

Abuse of XTAMPZA® ER is Rare Relative to Other Opioid Analgesics

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Introduction

- ER oxycodone products can be preferred drugs for abuse because they contain a large amount of active pharmaceutical ingredient
- Some individuals who abuse ER oxycodone tamper with the medication in order to bypass the controlled-release mechanism
- XTAMPZA® ER is an abuse deterrent ER oxycodone product that uses DETERx® technology designed to discourage tampering
- The FDA has granted XTAMPZA ER abuse-deterrent labeling with respect to oral, nasal and IV routes of administration
- This study examines the frequency and routes of abuse of XTAMPZA ER and other opioid analgesics using two surveillance systems.

Methods

- Descriptive data collected from 2016Q3 through 2018Q4 are presented from two Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) System data sources:
 - The Poison Center Program:** information on exposures is collected from participating poison centers within the United States. There were 5,531 intentional abuse exposure cases involving hydrocodone, morphine, or oxycodone included in this analysis
 - The Treatment Center Programs Combined:** respondents entering treatment for opioid use disorders complete a questionnaire where they select from a list of prescription medications the products they abused in the past month. There were 22,119 valid surveys returned in this analysis.
- Prescriptions dispensed information was obtained from the IQVIA® (Danbury, CT) US-Based Longitudinal Patient Data.
- Cases involving XTAMPZA ER were compared to three groups:
 - Other abuse deterrent formulation (ADF) ER opioids:** OXYCONTIN®, EMBEDA®, HYSINGLA® ER, ARYMO® ER, and MORPHABOND™ ER
 - Non-ADF ER opioids:** ZOHYDRO® ER, MS CONTIN®, and other extended-release morphine products
 - Immediate-release (IR) oxycodone**

Disclosure

The RADARS® System is supported by subscriptions from pharmaceutical manufacturers, government and non-government agencies for surveillance, research and reporting services. RADARS System is the property of Denver Health and Hospital Authority, a political subdivision of the State of Colorado. Denver Health retains exclusive ownership of all data, databases and systems. Subscribers do not participate in data collection nor do they have access to the raw data. This research was sponsored by Collegium Pharmaceutical.

Results

Table 1. Prescriptions dispensed by drug group, 2016Q3-2018Q4

Product Name	# of Prescriptions	Percentage of Group
XTAMPZA® ER	394,472	100%
Other ADF ER Opioid Products		
OXYCONTIN®	6,732,385	75.8%
Non-branded ER oxycodone	1,243,662	14.0%
HYSINGLA® ER	512,544	5.8%
EMBEDA®	337,866	3.8%
MORPHABOND® ER	36,806	0.4%
ARYMO® ER	22,639	0.3%
Non-ADF ER Opioid Products		
Non-branded ER morphine	13,749,750	98.0%
ZOHYDRO ER	197,821	1.4%
KADIAN	59,584	0.4%
MS CONTIN	17,398	0.1%
Other products	12,377	0.1%

XTAMPZA ER is a registered trademark of Collegium Pharmaceutical. OXYCONTIN and HYSINGLA ER are registered trademarks of Purdue Pharma. EMBEDA is a registered trademark of Pfizer, Inc.. MORPHABOND ER is a registered trademark of Daiichi Sankyo, Inc. ARYMO ER is a registered trademark of Egalet US, Inc.

Figure 1. Distribution of prescriptions dispensed, intentional abuse cases, and past-month abuse cases by drug group, 2016Q3-2018Q4

