

NOTE

Does the New Formulation of OxyContin® Deter Misuse? A Qualitative Analysis

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The purpose of this qualitative study is to understand changing illicit drug use patterns in rural Appalachia since a new formulation of OxyContin® was released with the goal of deterring diversion and misuse. Participants ($n = 25$) from a longitudinal study of rural drug users ($N = 192$) were approached to participate in semistructured qualitative interviews between April and June 2011. The primary finding is that the majority of participants switched from using the original formulation OxyContin to immediate-release oxycodone. We discuss the implications and limitations of these findings.

Keywords OxyContin®, prescription drug, rural, misuse deterrence

INTRODUCTION

Prescription drugs, and opioids in particular, are widely misused in the United States. In 2011, prescription drugs were only second to marijuana in terms of being the most commonly used illicit drugs in the United States (Substance Abuse and Mental Health Services Administration [SAMHSA], 2012). Prescription pain relievers, primarily including prescription opioids, are the most commonly misused prescription drugs (SAMHSA, 2012). OxyContin®, a single-ingredient controlled-release oxycodone, was FDA approved in 1995 for moderate to severe pain lasting several days or more (Cicero et al., 2005). The number of OxyContin prescriptions climbed sharply from just over 300,000 in 1998 to over 6 million in 2009 (GAO, 2003; Wolfe, 2010). Law enforcement officials reported that OxyContin, more than any other prescription drug, was being diverted and abused (National Drug Intelligence Center [NDIC], 2004). OxyContin was particularly widely available in Central Appalachia, where there were higher rates of prescriptions for OxyContin as compared to the US average in the early 2000s (Van Zee, 2009).

Prescription opioid misuse may be more concentrated in rural and suburban areas than urban centers (Cicero et al., 2005; NDIC, 2004; Rosenblum et al., 2007). In one study, rural probationers were five times more likely than urban probationers to have reported misuse of prescription opioids (Havens et al., 2007a). Reports of OxyContin misuse and diversion in rural Appalachia appeared as early as 2000 from local law enforcement, the FDA, the DEA, and media sources (Cicero et al., 2005; Passik, 2003; GAO, 2003). Studies have associated prescription drug misuse with high rates of poverty and unemployment, physically exploitative labor conditions, chronic pain, lack of appropriate medical care especially in rural areas, and increased accessibility to prescription drugs (Anglin & White, 1999; Davis et al., 2003; Dew, Elifson & Dozier, 2007; Havens, Walker & Leukefeld, 2008; Inciardi & Goode, 2003; NDIC, 2010; Passik, 2003; Rosenblum et al., 2007).

A reformulation of OxyContin (OP) replaced the original formulation OxyContin (OC) in August 2010. The reformulation is referred to as OP throughout this paper because the reformulation has an “OP” rather than an “OC” imprint (Purdue Pharma L.P., 2010). The reformulation is bioequivalent to the original formulation, but utilizes physical and chemical barriers to make tablets difficult to manipulate for misuse and abuse (Purdue Pharma L.P., 2010). These types of reformulations have been touted as an important element in a comprehensive strategy in deterring prescription drug misuse (Office of National Drug Control Policy [ONDCP], 2011; Webster & Fine, 2010). Little is known about the impact of the reformulation on drug use patterns, especially in rural Central Appalachia where OC misuse has been reported extensively (Havens, Walker & Leukefeld, 2007b; Jonas et al., 2012; Young & Havens, 2012). Therefore, the purpose of this qualitative study is to understand changing drug use patterns as a result of the reformulation of OxyContin in the larger context of prescription drug misuse in rural Appalachia.

This study is part of a broader evaluation of changing drug use patterns in rural Appalachia that includes quantitative surveys.

METHODS

The study was conducted in a rural Appalachian county in Kentucky. The county is economically distressed, with 29% residents falling below the federal poverty line (Appalachian Regional Commission, 2011; U.S. Census Bureau, 2000). One hundred ninety-two self-reported OxyContin users who resided in rural Appalachian Kentucky and were age 18 or above were recruited for a quantitative study examining changes in drug use patterns in rural Appalachia using respondent-driven sampling (RDS). RDS allows researchers to reach hidden populations, especially those who may be participating in stigmatized activities (Barendregt et al., 2005). The seeds, or initial participants who recruited additional participants, were recruited via flyers targeting OxyContin users that were posted on the main street in the largest town in the county and in post offices, gas stations, grocery stores, and convenience stores located throughout the county. Once the seed was interviewed, they were given three coupons that they were instructed to give to other OxyContin users. The original seed was compensated \$10 for each redeemed coupon. Of the 192 participants in the quantitative study, 25 were recruited to participate in qualitative interviews in order to further understand the impact of the reformulation on drug use patterns. Study staff recruited participants according to participants' randomly assigned participant identification numbers. Participants with the lowest identification numbers were contacted first and asked if they would be open to talking about drug use in a qualitative interview. After 18 participants were interviewed, data indicated that drug users under the age of 25 were underrepresented; therefore, efforts were made to recruit participants under the age of 25 until a total sample size of 25 participants was reached.

