

Methodological Advances in Evaluating Abuse-deterrent Opioid Analgesics - Pharmacist Survey

Thank you for taking the time to complete the survey. Your input will be valuable to us as we work to understand the prescribing and dispensing of abuse-deterrent formulation opioid analgesics.

Please note that you can move between pages of the survey, and, if you are interrupted, can return to complete the survey as long as you keep the window open.

You are invited to participate in a survey collecting information and opinions related to the prescribing and dispensing of abuse-deterrent formulation opioid analgesics. This study is being conducted on behalf of the U.S. Food and Drug Administration by researchers at the University of Kentucky Colleges of Pharmacy and Public Health.

You have been asked to participate in this survey because you are a licensed pharmacist with the ability to dispense controlled substances in the state of Kentucky. If you voluntarily complete the survey, you will be one of approximately 1,000 pharmacists to do so. The survey will take approximately 10 minutes to complete.

The survey asks about your stocking and dispensing of abuse-deterrent formulation opioid analgesics. The information generated from this research will assist in our understanding of how these medications are being utilized in practice.

Your response to the survey is anonymous. Neither the researchers nor the pharmacy board will know who did, or did not, respond to the survey. The research team will not attempt to trace responses back to individuals. There are no known risks associated with disclosure of your opinions about the prescribing and dispensing of abuse-deterrent formulations of opioid analgesics. Your information will be kept secure to the extent required by law.

You may receive two additional email invitations to participate in this survey over the next two weeks. If you have already responded, or elect not to respond to the survey, please ignore these additional emails.

Taking part in this research is completely voluntary. If you choose not to participate, there will be no penalty to you. You are free to skip any question that you do not want to answer, and you can discontinue the survey at any time. Although you will not personally benefit by completing the survey, the information that you provide may help us understand how abuse-deterrent formulations might be used more effectively.

This study has been reviewed by the University of Kentucky Medical Institutional Review Board. If you have questions about this study, you may call Patricia Freeman at 859-323-1381 or Svetla Slavova at 859-323-7873. If you have any questions about your rights as a volunteer in this research, you may contact the staff in the Office of Research Integrity at the University of Kentucky at 859-257-9428 or toll free at 1-866-400-9428.

Thank you for your time and we appreciate your consideration in completing this survey.

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OMB Control No.: 0910-0847

Expiration Date: 11/30/2020

Paperwork Reduction Act Statement: According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0847, and the expiration date is 11/30/2020. The time required to complete this information collection is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden, to PRASStaff@fda.hhs.gov.

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Do you dispense opioid analgesics in your practice?

- Yes
 No

Thank you for your willingness to participate. This survey focuses on the dispensing of opioid analgesics. We look forward to your participation in future surveys.

Section I. Questions about your perception of abuse-deterrent formulation opioids.

One of the ways that the U.S. Food and Drug Administration (FDA) has tried to address the opioid epidemic is by approving opioid analgesic products that are designed to be harder to manipulate and abuse. These so-called 'abuse-deterrent formulations' (e.g. OxyContin®, Embeda®, etc.) are intended to make certain types of abuse, such as crushing a tablet to snort or dissolving a capsule to inject, more difficult or less rewarding.

Considering your experience dispensing opioid analgesics, how would you rate your familiarity with abuse-deterrent formulation opioids?

- Not familiar at all
- Somewhat familiar
- Familiar
- Very familiar
- Unsure

Individuals who misuse/abuse prescription opioids do so using varied routes of administration. In your professional opinion, how effective are abuse-deterrent formulation opioids in mitigating misuse/abuse by each of these specific routes?

	Not effective at all	Somewhat effective	Effective	Very effective	Unsure
Smoking	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Snorting	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chewing or dissolving before swallowing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Swallowing intact	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Injection (intravenous, intramuscular, or subcutaneous)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please indicate the extent to which you agree or disagree with the following statement:

In my professional opinion, to gain and maintain FDA-approval, all opioid analgesics should meet FDA standards as abuse-deterrent formulations.

- Strongly disagree
- Disagree
- Agree
- Strongly agree
- Unsure

If you selected "Strongly agree," please elaborate.

If you selected "Strongly disagree," please elaborate.

Section II. Questions about your experience dispensing abuse-deterrent formulation opioid analgesics.

When making dispensing decisions regarding opioid analgesic prescriptions, do you consider whether or not the opioid is an abuse-deterrent formulation?

- Yes
- No

If you answered "Yes," please describe why you make this consideration.

If you answered "No," please describe why you do not make this consideration.

For each of the following abuse-deterrent formulation opioids, please indicate the frequency with which you have dispensed them in your practice.

	Not in stock, Never dispensed	In stock, Never dispensed	Rarely (i.e. a few times a year)	Occasionally (i.e. monthly)	Frequently (i.e. weekly)	Very frequently (i.e. daily)
Embeda® (morphine sulfate and naltrexone hydrochloride extended-release)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hysingla® ER (hydrocodone bitartrate extended-release)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
MorphaBond® ER (morphine sulfate extended-release)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
OxyContin® (oxycodone hydrochloride extended-release)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Xtampza® ER (oxycodone extended-release)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

In general, for those not stocked and never dispensed, please indicate the primary reason(s) why they are not stocked in your pharmacy. (select all that apply)

- Too few prescriptions presented to the pharmacy
- Inventory costs are too great
- Lack of third-party payer coverage makes them unaffordable for most patients
- Time/resources involved in securing third-party payment approval (e.g. prior authorization)
- Other

If you selected 'Other,' please describe.

