Short Acting, Long Acting and Abuse-deterrent Opioid Utilization Patterns among 15 Million Commercially Insured Members

C. I. Starner[1,2], **P.P. Gleason**[1,2] [1]Prime Therapeutics LLC, Eagan, MN, United States; [2]University of Minnesota, College of Pharmacy, Minneapolis, MN, United States

No external funding provided for this research

Background

- Death from drug overdoses in the United States was highest in 2014 and 61 percent (28,647 of 47,055) of drug overdose deaths involved some type of opioid, including heroin.[1]
- Opioid abuse and misuse is a serious public health problem. The development of opioids formulated to deter abuse may help create safer opioid analgesics. The U.S. Food and Drug Administration (FDA) considers the development of abuse-deterrent products a high public health priority.[2]
- The FDA has validated label changes for seven extended-release/long acting (ER/LA) opioids with abuse-deterrent properties consistent with the FDA's Guidance for Industry: Abuse-Deterrent Opioids – Evaluation and Labeling. The products are: OxyContin®, Targiniq™ ER, Embeda®, Hysingla® ER, MorphaBond™, Xtampza™ ER and Troxyca® ER.[2,3]
- An additional six products have data suggesting they may have abuse-deterrent properties, however they have not been validated by the FDA to make any label changes.
- In August 2014, Massachusetts became the first state to pass abuse-deterrent opioid legislation requiring FDA validated abuse-deterrent medications to be covered by insurers and put limits on cost-sharing requirements for patients. In 2015, Maryland and Maine passed similar abuse-deterrent opioid legislation. Florida and West Virginia passed abuse-deterrent opioid legislation in 2016. Roughly 30 bills relating to abuse-deterrent opioid drugs have been introduced in about 20 states across the country during this 2016 session.[4]

Objective

- To describe utilization patterns of short acting, long acting, FDA validated abuse-deterrent opioids, and opioids with abuse-deterrent properties not validated by the FDA, from January 2014 through March 2016 among 15 million commercially insured members, and provide guidance to managed care decision makers.

Methods

- Prime Therapeutics queried administrative pharmacy claims among 15 million commercially insured members between Jan. 1, 2014 and March 31, 2016.
- Opioid pharmacy claims were identified using their Medi-Span Generic Product Identifier.
- Opioids were categorized into non-abuse-deterrent short acting and long acting, FDA validated abuse-deterrent opioids and opioids with abuse-deterrent properties not validated by the FDA.
- Table 1 provides examples of drugs by opioid category.
- The decision to categorize an opioid as a long acting opioid was based on a dosing interval of 1 to 2 times daily or duration of action of 12 hours or more. All other opioids were defined as short acting.
- Buprenorphine/naloxone combination products, which are FDA approved for opioid dependence treatment, were excluded.
- All pharmacy claims were normalized to 30-day supplies. For example, a 90-day supply constituted three separate claims. All claims with one to 34 days supply were counted as one claim.
- Total paid amounts were the sum of insurer plus member paid.
- Descriptive statistics were used to describe overall and monthly utilization trends.

Results

- Between Jan. 1, 2014 and March 31, 2016 (27 months) there were 20.5 million opioid claims among the 15 million monthly eligible commercial members.
- Table 2 shows the annual change in opioid claims per 1,000 members from 2014 to 2015 by opioid category.
  - Short acting opioids decreased 4.5 percent, 563 claims per 1,000 members down to 537 claims per 1,000 members, from 2014 to 2015.
  - Long acting opioids without any abuse-deterrent properties increased 2.0 percent, 30.9 claims per 1,000 members to 31.5 claims per 1,000 members, from 2014 to 2015.
  - Long acting abuse-deterrent opioids without FDA validation increased 26 percent, 3.5 claims per 1,000 members to 4.4 claims per 1,000 members, from 2014 to 2015.
  - Long acting FDA validated abuse-deterrent opioids increased 3.2 percent, 12.2 claims per 1,000 members to 12.6 claims per 1,000 members, from 2014 to 2015.

