

Methodological Advances in Evaluating Abuse-deterrent Opioid Analgesics - Physician 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 physician with the ability to prescribe controlled substances in the state of Kentucky. If you voluntarily complete the survey, you will be one of approximately 1,500 physicians to do so. The survey will take approximately 10 minutes to complete.

The survey asks about your prescribing 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 licensure 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 provided 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.

Patricia Freeman, PhD
Associate Professor
University of Kentucky College of Pharmacy

Svetla Slavova, PhD
Associate Professor
University of Kentucky College of Public Health

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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.

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.

Do you prescribe opioid analgesics in your practice?

- Yes
 No

Thank you for your willingness to participate. This survey focuses on the prescribing 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 prescribing 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 abuse/misuse 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 prescribing medications newly-approved by the FDA and abuse-deterrent formulation opioid analgesics.

Which of these describes you well when it comes to prescribing medications newly approved by the FDA? (select all that apply)

- Usually prescribe new medications before others do
- Prefer medications which have worked well for patients in the past
- Like being able to share with colleagues about new medications I've prescribed
- Like the variety of prescribing new medications
- Feel more comfortable using familiar medications
- Prefer to wait until I hear about colleagues' experiences with prescribing new medications
- Other

If you selected 'Other,' please describe.

When making prescribing decisions regarding which opioid analgesic to prescribe, do you consider whether or not the opioid is an abuse-deterrent formulation?

- Yes
- No

To what extent do each of the following patient-specific factors influence your decision to prescribe an abuse-deterrent formulation opioid over a non-abuse-deterrent opioid analgesic?

| | No influence | Little influence | Some influence | Great influence |
|--|-----------------------|-----------------------|-----------------------|-----------------------|
| Patient demographics (e.g. age, ethnicity) | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Patient preference for a specific opioid product | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Concern for misuse/abuse by patient or patient's family member | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Anticipated cost to patient | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Risk of diversion by patient or patient's family members | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Total daily dosage of opioid patient requires | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Patient's risk stratification score | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Patient's concomitant medication use | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Concern over patient switching to illicit opioid | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Which of the following risk-stratification tools do you most commonly utilize?

- Opioid risk tool
- Screener and Opioid Assessment for Patients with Pain - Version 1 (SOAPP-1)
- Screener and Opioid Assessment for Patients with Pain - Revised (SOAPP-R)
- Brief Risk Interview
- Other

If you selected 'Other,' please provide the name of the risk-stratification tool you most commonly utilize.

To what extent do each of the following non-patient-specific factors influence your decision to prescribe an abuse-deterrent formulation opioid over a non-abuse deterrent opioid analgesic?

| | No influence | Little influence | Some influence | Great influence |
|--|-----------------------|-----------------------|-----------------------|-----------------------|
| Past experience prescribing abuse-deterrent formulations | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| System or government oversight of prescribing patterns | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Anecdotal prescribing experience of colleagues | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Third-party payer considerations | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Effectiveness compared to traditional formulations | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Practice- or system-level policies | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Information provided by sales reps, medical liaisons, etc. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Innovative nature of abuse-deterrence mechanisms | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Potential public health impact of reducing the supply of abusable prescription opioids | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

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

| | Never | 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"/> |
| Hysingla® ER (hydrocodone bitartrate extended-release) | <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"/> |
| Xtampza® ER (oxycodone extended-release) | <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"/> |

For the abuse-deterrent formulations that you have never prescribed, please indicate to what extent the following factors generally influenced your decision NOT to prescribe these agents?

| | No influence | Little influence | Some influence | Great influence |
|---|-----------------------|-----------------------|-----------------------|-----------------------|
| Generally prescribe generic medications over brand-name medications | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Lack of familiarity with the product(s) | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Patient preference for a non-abuse deterrent formulation | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Lack of third-party coverage or high copays makes them unaffordable for most patients | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Concern that patients will switch to illicit alternative (e.g. heroin) | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Skepticism that abuse-deterrent properties will prevent addiction or overdose | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Concern that the abuse-deterrent formulation may provide inadequate analgesia | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Patients to whom I prescribe opioid analgesics are at low risk for misuse/abuse | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Evidence-based guidelines do not list abuse-deterrent formulations as preferred over non-abuse deterrent formulations | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

In general, please indicate the primary reason you have prescribed OxyContin®.