Potential participants were contacted by telephone or in-person, invited to learn about the qualitative study, and asked to participate. After agreeing to participate, the informed consent was read aloud by the interviewer, stressing that participation was voluntary and that participants could withdraw from the study at any time. Participants were given an opportunity to ask questions before providing written informed consent. The University of Kentucky Institutional Review Board approved the study. Participants were compensated \$50 for participating in the interview.

The first author conducted face-to-face in-depth interviews with 25 self-identified OxyContin users between April and June 2011. Interviews lasted from 35 to over 60 minutes. An interview guide focused the interview, permitting comparability across interviews. The guide included open-ended questions about perceived changes in county drug use patterns, changes in individual drug use patterns, sources of prescription drugs, and past and current illicit and prescription drug use. Although the in-

terviews were structured, the interviewer had flexibility in clarifying and exploring topics introduced by participants. Notes were taken during interviews and all interviews were audio-taped and transcribed. Information on participant characteristics and drug use history were also incorporated from the baseline quantitative survey data and provided context to participants' perspectives. The data consisted of transcribed interviews and field notes. All data were analyzed with ATLAS.ti (Muhr, 2010), a qualitative analysis software program. Variables and concepts from the extant literature and emergent codes from the data were used to develop the coding framework.

RESULTS

Thirteen participants identified as female, 92% were non-Hispanic white, 2% were African-American/Black, 56% had earned a high school degree or higher, and 52% were employed at the time of the interview. The mean age of participants was 32.4 years. Seventeen (68%) respondents had been incarcerated, spending an average of 17.4 months in correctional facilities. The majority of participants were uninsured and 72% had been treated for substance abuse at least once. In the 30 days prior to the interview, the following percentage of participants had used each of the listed opioids: 92% had used a non-OxyContin oxycodone formulation, 76% hydrocodone, 60% OC, 40% OP, 36% illegal methadone, 32% oxymorphone, 8% hydromorphone, 8% morphine, and 4% extended release oxymorphone. No participants reportedly used heroin. Over three-quarters of participants (76%) regularly injected prescription opioids.

All participants reported that OxyContin had become unpopular and difficult to find since the formulation was changed to OP in August 2010. Participants uniformly reported a dislike of OP because of their perceived inability to inject or snort the pill, "You can't do nothin' with [OPs] but swallow 'em so a lot of people, they won't buy 'em." Participants who swallowed OP and those who claimed to be able to inject or snort OP also suggested that OP was not as potent and did not last as long as OC. The unpopularity of OP made it difficult to sell and cheaper than OC. While OC was generally selling for \$1.25 to \$2 per milligram when it was available, OP was selling for \$.50 to \$1 per milligram. People therefore stopped requesting prescriptions for OP, "I think most of the people try to get their doctors to quit writin' the OPs, and go to the [IR] 30s 'cause they can't make any money off [OP]." Therefore, OP was hard to find in the county. OP was so infrequently seen that eight participants were confused about the difference between OP and the oxymorphone tablet Opana®, which has also been reformulated to deter misuse and appeared in the county about the same time as OP. Several participants did not think the reformulated OP would affect drug use in the area, "I mean once you take one away they're just goin' to rely on somethin' else you know, it really, no it don't really help I don't think 'cause like I said, they'll just rely on somethin' else."

Despite the unpopularity of OP for not being able to be injected or snorted and being less potent than OC, three participants claimed they could inject OP and six said they could snort OP. The majority of other participants had heard others say they could inject or snort OP, but many were skeptical as to whether users were actually able to inject or snort OP. Although two participants claimed to be able to inject OP through a tedious process of working up the drug, the third participant who injected OP developed a large knot in her arm after she injected; she did not try to inject OP again after that experience. Even participants who said they could inject or snort OP did not like OP because they said it was too difficult to inject or snort as compared to other pharmaceuticals that were available for purchase on the street.

All participants agreed that during 2010, single-ingredient immediate-release oxycodone hydrochloride (IR) had replaced OxyContin as the most popular, most available, and most misused prescription drug.

I mean it just seems like everybody, it seems like everybody's hooked on [IR] 30s now, it seems like they're everywhere. Everybody I know is trying to go to the doctor or tryin' to buy 'em cheap and get 'em and doin' 'em. It just really seems like the 30s have boomed.

