Monitoring internet postings for mentions of an extended-release (ER) hydrocodone formulation with abuse-deterrent properties

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BACKGROUND

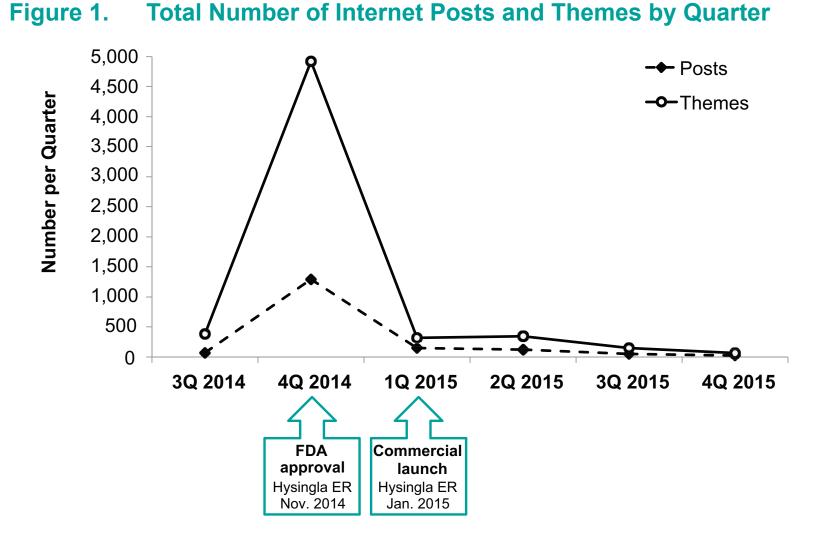
- The first single-entity extended-release (ER) hydrocodone formulation with abuse **Figure 1**. deterrent properties, Hysingla[®] ER, was approved by FDA in November 2014 and launched in January 2015.
- Because of the potential for abuse of opioids it is important to understand the interest of potential abusers.
- Therefore, internet mentions of Hysingla ER were examined before (3-4Q 2014) and after (1-4Q 2015) launch.

METHODS

- Over 150 million websites (eg, public social media websites, forums, blogs) worldwide were searched using a commercially available web monitoring platform operated by the Researched Abuse, Diversion, and Addiction-Related Surveillance (RADARS®) System Web Monitoring Program
- All posts that mentioned Hysingla ER, regardless of content, were identified.
- Trained coders reviewed posts to characterize salient themes and identify posts related to (Table 1):
 - Misuse ٠
 - Abuse ٠
 - Addiction •
 - Overdose ٠
 - Death ٠
 - Route of administration
 - Source of drug acquisition •
- Post sentiment (positive, neutral, negative) was also characterized (Table 1)
- For contextual information about product availability during this time, the number of Hysingla ER prescriptions dispensed was also examined using IMS Xponent data

Table 1. Definitions Used for Characterization of Internet Activity

Term	Definition
Content	
Post	A single communication about a drug by one individual



- Few posts mentioned abuse or misuse as the reason for Hysingla ER use. No posts mentioned addiction, overdose, death, or route of administration
- associated with Hysingla ER.

Reasons for Use and Coded Outcomes by Quarter Table 3.

	3Q 2014 n=70	4Q 2014 n=1,293	1Q 2015 n=149	2Q 2015 n=120	3Q 2015 n=49	4Q 2015 n=24
Misuse	0%	0%	0%	0%	2%	0%
Abuse	0%	0%	0%	0%	0%	0%
Potential Misuse/Abuse	0%	0%	0%	0.8%	4.1%	0%
Addiction	0%	0%	0%	0%	0%	0%
Overdose	0%	0%	0%	0%	0%	0%
Death	0%	0%	0%	0%	0%	0%

RESULTS (CONT.)