- It is an extended-release opioid product covered by most third-party payers
- It is an abuse-deterrent formulation
- It is an appropriate extended release regimen for patients who have been on oxycodone immediate-release
- It has been an effective treatment for previous patients
- Patient was started on OxyContin by another provider and appears to be benefiting from it

Section III. Communication with patients and pharmacists regarding abuse deterrent formulation opioids.

To your recollection, have any of your patients ever specifically requested to receive an abuse-deterrent opioid formulation instead of a non-abuse-deterrent opioid formulation?

- Yes
 No

What circumstances best describe the reason(s) a patient specifically requested an abuse-deterrent formulation opioid instead of a non-abuse-deterrent opioid? (select all that apply)

- Past medical history
 Concern about misuse/abuse potential of non-abuse-deterrent formulations by others
 Belief that abuse-deterrent formulations were safer than non-ADFs
 Other

If you selected 'Other,' please describe.

To your recollection, has a patient to whom you prescribed an abuse-deterrent formulation opioid ever specifically requested to switch to a non-abuse-deterrent formulation?

- Yes
 No

Please describe the reason(s) the patient requested to switch to a non-abuse-deterrent formulation opioid.

To your recollection, have you ever been contacted by a pharmacist who recommended an abuse-deterrent formulation opioid for a patient SPECIFICALLY because of its abuse-deterrent properties?

- Yes
 No

To your recollection, have you ever been contacted by a pharmacist to request substitution of a non-abuse-deterrent formulation opioid for an abuse-deterrent formulation opioid? (e.g. MorphaBond® ER to MS Contin)?

- Yes
 No

What circumstance(s) best describe(s) the reason(s) a pharmacist contacted you to request substitution of a non-abuse-deterrent formulation opioid for an abuse-deterrent formulation opioid? (select all that apply)

- Abuse-deterrent formulation was out of stock
 Cost to patient was lower for non-abuse-deterrent formulation
 Patient preferred / requested a non-abuse-deterrent formulation
 Claim to third-party payer for abuse-deterrent formulation was rejected
 Other

If you selected 'Other,' please describe.

Did you approve the pharmacist's request to substitute a non-abuse-deterrent formulation opioid?

- Yes
- No

Section IV. Questions about third party payer requirements for abuse deterrent formulation opioids.

For each of the following abuse-deterrent formulation opioids that you have prescribed, please indicate how often prescriptions are subject to additional requirements from third-party payers (e.g. prior authorization).

| | Rarely | Occasionally | Almost always | I am unsure how often prescriptions are subject to additional requirements. |
|--|-----------------------|-----------------------|-----------------------|---|
| 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"/> |

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 support this legislation.

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

Section V. 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 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. _____

Please indicate your total number of years in practice following completion of residency training.

- Currently in residency training
- < 5
- 5 -15
- 16 - 25
- 26 - 35
- > 35

Which of the following best describes your primary specialty?

- Addiction medicine
- Anesthesiology
- Cardiovascular disease
- Critical care medicine or Pulmonary disease
- Emergency medicine
- Family medicine
- Gastroenterology
- General surgery
- Hematology & Oncology
- Internal medicine
- Neurology or Neurological surgery
- Obstetrics & Gynecology
- Ophthalmology
- Orthopedic surgery
- Otolaryngology
- Pain medicine
- Pediatrics or Neonatal-Perinatal medicine
- Plastic surgery
- Psychiatry
- Radiology & Diagnostic radiology
- Urology
- Other

If you selected 'Other,' please describe. _____

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

Which of the following best characterizes your primary practice setting?

- Solo practice
- Small private group practice (5 or less practitioners)
- Large private group practice (6 or more practitioners)
- Academic practice
- Emergency department
- Hospital-based clinic
- Hospital inpatient
- Managed care organization
- VA health-system or another governmental agency
- Other

If you selected 'Other,' please describe.

On average, across all practice sites (primary practice and other practice) how many patients do you see each week?

- < 25
- 25-49
- 50-74
- 75-100
- > 100

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.
