

National Surveys: Opportunities for Evaluation of ADFs

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Outline

- Why focus on national surveys?
- Building on established national surveys
- Emerging survey methodologies
- Ideal elements in national surveys
- Discussion questions

Why focus on national surveys?



- Some outcomes may be best captured in selfreported data
- Active surveillance
 - Selection not dependent on outcome, treatment availability, etc.
 - Can use probability sampling methods
 - Drug abuse patterns vary geographically—cannot generalize smaller areas to U.S.
 - Can make valid comparisons between products
 - Can reliably trend over time (except when major survey redesign)—useful for pre-post studies



Building on Established National Surveys

National Survey on Drug Use and Health (NSDUH)



- Ongoing nationally representative household survey of the civilian, noninstitutionalized U.S. population aged ≥12 years
- N ~ 70,000 interviews per year
- National estimates on drug-taking behaviors, including nonmedical use of prescription pain relievers.
- Major survey redesign in 2015
 - > Trend break
 - > New data
 - ➤ Past-year use and misuse of specific opioid molecules (e.g., hydrocodone, fentanyl)
 - >Information on reasons for misuse
 - > Still limited data on specific products, formulations, routes

NSDUH 2015: Example Table



Table 1.139B Any Use and Misuse of Pain Relievers in Past Year among Persons Aged 12 or Older and Misuse of Pain Relievers in Past Year among Past Year Any Users of Pain Relievers Aged 12 or Older, by Pain Reliever Subtype: Percentages, 2014 and 2015

Pain Reliever Subtype	Any Use in Past Year (2014)	Any Use in Past Year (2015)	Misuse in Past Year among Total Population (2014)	Misuse in Past Year among Total Population (2015)	Misuse in Past Year among Past Year Any Users (2014)	Misuse in Past Year among Past Year Any Users (2015)
ANY PRESCRIPTION PAIN RELIEVER ¹		36.4	nc	4.7		12.8
Hydrocodone Products		21.8		2.7		12.3
Zohydro® ER		0.1		0.0		*
Oxycodone Products		10.4		1.6		15.3
OxyContin®		3.4	nc	0.7		19.3
Tramadol Products		6.9		0.7		9.7
Morphine Products		2.7		0.3		9.7
Fentanyl Products		0.7		0.1		15.0
Buprenorphine Products		0.9		0.3		29.3
Oxymorphone Products		0.5		0.1		28.9
Demerol®		0.5		0.0		7.4
Hydromorphone Products		0.9		0.1		10.5
Methadone		0.6		0.2		32.0
Any Other Prescription Pain Reliever ²		8.9		0.3		3.8

^{* =} low precision; -- = not available; da = does not apply; nc = not comparable due to methodological changes; nr = not reported due to measurement issues.

NOTE: Any Use of prescription drugs is defined as (a) the use of one's own prescription medication as directed by a doctor or (b) misuse of prescription drugs. Misuse of prescription drugs is defined as use in any way not directed by a doctor, including use without a prescription of one's own medication; use in greater amounts, more often, or longer than told to take a drug; or use in any other way not directed by a doctor. Prescription drugs do not include over-the-counter drugs.

Source: SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2014 and 2015.

¹ Includes hydrocodone products (Vicodin®, Lortab®, Norco®, Zohydro® ER, generic hydrocodone, or other similar products); oxycodone products (OxyContin®, Percocet®, Percodan®, Roxicet®, Roxicodone®, generic oxycodone, or other similar products); tramadol products (Ultram®, Ultram® ER, Ultracet®, generic tramadol, generic extended-release tramadol, or other similar products); codeine products (Tylenol® with codeine 3 or 4, generic codeine pills, or other similar products); morphine products (Avinza®, Kadian®, MS Contin®, generic morphine, generic extended-release morphine, or other similar products); fentanyl products (Actiq®, Duragesic®, Fentora®, generic fentanyl, or other similar products); buprenorphine products (Suboxone®, generic buprenorphine, or other similar products); oxymorphone products (Opana®, Opana® ER, generic oxymorphone, generic extended-release oxymorphone, or other similar products (Demerol® or other similar products); hydromorphone products (Dilaudid® or generic hydromorphone, Exalgo® or generic extended-release hydromorphone, or other similar products); methadone products (methadone or other similar products); or any other prescription pain reliever. Over-the-counter drugs are not included.

² Includes use or misuse of pain relievers containing other active ingredients. Reports of misuse of "any other prescription pain reliever" that correspond only to the specific pain reliever categories shown in the table are excluded from estimates for Any Other Prescription Pain Reliever and are included instead in the relevant pain reliever category.

