Nonmedical Use of Xtampza® ER versus Other Oxycodone-Containing Products

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Introduction

Opioid therapy for chronic pain remains a challenge as providers weigh the medical need for therapy with the risks of misuse, abuse, and overdose. A systematic review of literature evaluated the efficacy of opioid therapy in chronic pain. Based upon 15 studies that met the inclusion criteria, opioids appear to be efficacious for treatment of non-cancer chronic pain for up to 3 months.[1] Other published studies suggest that rates of misuse range from 21-29% and rates of addiction range from 8-12%.[2] Prescription opioid medications with abuse-deterrent properties are designated by the FDA as products that may meaningfully deter abuse, even if they do not fully prevent abuse. Currently marketed abuse-deterrent opioid products are intended to deter manipulation for the purpose of ingestion, snorting or injecting of the active ingredient. Compared with immediate-release (IR) formulations, extended-release (ER) products contain higher amounts of the active ingredient, because the drug is intended to be released in the body over an extended period of time (up to 12 hours). When an ER mechanism can be defeated, the product becomes particularly attractive for abuse by manipulated oral routes, nasal administration, or injection.

The purpose of this study was to estimate the real-world rate of nonmedical use (NMU) of Xtampza ER® (a Schedule II drug with abuse-deterrent properties introduced to the US market in Q3 2016) and comparator prescription oxycodone-containing products in a population of adult patients evaluated for substance abuse treatment.

Methods

Study Design

Cross-sectional surveillance study among adults (>=18 years) assessed for substance abuse problems and treatment planning using the Addiction Severity Index-Multimedia Version (ASI-MV®) assessment tool from 01 July 2016 (Q3 2016) through 31 December 2019 (Q4 2019). Xtampza ER was added to the ASI-MV tool on 17 September 2017.

Study Outcome and Comparators

Past 30-day NMU of Xtampza ER (alone or in combination with other prescription opioids) and comparator opioids (other oxycodone ER and oxycodone IR), overall and by specific routes of administration (i.e., oral, snorting, smoking, and injecting). NMU is defined as use in any way or for any reason other than as prescribed or use without the user's own prescription. Rates were adjusted for volume of assessments (per 100 ASI-MV assessments) and for drug utilization (per 100,000 prescriptions dispensed; data from IQVIA).

Strengths and Limitations

This study includes access to a hard-to-reach, enriched population of opioid users; data collection via a clinical tool used in standard workflow that captures product-specific utilization (using pictures and product names) and route of administration; and a large sample of assessments during the study period. Limitations of this study include reliance on self-report for use and product identification; and that the sample is obtained from sites that use ASI-MV in clinical practice and may not be representative of all individuals evaluated for substance abuse treatment or users not seeking treatment.

Results

Study Sample

- 647 ASI-MV sites located in 44 states contributed 192,810 assessments to the ASI-MV network during the study period.
- 21.9% (n=42,279) of assessments reported past 30-day NMU of at least one prescription opioid.
- The majority of past 30-day prescription opioid NMU reports were among males (52.0%), those who were Caucasian (77.7%), and those age 18 to 34 years (58.1%).
- Less than 1% of those reporting prescription opioid NMU specified past 30-day use of Xtampza ER (N=73; 0.2%).

Past 30-day NMU per 100 assessments

- Past 30-day NMU of Xtampza ER per 100 ASI-MV assessments ranged from 0.01 (Q3 2017) to 0.10 (Q1 2018) (Figure 1).
- Past 30-day other oxycodone ER NMU rates ranged from 1.25 (Q4 2019) to 2.97 (Q4 2016), while oxycodone IR NMU rates ranged from 10.87 (Q4 2019) to 23.37 (Q3 2016) mentions per 100 ASI-MV assessments (Figure 1).
- All quarterly Xtampza ER NMU rates per 100 ASI-MV assessments were significantly lower than those for other oxycodone ER and oxycodone IR. Past 30-day oxycodone IR NMU quarterly rates per 100 ASI-MV assessments were significantly higher than all other groups.

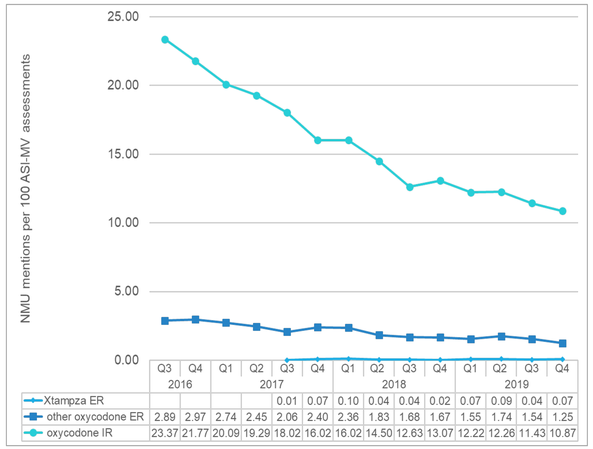
Past 30-day NMU per 100,000 prescriptions dispensed

- When adjusting for the volume of prescriptions dispensed during the study period, past 30-day NMU of Xtampza ER was reported at rates between 4.46 (Q4 2018) and 31.10 (Q4 2017) (Figure 2).
- Past 30-day other oxycodone ER NMU rates ranged from 38.65 (Q4 2019) to 59.94 (Q3 2016), while oxycodone IR NMU rates ranged from 16.35 (Q4 2019) to 36.37 (Q3 2016) mentions per 100,000 prescriptions (Figure 2).
- Overall, Xtampza ER rates were significantly lower than quarterly rates observed for other oxycodone ER NMU but not significantly lower than oxycodone IR NMU rates.