Short Acting Opioids

- Short acting opioids represented 92.0 percent (18.9 million) of all opioid claims and 51 percent ($465,870,752) of total paid.
- Per month short acting opioid claims per 100,000 members started at 4,660 in January 2014 and ended at 4,586 in March 2016 representing a 1.6 percent decline (Figure 1).

Long Acting Opioids

- Long acting opioids represented 8.0 percent (1.6 million) of all opioid claims and 49 percent ($440,198,443) of total paid.
  - Long acting opioids without any abuse-deterrent properties accounted for 65.4 percent (1.1) of long acting opioid claims overall and 36.1 percent ($159,050,620) of total paid.
  - Long acting opioids without any abuse-deterrent properties started at 245 claims per 100,000 members in January 2014 and ended at 266 in March 2016, an 8.5 percent increase (Figure 1).

FDA Validated Abuse-deterrent Opioids

- 425,856 (2.1 percent) of all opioid claims were for FDA validated abuse-deterrent opioids and accounted for 22.3 percent ($201,743,409) of total paid.
- OxyContin ER FDA validated abuse-deterrent represented 96.4 percent (410,619) of all FDA validated abuse-deterrent opioid claims.
- FDA validated abuse-deterrent opioids started at 99 per 100,000 members in January 2014 and ended at 104 claims per 100,000 members per month in March 2016, a 5.1 percent increase (Figure 2).
- There were no claims for four of the seven FDA validated abuse-deterrent opioids due to:
  - MorphaBond had no active claims during the time of the analysis.
  - Targiniq ER (oxycodone/naloxone) was approved in 2014, however no product has been launched.
  - Troxyca ER (oxycodone/naltrexone) was approved on Aug. 22, 2016.
  - Xtampza ER (oxycodone) was approved on April 29, 2016.

Abuse-deterrent Opioids Without FDA Validation

- 141,411 (0.7 percent) of all opioid claims were for abuse-deterrent opioids without FDA validation. Oxycodone ER, Exalgo®, Opana® ER, and Nucynta™ ER made up 92 percent of the claims.
- Abuse-deterrent opioids without FDA validation started at 28 claims per 100,000 in January 2014 and ended at 45 claims per 100,000 members in March 2016, a 61 percent increase in claims.

Limitations

- Administrative pharmacy claims data have the potential to be miscoded and include assumptions of members' drug utilization and medication taking behaviors.
- Cash paid opioid prescriptions are generally not submitted to the pharmacy benefit manager and are not included in these utilization patterns.
- The data used in this study was limited to the commercial population, primarily in the central and southern regions of the U.S., and therefore may not be generalizable to Medicare and Medicaid or to commercially insured individuals residing in other regions of the U.S.
- This analysis focused on percentages of claims and patterns of claims. A more in-depth analysis at the member level may be necessary to guide additional decision-making.
- Over-counting of claims may have occurred because all claims with one to 34 days supply were counted as one claim.

Conclusions

- Short acting opioid claims represent the vast majority of opioid claims and declined over the 27 month analysis period. Currently, no short acting opioids have abuse-deterrent properties.
- All long acting opioids accounted for approximately 1 in 12 opioid claims, yet accounted for nearly half of the opioid costs. Long acting opioid claims increased 11.3 percent over the 27 month analysis period.
- FDA validated long acting abuse-deterrent opioids represented 1 in 4 of all long acting opioid claims and their use increased 3.2 percent. Insurers need to understand their own utilization patterns to help forecast utilization and expenditures associated with new and existing abuse-deterrent opioid legislation.
- Opioids with abuse-deterrent properties are not proven to eliminate abuse. Future research should focus on the relationship between abuse-deterrent opioids and decreased opioid overdoses and death.