Mention	Any occasion of a reference to a drug in a post
Theme	The main message of a post
Reason for Use*	A mention that indicates:
Misuse	Improper or incorrect use of a drug for reason other than a psychotropic effect
Abuse	Use of a drug to gain a high, euphoric effect or some other psychotropic effect
Outcome	A mention that indicates:
Addiction	 One or more of the following: 1) psychological or physical dependence on a drug 2) tolerance to the psychotropic effects of a drug 3) withdrawal effects when discontinuing a drug
Overdose	 Accidental or intentional overdose of a drug, using a dangerous amount of a drug (ie, a quantity greater than recommended or generally prescribed), or use which may result in a medical intervention
Death	A death occurring due to a drug of interest
Sentiment	
Positive	 Promotes therapeutic benefits and safe use; discourages misuse, abuse, and diversion; or refers to a drug positively in other ways
Neutral	 A post from which no sentiment can be determined (eg, a post mentions use of a drug but makes no reference to either a positive or negative experience)
Negative	 Promotes misuse, abuse, and diversion; discourages safe and appropriate use; reports ineffectiveness or side effects, or refers to a drug negatively in other ways

*Overall 5 categories: abuse, misuse, potential misuse/abuse (a mention that indicates likely abuse/misuse), both abuse/misuse, neither

RESULTS

- Prior to the January 2015 launch, most posts were found on social media (>95% in 1Q and 2Q 2014).
- After launch, particularly 2Q 2015 4Q2015, the distribution shifted to posts primarily from blogs/forums.

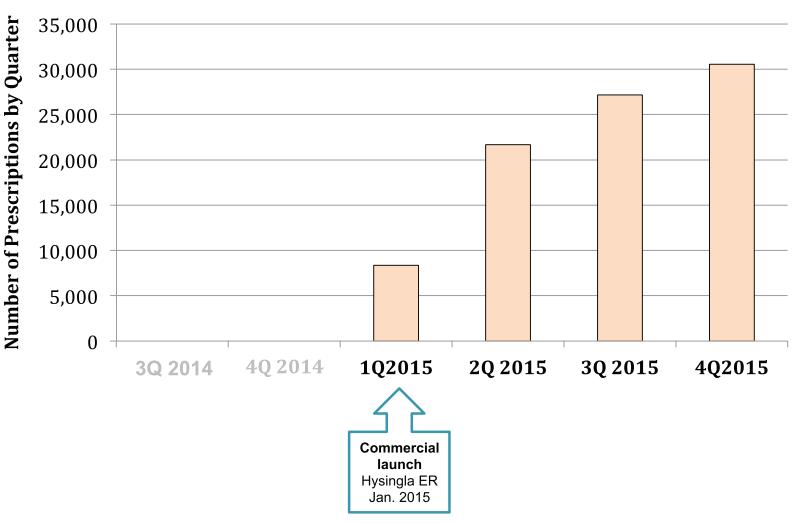
Source of Posts (Social Media, Blog/Forum) by Quarter Table 2.

	3Q 2014	4Q 2014	1Q 2015	2Q 2015	3Q 2015	4Q 2015
Blog/Forum	2.9%	4.3%	53.0%	93.3%	83.7%	79.2%
Social Media	97.1%	95.6%	47.0%	6.7%	16.3%	20.8%
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- After launch, the most common theme for posts (>90%) was opinion or sharing experience.
- The sentiment was primarily positive prior to the product launch in 1Q 2015.
- After launch in January 2015, sentiment remained relatively stable, with approximately 35%-50% of posts having a negative sentiment and approximately 15%-30% of posts having a positive sentiment.
- The highest number of posts about Hysingla ER occurred prior to launch, increasing from 70 in 3Q 2014 (385 themes) to a peak of 1,293 in 4Q 2014 (4,920 themes).

Figure 2. Hysingla ER Prescriptions by Quarter



DISCUSSION

- The RADARS Web Monitoring Program provides a rich source of information not available in other surveillance systems, and provides context for trends in discussion related to drugs of abuse.
- However, internet postings are spontaneously reported and it is not possible to confirm the content of reports.
- Additionally, few posts reported a reason for use (eg, abuse, misuse, etc.) which may limit the interpretability of these data.
- The pattern of results could change as product availability (ie, the number of prescriptions dispensed) increases.
- Therefore, it is important to continue monitoring abuse of Hysingla ER via a variety of data sources.

CONCLUSION

There was a peak in internet discussion after FDA approval in anticipation of the launch, though overall discussion of Hysingla ER has been low with very few posts mentioning abuse, misuse, addiction, overdose, or death.

Disclosure Statement

After launch, as shown in Figure 1, the number of posts was low.

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Dr. DeVeaugh-Geiss, Dr. Coplan, and Mr. Harikrishnan are employees of Purdue Pharma L.P.

*Dr. Chilcoat was an employee of Purdue Pharma L.P. at the time the analysis was conducted.

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