Routes of Administration

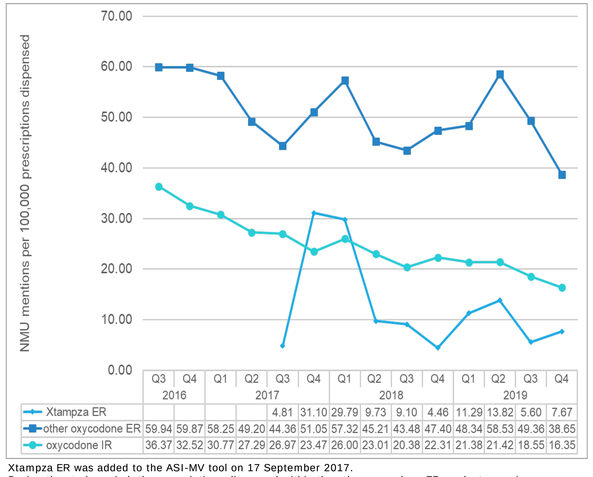
- Nonmedical users of Xtampza were less likely to report any non-oral route of administration (28.8%) compared to nonmedical users of other oxycodone ER products (57.9%) and nonmedical users of oxycodone IR products (60.1%) (Table 1).
- Snorting and injecting were reported less frequently for Xtampza ER NMU (17.8% and 6.8%, respectively) compared to other oxycodone ER NMU (31.9% snorting and 21.9% injecting) and oxycodone IR NMU (40.6% snorting and 15.5% injecting) (Table 1).

Figure 1. Quarterly past 30-day NMU mention rates per 100 ASI-MV assessments: Xtampza ER and comparator opioid groups (07/01/2016 – 12/31/2019)



Note that Xtampza ER was added to the ASI-MV tool on 17 September 2017.

Figure 2. Quarterly past 30-day NMU mention rates per 100,000 prescriptions dispensed: Xtampza ER and comparator opioid groups (07/01/2016 – 12/31/2019)



Xtampza ER was added to the ASI-MV tool on 17 September 2017.
During the study period, the prescriptions dispensed within the other oxycodone ER product grouping were almost solely comprised of OxyContin and authorized generics (>99%).

Table 1. Route of administration for past 30-day NMU of Xtampza ER and comparator opioid groups (07/01/2016 – 12/31/2019)

	Xtampza ER		Other oxycodone ER		Oxycodone IR	
	n	%	n	%	n	%
Total NMU Mentions*	**73**	**100.0**	**4,114**	**100.0**	**31,281**	**100.0**
Route of Administration**						
Any Oral	**45**	**61.6**	**3,261**	**79.3**	**21,977**	**70.3**
Swallow whole	38	52.1	2,262	55.0	15,498	49.5
Chew then swallow	5	6.8	658	16.0	4,287	13.7
Dissolve like a cough drop	2	2.7	230	5.6	1,489	4.8
Dissolved in liquid then drank	0	0.0	111	2.7	703	2.2
Any non-oral	**21**	**28.8**	**2,380**	**57.9**	**18,787**	**60.1**
Snort	13	17.8	1,314	31.9	12,696	40.6
Smoke	3	4.1	165	4.0	1,250	4.0
Inject	5	6.8	901	21.9	4,841	15.5
Other	8	11.0	189	4.6	685	2.2

*Total mentions are the total number of products within each drug group/category that respondents endorsed for past 30-day NMU. Assessments may have endorsed multiple drugs in any category and product/comparator categories are not mutually exclusive.
**Multiple drugs and multiple routes of administration for each drug could be selected by respondents for each product/comparator. Any mention of any route of administration for each product/opioid group is included. Thus, the total number of routes may be greater than total NMU mentions.

Conclusions

- The ability to provide effective pain management therapy while reducing the risk of opioid misuse and abuse continues to be a challenge for medical professionals.
- Oxycodone-containing products are some of the most commonly prescribed opioids.
- Xtampza ER, an opioid with abuse deterrent properties, had significantly lower rates of NMU, including by non-oral routes, than other oxycodone ER products and oxycodone IR products in a population of individuals seeking substance abuse treatment.
- Use of real-world data to understand potential NMU of prescription opioids should be considered by clinicians when making treatment decisions.

References

[1]Meske DS, Lawal OD, Elder H, Langberg V, Paillard F, Katz N. Efficacy of opioids versus placebo in chronic pain: a systematic review and meta-analysis of enriched enrollment randomized withdrawal trials. J Pain Res. 2018;11:923-934.

[2]Vowles KE, McEntee ML, Julnes PS, Frohe T, Ney JP, van der Goes DN. Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis. Pain. 2015;156(4):569-576.

Support

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