References

1. Rudd RA *et al.* Increases in Drug and Opioid Overdose Deaths — United States, 2000–2014 Morbidity and Mortality Weekly Report. Centers for Disease Control and Prevention. January 1, 2016. 64(50);1378-82.
2. U.S. Food and Drug Administration. Abuse-Deterrent Opioids — Evaluation and Labeling Guidance for Industry. April 2015. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM334743.pdf.
3. U.S. Food and Drug Administration. FDA Facts: Abuse-Deterrent Opioid Medications. Updated 8/19/16. Available at: http://www.fda.gov/newsevents/newsroom/factsheets/ucm514939.htm.
4. Wagner A and Thyson A. States Address Opioid Epidemic with Abuse Deterrent Formulation Legislation. 5/12/16. Available at: https://www.multistate.com/insider/2016/05/states-address-opiod-epidemic-with-abuse-deterrent-formulation-legislation/

Table 1. Opioid Categories

Category	Products*
Short acting (products with a duration of action of less than 12 hours)	Immediate release morphine, hydromorphone, hydrocodone and combination products
Long acting without abuse-deterrence	SR and ER morphine, hydromorphone, fentanyl, tramadol and combination products
Long acting FDA validated abuse-deterrent opioids	OxyContin® (oxycodone ER), Targiniq™ ER (oxycodone/naloxone), Embeda® (morphine/naltrexone), Hysingla® ER (hydrocodone bitartrate), MorphaBond™ (morphine), Xtampza™ ER (oxycodone) and Troxyca® ER (oxycodone/naltrexone)
Long acting abuse-deterrent opioids without FDA validation	Zohydro® ER (hydrocodone bitartrate), Exalgo® (hydromorphone), Xartemis™ XR (oxycodone/acetaminophen), Opana® ER (oxymorphone), Nucynta® ER (tapentadol), oxycodone ER, Oxaydo® (oxycodone)

*Not all products are listed in long and short acting categories.
XR/ER=extended release; SR=sustained release

Table 2. Opioid Claims per 1,000 Members in 2014 and 2015 by Category

Category	2014 claims per 1,000 members	2015 claims per 1,000 members	% change 2014 to 2015
Short acting (products with a duration of action of less than 12 hours)	563.0	537.4	-4.5%
Long acting without abuse-deterrence	30.9	31.5	2.0%
Long acting FDA validated abuse-deterrent opioids	12.2	12.6	3.2%
Long acting abuse-deterrent opioids without FDA validation	3.5	4.4	26.0%

Table 3. Opioid Claims and Total Paid by Category among 15 Million Commercially Insured Members From Jan. 1, 2014 through March 31, 2016

Category	Claims	%	Total Paid Amount*	%
Short acting	18,864,326	92.0%	$465,870,752	51.4%
Long acting	1,640,171	8.0%	$440,198,443	48.6%
Without abuse-deterrence	1,072,904	65.4%	$159,050,620	36.1%
FDA validated abuse-deterrent opioids	425,856	26.0%	$201,743,409	45.8%
Abuse-deterrent opioids without FDA validation	141,411	8.6%	$79,404,814	18.0%
Overall	**20,504,497**	**100.0%**	**$906,069,595**	**100.0%**

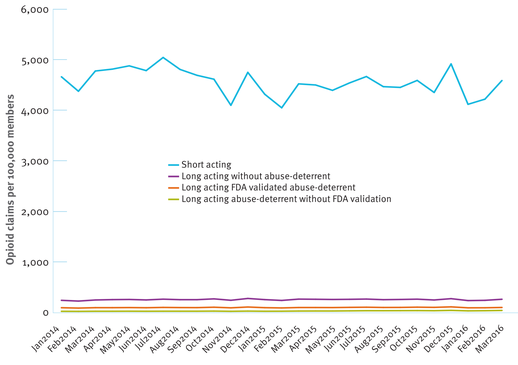
Total paid amounts are insurer plus member paid amounts. All pharmacy claims were normalized to 30-day supplies. For example, a 90-day supply constituted three separate claims. All claims with one to 34 days supply were counted as one claim.