NSDUH—



Useful in Evaluation of ADF Opioids?

- Has been used to assess changes in OxyContin nonmedical use after reformulation¹
- Suggestions for future NSDUH redesign?
 - ➤ New/revised questions, modules?
 - ➤ Adequate sample size to get reliable estimates for products with low market share?
 - Must be feasible to add to lengthy interview

Other National Health Surveys



What can we learn from these other surveillance systems?

Monitoring the Future	School-based survey on adolescent drug abuse Limited product-specific data Longitudinal follow-up component
National Health and Nutrition Examination Survey	Interviews, physical exam, labs Longitudinal follow-up component
National Health Interview Survey	General health survey Methods similar to NSDUH
Behavioral Risk Factor Surveillance System	Telephone survey >400,000 adults per year Core and optional modules/questions
Youth Risk Behavior Surveillance System	School-based survey health risk behaviors National, state and district level data
Pregnancy Risk Assessment Monitoring System	Surveys women with recent live birth Oversamples some high-risk groups Longitudinal follow-up component

Building on Established National Surveys



Challenges

- ➤ Burdensome to include detailed data on specific marketed products—surveys already lengthy
- Cumbersome redesign process, not easily adaptable
- ➤ May not capture highest risk individuals
- Likely low precision for some products, routes
- ➤ Data lag



Emerging Survey Methodologies: Internet-Based Surveys

Emerging Survey Methodologies: "Opt-in" Internet Panels



- Population
 - > Survey administration company invites individuals to subscribe to online survey panel
 - Member of this "opt-in" panel volunteer for various surveys
- Sample-matching and weighting techniques can be used to get sample demographic distribution similar to target population (e.g., US adults)
- Surveys can be tailored to examine specific products and questions

"Opt-in" Internet Panels: Examples



Inflexxion® Internet Surveys

- Cassidy, 2015: Internet-based study on nonmedical use of prescription stimulants¹
- Used independent survey research company YouGov®

RADARS® NMURx

- ➤ U.S. launch in 3Q 2016
- ➤ Uses several panel recruiting partners/methods
- ➤ Lifetime, past-year, past 90/30/7-day nonmedical use
- Product/formulation and route
- > Reasons for nonmedical use
- 1. Cassidy et al. Nonmedical Use and Diversion of ADHD Stimulants Among U.S. Adults Ages 18-49: A National Internet Survey. *J Attention Dis* 2015

Internet Surveys with Enriched Samples



- Recruit participants from online drug abuse discussion forums (e.g., Bluelight.org¹)
- Therefore, samples enriched with people abusing drugs
- 2014, 2015 Inflexxion hydrocodone surveys
 - Conducted surveys of visitors to Bluelight.org evaluating patterns of hydrocodone nonmedical use²
- 1. www.bluelight.org
- https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM498784.pdf

Internet Surveys— Challenges and Questions



- What is underlying population for Opt-in panels?
 For drug abuse discussion forum surveys?
- What kinds of selection forces might exist? Might it change over time?
- How valid are inferences to general population, other underlying population?
- Data quality

Designing the Ideal National Survey— Key Elements



- Product- and route-specific
- Rapidly modifiable in response to market changes
- Rigorous efforts to minimize misclassification especially differential product misclassification
 - ➤ Question format: "yes/no/not sure" vs. "select all that apply"?
 - ➤ Pill photos?
 - > Randomize order of drug groups/products?

FDA

Designing the Ideal National Survey— Key Elements

- Probability sampling methods, enabling estimation in different subgroups:
 - ➤ Geographic regions
 - ➤ Demographic groups
 - >Severity of substance use disorder
- Oversampling of high-risk subgroups, regions?
- Opportunity for longitudinal follow-up??

Prospective data collection: even ideal survey can't collect historical data very well



Discussion Questions



1. Discuss the feasibility, advantages, and disadvantages of modifying established national surveys to collect data for ADF evaluation



2. Discuss the advantages and disadvantages of internet-based surveys, both opt-in general population panels and enriched samples, for evaluating ADFs. In particular, what are the potential selection forces operating, and how might these affect the inferences that we can make?



3. Discuss design strategies for minimizing misclassification, particularly differential product misclassification, in surveys being used to evaluate ADFs.



4. Discuss whether a novel survey is needed to collect data for evaluation of ADFs? If so, discuss the feasibility of and ideal approach to developing such a survey.



 Discuss the feasibility of using internet or other types of survey panels <u>longitudinally</u> (following individual participants over time) to evaluate ADFs.