When asked how prevalent IRs were in the county, one participant stated, "I can leave here and go to ten different places, and you know, and get 'em right now." There was no indication that other types of opioids, including heroin, had replaced OC in the county. Participants started using IRs as early as 2007 because IRs were cheaper than OCs, were easily obtained, and IRs can be snorted and injected, "Everyone's tryin' to buy that...they call 'em IR 15s, IR 30s, it's somethin' you can snort or inject." Although most participants liked using IRs, they generally preferred OCs, "OCs are stronger, but the new IRs that they've been coming out with everybody's likin' them a lot."

DISCUSSION

The misused prescription opioids which were most prevalent in this Central Appalachian county changed after the reformulation of OxyContin. As expected (ONDCP, 2011; Webster & Fine, 2010), the reformulation of OxyContin (OP) deterred use of this new OxyContin. Most participants did not think that OP could be injected or snorted and therefore did not want to try the drug. Other participants, even those who claimed to be able to inject or snort OP, thought that OP was difficult to inject or snort and was less potent and did not last as long as OC. However, use of OCs was largely replaced with use of IR oxycodone, although use of OCs was still preferred, if available.

Overall, based on these extensive qualitative interviews, it appears that the reformulated OxyContin has been effective in deterring misuse of this new formulation. However, misuse of other prescription opioids was not affected by the reformulation; in fact, it appears that there have been increases in use of other oxycodone

formulations, especially immediate-release oxycodone. Therefore, these data provide strong support for the development of reformulations that make opioid analgesic tablets difficult to inhale or inject for all single-ingredient formulations that are subject to misuse. However, reformulation is not enough. Interstate reporting to prescription drug monitoring programs, clinician education to prevent overprescribing, access to pain treatment, access to mental health services, and availability of drug treatment could also decrease prescription opioid misuse (Havens et al., 2008; Lipman, 2003; Regier et al., 1990; ONDCP, 2011).

There are study limitations. First, these data offer an in-depth understanding of changing drug use patterns among only a small sample of individuals in a Central Appalachian county who reported OxyContin use. The area and participants were purposively selected. Therefore, these findings may not be generalizable to other populations who are misusing prescription opioids. Also, these data rely on self-report, which may be subject to recall bias when discussing temporally remote events (Kokkevi, Richardson, Palermou & Leventakou, 1997) or to social desirability responder bias when discussing risk behaviors (Latkin, Vlahov & Anthony, 1993).

Declaration of Interest

This study was funded by Purdue Pharma LP, Inc. The authors alone are responsible for the content and writing of the article.

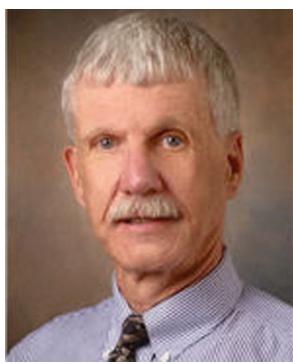
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GLOSSARY

- OC:** Original formulation of OxyContin.
OP: Reformulation of OxyContin that utilizes physical and chemical barriers to make tablets difficult to manipulate for misuse.
Prescription drug misuse: The use of prescribed drugs without a prescription or against a licensed medical provider's directions (Quintero, Peterson & Young, 2006).
Prescription opioids: Prescribed by a licensed medical provider to relieve pain and includes such pharmaceuticals as hydrocodone (e.g. Lortab®), oxycodone (e.g. OxyContin), and morphine (e.g. Avinza®).

