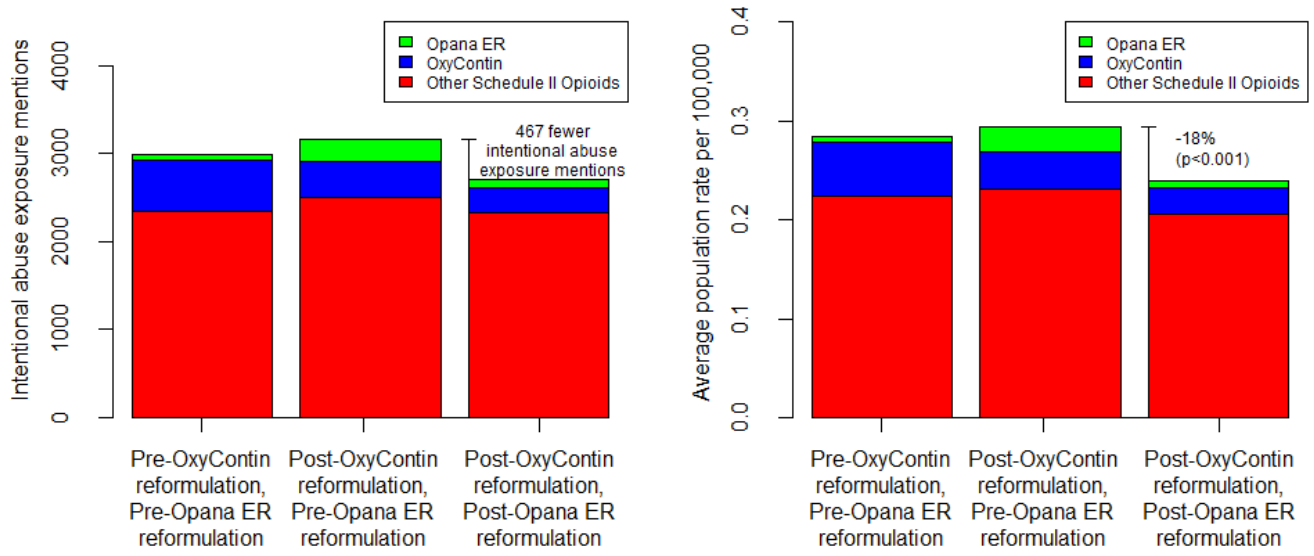


Figure 2: The RADARS® System Poison Center Program Average Intentional Abuse Exposure Mention Population Rates by Time Period and Drug from 2009Q3 through 2013Q2



Conclusions

Following the introduction of two tamper resistant formulations, mentions of intentional abuse exposures of all Schedule II opioids declined; not just mentions of the products that were reformulated. This could suggest that individuals who abused OxyContin and/or Opana ER may not be transitioning to other Schedule II opioids. This analysis is limited in that it does not examine whether heroin rates increased, a finding that has been noted in other studies (3, 4). Furthermore, the impact of other interventions (e.g. prescription monitoring programs) was not assessed. Further investigation is needed to determine whether these findings are the result of secular trends in poison center calls. Despite these limitations, this analysis does suggest that release of tamper resistant formulations coincided with reductions in abuse of Schedule II prescription opioids.

Suggested citation

Severtson SG, Bucher Bartelson B, Green JL, Dart RC. (2013). Impact of tamper resistant formulations on rates of abuse of schedule II opioids. RADARS System Technical Report, 2013Q4.

References

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