Considering your past dispensing experience, please indicate the frequency with which you have taken the following actions?

	Never	Rarely	Occasionally	Frequently	Very frequently
Substituted a generic non-abuse-deterrent formulation opioid when presented with a prescription for an abuse-deterrent formulation opioid	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dispensed an abuse-deterrent formulation opioid when presented with a prescription written generically (e.g. dispensed MorphaBond® ER for morphine sulfate ER)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Contacted a prescriber to recommend an abuse-deterrent formulation opioid for a patient SPECIFICALLY because of its abuse-deterrent properties	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Declined to fill an abuse-deterrent formulation prescription because it was not in stock	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Asked patient with an abuse-deterrent formulation prescription not in stock to return next day to pick up the prescription	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

What circumstance(s) best describe(s) your reason(s) for substituting a generic non-abuse-deterrent formulation opioid when presented with a prescription for an abuse-deterrent formulation opioid? (select all that apply)

- Patient preferred / requested non-abuse-deterrent formulation
- Only product stocked was non-abuse-deterrent formulation
- Abuse-deterrent formulation opioid was not covered by patient insurance
- Patient copay/coinsurance for the abuse-deterrent formulation was not affordable for the patient
- Other

If you selected 'Other,' please describe.

What circumstance(s) best describe(s) your reason(s) for dispensing an abuse-deterrent formulation opioid when presented with a generically-written prescription ? (select all that apply)

- Patient's past medical history
- General concern about potential misuse/abuse
- Patient preferred / requested abuse-deterrent formulation
- Only product stocked is abuse deterrent formulation
- Reimbursement for abuse-deterrent formulation is more favorable
- Other

If you selected 'Other,' please describe.

Section III. Questions about third-party payer requirements and reimbursement for abuse-deterrent formulation opioids that you have dispensed.

For each of the following abuse-deterrent formulation opioids that you have in stock or have dispensed, please indicate how often the claims you submit for reimbursement are rejected by third-party payers.

	Rarely	Occasionally	Almost always	I am unsure how often claims are rejected.
Embeda® (morphine sulfate and naltrexone hydrochloride extended-release)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hysingla® ER (hydrocodone bitartrate extended-release)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
MorphaBond® ER (morphine sulfate extended-release)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
OxyContin® (oxycodone hydrochloride extended-release)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Xtampza® ER (oxycodone extended-release)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Considering your past experience, when a claim submitted for an abuse-deterrent formulation opioid was rejected, which of the following actions have you taken? (select all that apply)

- Contacted the third-party payer and/or prescriber to request a prior authorization
- Asked the patient to contact the third-party payer and/or prescriber to request a prior authorization
- Substituted a generic non-abuse-deterrent formulation
- Contacted the prescriber to request a new e-script for a different product
- Asked the patient to contact the prescriber to get a new script for a different product
- Allowed patient to pay cash or use copay/discount card
- Other
- I have never submitted a claim for an abuse-deterrent formulation that was rejected by the payer

If you selected 'Other' please describe.

Considering your past experience dispensing abuse-deterrent formulation opioids, how often has high cost-sharing (i.e. copayment or coinsurance) resulted in a patient being unable or unwilling to obtain the abuse-deterrent formulation?

- Never
- Rarely
- Occasionally
- Frequently
- Very frequently

Considering your past experience dispensing abuse-deterrent formulation opioids, which of the following types of third-party payer claims are most often rejected or subject to high cost-sharing such that the patient does not receive the prescribed abuse-deterrent formulation opioid?

- Medicare
- Medicaid
- Commercial
- TRICARE
- Unsure
- These issues appear to be similar among third-party payers

At this time, would you support state legislation mandating third-party payer coverage of abuse-deterrent formulation opioids?

- Yes
- No

Please elaborate as to why you would not support this legislation.

Please elaborate as to why you would support this legislation.

Section IV. Questions about your perception of opioid misuse/abuse.

Please indicate to what extent you agree or disagree with the following statements.

	Strongly disagree	Disagree	Agree	Strongly agree	Unsure
The misuse/abuse of prescription opioids is a problem in my community.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The misuse/abuse of prescription opioids is a problem among patients at my practice.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I am confident in my ability to identify a patient who is misusing/abusing prescription opioids.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

In your professional opinion, which of the following routes of administration is used most commonly by individuals who misuse/abuse opioid medications?

- Smoking
- Snorting
- Chewing or dissolving before swallowing
- Swallowing intact
- Injection (intravenous, intramuscular, or subcutaneous)
- Unsure

In your professional opinion, how effective are the following strategies in mitigating the misuse/abuse of prescription opioids?