REFERENCES

- Anglin, M. K., & White, J. C. (1999). Poverty, health care, and problems of prescription medication: a case study. *Substance Use Misuse*, 34(14), 2073–2093.
- Appalachian Regional Commission. (2011). *County Economic Status and Number of Distressed Areas in Appalachian Kentucky, Fiscal Year 2012*. Retrieved from http://www.arc.gov/images/appregion/economic_statusFY2012/CountyEconomic_StatusndDistressAreasFY2012Kentucky.pdf
- Barendregt, C., van der Poel, A., & van de Mheen, D. (2005). Tracing selection effects in three non-probability samples. *European Addiction Research*, 11(3), 124–131.
- Cicero, T. J., Inciardi, J. A., & Muñoz, A. (2005). Trends in abuse of OxyContin® and other opioid analgesics in the United States: 2002–2004. *Journal of Pain*, 6(10), 662–672.
- Davis, M. P., Varga, J., Dickerson, D., Walsh, D., LeGrand, S. B., & Lagman, R. (2003). Normal-release and controlled-release oxycodone: pharmacokinetics, pharmacodynamics, and controversy. *Supportive Care in Cancer*, 11(2), 84–92.
- Dew, B., Elifson, K., & Dozier, M. (2007). Social and environmental factors and their influence on drug use vulnerability and resiliency in rural populations. *Journal of Rural Health*, 23(S1), 16–21.
- Havens, J. R., Oser, C. B., Leukefeld, C. G., Webster, J. M., Martin, S. S., O'Connell, D. J., et al. (2007a). Differences in prevalence of prescription opiate misuse among rural and urban probationers. *American Journal of Drug and Alcohol Abuse*, 33(2), 309–317.
- Havens, J. R., Walker, R., & Leukefeld, C. G. (2007b). Prevalence of opioid analgesic injection among rural nonmedical opioid analgesic users. *Drug and Alcohol Dependence*, 87(1), 98–102.
- Havens, J. R., Walker, R., & Leukefeld, C. G. (2008). Prescription opioid use in rural Appalachia: A community based study. *Journal of Opioid Management*, 4(2), 63–71.
- Inciardi, J. A., & Goode, J. L. (2003). Miracle medicine or problem drug? OxyContin and prescription drug abuse. *Consumer Research*, July 2003, 17–21.
- Jonas, A. B., Young, A. M., Oser, C. B., Leukefeld, C. G., & Havens, J. R. (2012). OxyContin as currency: OxyContin use and increased social capital among rural Appalachian drug users. *Social Science and Medicine*, 74(10), 1602–1609.
- Kokkevi, A., Richardson, C., Palermou, B., & Leventakou, V. (1997). Reliability of drug dependents' self-reports. *Drug and Alcohol Dependence*, 45(1–2), 55–61.
- Latkin, C. A., Vlahov, D., & Anthony, J. C. (1993). Socially desirable responding and self-reported HIV infection risk behaviors among intravenous drug users. *Addiction*, 88(4), 517–526.
- Lipman, A. G. (2003). What have we learned from OxyContin? *Journal of Pain and Palliative Care Pharmacotherapy*, 17(1), 1–4.
- Muhr, T. (2010). *ATLAS.ti*. Berlin: Scientific Software Development.
- Passik, S. D. (2003). Same as it ever was? Life after the OxyContin® media frenzy. *Journal of Pain and Symptom Management*, 25(3), 199–201.
- Purdue Pharma L. P. (2010). *Statement of Purdue Pharma L. P. Regarding FDA's Approval of Reformulated OxyContin® (Oxycodone HCl Controlled-Release) Tablets*. Retrieved from <http://www.purduepharma.com/News-and-Media/News/Pages/20100405.aspx>
- Quintero, G., Peterson, J., & Young, B. (2006). An exploratory study of socio-cultural factors contributing to prescription drug misuse among college students. *Journal of Drug Issues*, 36(4), 903–932.
- Reiger, D. A., Farmer, M. E., Rae, D. S., Locke, B. Z., Keith, S. J., Judd, L. L., et al. (1990). Comorbidity of mental disorders with alcohol and other drug abuse. *Journal of the American Medical Association*, 264(19), 2511–2518.
- Rosenblum, A., Parrino, M., Schnoll, S. H., Fong, C., Maxwell, C., Cleland, C. M., et al. (2007). Prescription opioid abuse among enrollees into methadone maintenance treatment. *Drug and Alcohol Dependence*, 90(1), 64–71.
- U.S. Census Bureau. *United States Census 2000*. Washington, DC: U.S. Census Bureau.
- U.S. General Accounting Office. (2003). *Prescription drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*. Washington, DC: U.S. General Accounting Office.
- U.S. National Drug Intelligence Center. (2004). *Intelligence Bulletin: OxyContin Diversion, Availability, and Abuse*. Johnstown, PA: U.S. National Drug Intelligence Center.
- U.S. National Drug Intelligence Center. (2010). *Appalachia High Intensity Drug Trafficking Area: Drug Market Analysis 2010*. Johnstown, PA: U.S. National Drug Intelligence Center.

- U.S. Office of National Drug Control Policy. (2011). *Epidemic: Responding to America's Prescription Drug Abuse Crisis*. Washington, DC: U.S. Office of National Drug Control Policy.
- U.S. Substance Abuse and Mental Health Services Administration. (2012). *Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings*. Rockville, MD: U.S. Substance Abuse and Mental Health Services Administration.
- Van Zee, A. (2009). The promotion and marketing of OxyContin: Commercial triumph, public health tragedy. *American Journal of Public Health, 99*(2), 221–227.
- Webster, L. R., & Fine, P. G. (2010). Approaches to improve pain relief while minimizing opioid abuse liability. *Journal of Pain, 11*(7), 602–211.
- Wolfe, S. (2010). Annual U.S. OxyContin prescriptions (millions). U.S. Food and Drug Administration. Retrieved from <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndLifeSupportDrugsAdvisoryCommittee/UCM220954.pdf>
- Young, A. M., & Havens, J. R. (2012). Transition from first illicit drug use to first injection drug use among rural Appalachian drug users: A cross-sectional comparison and retrospective survival analysis. *Addiction, 107*(3), 587–596.