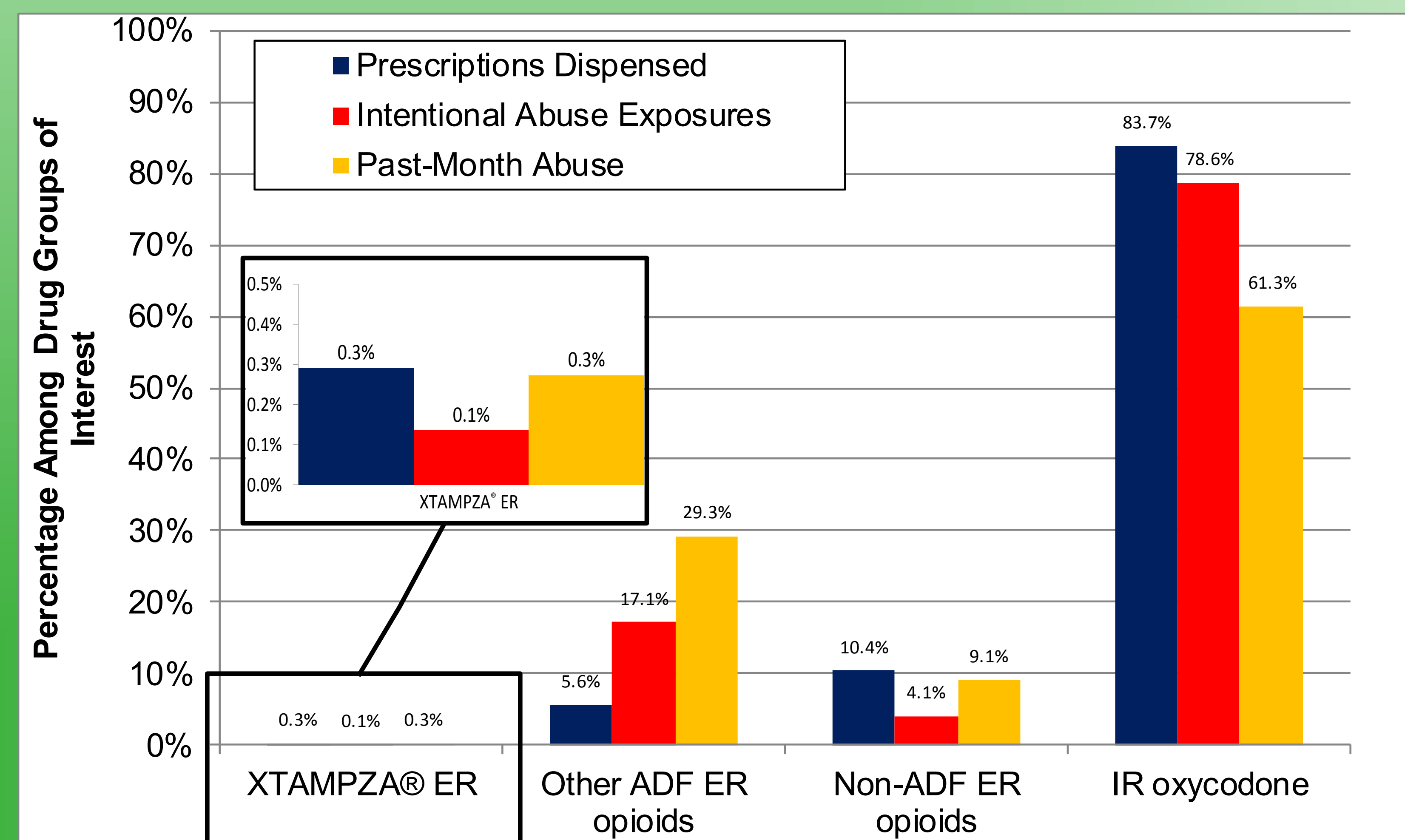


Table 2. Unintended routes of administration for intentional abuse cases and past-month abuse cases by drug group, 2016Q3-2018Q4

Drug Group	Poison Center Program			Treatment Center Programs Combined		
	Abuse cases	Injection N (%)	Inhalation N (%)	Abuse cases	Injection N (%)	Inhalation N (%)
XTAMPZA® ER	3	0 (0%)	0 (0%)	17	2 (11.8%)	4 (23.5%)
Other ADF ER opioids	380	28 (7.4%)	58 (15.3%)	1,826	301 (16.5%)	555 (30.4%)
Non-ADF ER opioids	91	5 (5.5%)	5 (5.5%)	569	167 (29.3%)	102 (17.9%)
IR oxycodone	1,743	49 (2.8%)	214 (12.3%)	3,825	486 (12.7%)	1461 (38.2%)

Results (cont.)

Poison Center Program – Intentional Abuse Exposures

- 3 cases involved XTAMPZA ER, fewer than each comparator group
- A smaller proportion of intentional abuse exposures involved XTAMPZA ER than expected based on prescriptions dispensed
- No intentional abuse exposures involved injection or inhalation of XTAMPZA ER

Treatment Center Programs Combined – Past month abuse

- 17 respondents endorsed XTAMPZA ER, fewer than each comparator
- The percentage of XTAMPZA ER past month abuse cases was proportional to the percentage of XTAMPZA ER prescriptions
- Injection use among those who reported abuse was lower for XTAMPZA ER than each comparator drug group
- Inhalation use among those who reported abuse was lower for XTAMPZA ER than comparator groups except non-ADF ER opioids

Conclusions

- Abuse of XTAMPZA ER is infrequent compared to other ADF and non ADF ER opioids
- No abuse of XTAMPZA ER via unintended routes of administration was reported in the Poison Center Program
- The proportion of cases involving use via unintended routes of administration tended to be lower for XTAMPZA than for comparator drug groups among individuals entering treatment for opioid use disorders

Limitations

- Abuse of specific products was self-reported, therefore subject to recognition and recall biases
- In more than 10% of cases formulation is not known therefore counts for all drug groups may be underestimated
- Even rare false positive endorsements on surveys may inflate estimates of infrequent events; less prescribed products may be overestimated relative to commonly prescribed products
- The analysis in this poster is descriptive through 2018Q4, results may change as additional quarters of data become available