	Not effective at all	Somewhat effective	Effective	Very effective	Unsure
Checking the prescription drug monitoring program (KASPER)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pharmacist-driven pill counts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Abuse-deterrent formulation opioids	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Urine drug screening	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Prescriber-driven pill counts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Payer restriction programs to a single pharmacy and/or single prescriber (e.g. lock-in program)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Prescribing (days' supply) limits	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Section V. Questions about calculating days' supply for controlled substances.

The calculation of days' supply for controlled substance prescriptions is not standardized and may vary based upon pharmacist interpretation and clinical judgment. This section seeks to better understand how pharmacists determine days' supply and the factors that might influence days' supply calculations.

You are presented with the following prescription:

Hydrocodone/Acetaminophen 5 mg/325 mg
1-2 tabs Q 4-6H PRN breakthrough pain
#360

What days' supply would you enter for this prescription?

Please explain the rationale you used to determine the days' supply to enter for this prescription.

You are presented with the following prescription:

Morphine sulfate 10 mg/5 mL
2 tsp Q6H PRN breakthrough pain
#280 mL

What days' supply would you enter for this prescription?

When determining the days' supply of a controlled substance prescription, which of the following factors do you consider? (check all that apply)

- Likelihood that patient misuses/abuses the prescription
- Patient fill history patterns
- If the prescription is written on a scheduled or on an 'as needed' basis
- Concomitant use of other controlled substances
- Familiarity with practitioner's prescribing patterns
- Third-party payer restrictions on days' supply
- Schedule of the prescription (C-II to C-V)
- Instructions from the prescriber regarding intended duration of the prescription
- System or government oversight of dispensing patterns
- Other
- I calculate days' supply without considering any of these factors

If you selected 'Other,' please describe.

In your professional opinion, accurate days' supply calculations is/are important to: (check all that apply)

- Satisfy 3rd party payer requirements
- Satisfy DEA regulations and KY Board of Pharmacy Rules
- Ensure accurate assessment of doctor shopping behavior in KASPER
- Ensure accurate calculation of morphine milligram equivalents in KASPER
- Determine when medication is due to be filled/refilled
- Support safe medication use for patients

Section VI: Questions about you and your practice.

What is your gender?

- Male
- Female
- Prefer not to answer
- Prefer to self-describe

If you selected 'Prefer to self-describe,' you may do so here. _____

What is your terminal degree?

- BS Pharmacy
- PharmD

Which of the following best characterizes your primary practice setting?

- Community pharmacy - chain/supermarket/mass merchandiser
- Community pharmacy - independent
- Health-system outpatient pharmacy
- Long-term care pharmacy
- Mail order or specialty pharmacy
- Hospital inpatient pharmacy
- Other

If you selected 'Other,' please describe. _____

Please indicate your total number of years in practice.

- < 5
- 5-15
- 16-25
- 26-35
- > 35

In which county is your primary practice site located (i.e. the site where you spend the most time each week)?

- Adair
- Allen
- Anderson
- Ballard
- Barren
- Bath
- Bell
- Boone
- Bourbon
- Boyd
- Boyle
- Bracken
- Breathitt
- Breckinridge
- Bullitt
- Butler
- Caldwell
- Calloway
- Campbell
- Carlisle
- Carroll
- Carter
- Casey
- Christian
- Clark
- Clay
- Clinton
- Crittenden
- Cumberland
- Daviess
- Edmonson
- Elliott
- Estill
- Fayette
- Fleming
- Floyd
- Franklin
- Fulton
- Gallatin
- Garrard
- Grant
- Graves
- Grayson
- Green
- Greenup
- Hancock
- Hardin
- Harlan
- Harrison
- Hart
- Henderson
- Henry
- Hickman
- Hopkins
- Jackson
- Jefferson
- Jessamine
- Johnson
- Kenton
- Knott
- Knox
- LaRue
- Laurel
- Lawrence
- Lee
- Leslie
- Letcher

- Lewis
- Lincoln
- Livingston
- Logan
- Lyon
- McCracken
- McCreary
- McLean
- Madison
- Magoffin
- Marion
- Marshall
- Martin
- Mason
- Meade
- Menifee
- Mercer
- Metcalfe
- Monroe
- Montgomery
- Morgan
- Muhlenberg
- Nelson
- Nicholas
- Ohio
- Oldham
- Owen
- Owsley
- Pendleton
- Perry
- Pike
- Powell
- Pulaski
- Robertson
- Rockcastle
- Rowan
- Russell
- Scott
- Shelby
- Simpson
- Spencer
- Taylor
- Todd
- Trigg
- Trimble
- Union
- Warren
- Washington
- Wayne
- Webster
- Whitley
- Wolfe
- Woodford

On average, how many total prescriptions (opioid and non-opioid) are dispensed daily from your primary practice site?

- < 150
- 150-249
- 250-349
- 350-450
- > 450
- Unsure

To your recollection, have you ever completed continuing education that discussed the use of abuse-deterrent formulation opioids as a means of promoting safe opioid use?

- Yes
- No

Section VII. Opportunity to provide additional thoughts on survey topics.

Please share any additional thoughts you have about abuse-deterrent formulation opioids and opioid misuse/abuse.