Table 4. Long Acting Opioid Claims by Products With and Without FDA Validated Abuse-deterrent Properties and Total Paid Amount among 15 Million Commercially Insured Members from Jan. 1, 2014 through March 31, 2016

Products	Claims 567,267	%	Total Paid Amount* $281,148,224	%
FDA Validated Abuse-deterrent Opioids				
OxyContin® (oxycodone ER)	410,619	72.4%	$195,547,727	69.6%
Hysingla® ER (hydrocodone bitartrate)	11,930	2.1%	$4,704,325	1.7%
Embeda® (morphine/naltrexone)	3,307	0.6%	$1,491,357	0.5%
Abuse-deterrent Opioids Without FDA Validation				
Opana® ER (oxymorphone)	50,521	8.9%	$28,566,452	10.2%
Nucynta® ER (tapentadol)	43,358	7.6%	$20,573,087	7.3%
Exalgo® (hydromorphone)	21,068	3.7%	$19,348,710	6.9%
Oxycodone ER	15,878	2.8%	$7,539,726	2.7%
Zohydro® ER (hydrocodone bitartrate)	6,405	1.1%	$2,643,625	0.9%
Xartemis™ XR (oxycodone/acetaminophen)	4,048	0.7%	$660,840	0.2%
Oxaydo® (oxycodone)	133	0.02%	$72,375	0.03%

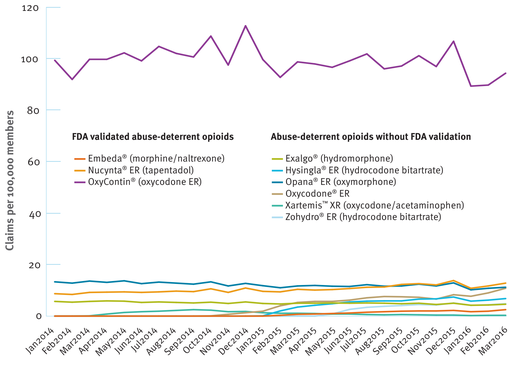
XR/ER=extended release. *Total paid amounts are insurer plus member paid amounts. All pharmacy claims were normalized to 30-day supplies. For example, a 90-day supply constituted three separate claims. All claims with one to 34 days supply were counted as one claim. Targiniq™ ER (oxycodone/naloxone) was approved in 2014 however no product has been launched. Troxyca® ER (oxycodone/naltrexone) was approved on August 22, 2016. MorphaBond™ had no active claims during the time of the analysis. Xtampza™ ER (oxycodone) was approved on April 29, 2016.

Figure 1. Opioid Claims per Month per 100,000 Commercially Insured Members by Opioid Category From Jan. 1, 2014 through March 31, 2016



All pharmacy claims were normalized to 30-day supplies. For example, a 90-day supply constituted three separate claims. All claims with one to 34 days supply were counted as one claim. Claims from 15 million commercially insured members.

Figure 2. Long Acting Abuse-deterrent Opioid Claims With and Without FDA Validation, per Month per 100,000 Commercially Insured Members from Jan. 1, 2014 through March 31, 2016



All pharmacy claims were normalized to 30-day supplies. For example, a 90-day supply constituted three separate claims. All claims with one to 34 days supply were counted as one claim. Claims from 15 million commercially insured members. Oxaydo (oxycodone) was excluded from the graph because it represented only 133 claims over the 27 month analysis period.

4085-C © Prime Therapeutics LLC 09/16
1305 Corporate Center Drive, Eagan, MN 55121

AMCP, October 2016, National Harbor, MD, U.S.A

Catherine Starner, 800.858.0723, ext. 5073
cstarner@primetherapeutics.com

03002808