

# **Review of Alternative Approaches to Assess Drug Misuse, Abuse, Addiction, and Death in the Community Setting**



## **THE POTENTIAL VALUE AND LIMITATIONS OF USING CLAIMS DATABASES**

**17-APRIL-2015**

**Carl L. Roland, PharmD, MS  
Pfizer Inc.  
Clinical Sciences/Global Health & Value**

**off the mark** by Mark Parisi  
www.offthemark.com



# Outline

- Importance of Terminology
- Review Potential Data Sources to Assess Drug Misuse, Abuse, Addiction in the Community
- Review of Claims Data
  - Description
  - Provide Examples of Prevalence
  - Advantages
  - Limitations
- Summary

# Terminology is Important

“Analgesic clinical trial investigators and sponsors, as well as regulators evaluating study findings, require precise estimates of inappropriate drug use events ... a critical weakness is that distinct patterns of inappropriate use are typically grouped under ill-defined terms such as “misuse” or “abuse.””

## ACTION Consensus

- **Misuse-Event Indicator:** any intentional therapeutic use of a drug product in an inappropriate way. Misuse specifically excludes those events that meet the definition of an Abuse-event Indicator.
- **Abuse-Event Indicator:** any intentional, nontherapeutic use of a drug product or substance, even once, for the purpose of achieving a desirable psychological or physiological effect.
- **Addiction-related Indicator:** includes behavioral, cognitive, and physiological phenomena that may develop after exposure to a substance (typically on a repeated basis), which may include a strong desire to take the drug, difficulties in controlling drug use, persistent drug use despite harmful consequences, intractable and distracting thoughts about the drug, or placing a higher priority on drug use than on other activities and obligations.

Source: Pain 2013;154(11):2287-96

# Types of Databases

- Insurance Claims Records
- Electronic Medical Records
  - Medical records are transcribed into a database that can be accessed throughout the healthcare system
    - ✦ Natural Language Processing (NLP)
- National Data (some examples)
  - NSDUH (National Survey on Drug Use and Health)
  - DAWN (Drug Abuse Warning Network)
  - TEDS (Treatment Episode Data Set)
  - MTF (Monitoring The Future)
  - NHWS (National Health and Wellness Survey) Kantar Health



# Insurance Claims Records

- Records from healthcare providers
  - Pharmacy, pharmacists
  - Physicians, nurse practitioners
  - Laboratories, ancillary services
  - Institutions, clinics



Used to provide information to insurer for reimbursement of products and services

# Type of Data Captured

- Demographic: age, sex, location, eligibility
- Clinical diagnosis of underlying disease states
- Concomitant medications
- Procedures performed
  - e.g., urinalysis, x-ray, MRI, CT scan, etc.
- Healthcare utilization
  - ER visits
  - Hospitalizations
  - Outpatient visits
  - Substance abuse admissions

# Examples of Claims Data

## CLAIMS, ADMIN.



- **OPTUM Insight™** US: UnitedHealth database of administrative, claims data



- **TRUVEN** US: Formerly Thomson MarketScan administrative, claims data



- **PREMIER** US: Administrative, claims data from hospitals



- **SDI** US: IMS subsidiary provider-level written Rx



# Summary Statistics of Claims databases



	OPTUMInsight™	TRUVEN HEALTH ANALYTICS™	PREMIER	SDI
<b>Geography</b>	U.S.	U.S.	U.S	U.S.
<b>Lives (mm)</b>	40	44	50 (discharges)	260
<b>Coverage</b>	UNH members	Large employers, health plans	500 hospitals	80% pharmacies
<b>Claims types</b>	Medical, Rx, labs	Medical, Rx, Medicare Suppl.	Medical, Rx, labs	Prescription
<b>Content</b>	Outpatient, some inpatient, labs	Outpatient, some inpatient, some labs	Inpatient	Physician identifiers

# ICD-9 Codes for Dependence, Abuse, and Poisoning

- Dependence (Addiction)
  - 304.0: Opioid type dependence
  - 304.1: Sedative, hypnotic or anxiolytic dependence
  - 304.4: Amphetamine and other psychostimulant dependence
- Nondependent Abuse
  - 305.4: Nondependent sedative, hypnotic or anxiolytic abuse
  - 305.5: Nondependent opioid abuse
  - 305.7: Nondependent amphetamine or related sympathomimetic abuse
  - 305.8: Nondependent antidepressant type abuse
- Poisoning
  - 965.0: Poisoning by opiates and related narcotics
  - 967: Poisoning by sedatives and hypnotics
  - 968: Poisoning by other central nervous system depressants and anesthetics
  - 969: Poisoning by psychotropic agents
  - 969.0: Poisoning by antidepressants
  - 969.7: Poisoning by psychostimulants

# ICD-10 Codes for Dependence, Abuse, and Poisoning

- Dependence
  - F11.2x: Opioid dependence
  - F13.2x: Sedative, hypnotic or anxiolytic dependence
  - F15.2x: Other stimulant dependence
- Abuse
  - F11.1x: Opioid abuse
  - F13.1x: Sedative, hypnotic or anxiolytic abuse
  - F15.1x: Other stimulant abuse
- Poisoning
  - T40.2Xxx: Poisoning by other opioids
  - T42.6Xxx: Poisoning by other antiepileptic and sedative-hypnotic drugs
  - T43.60xx: Poisoning by unspecified psychostimulants

# Claims Data for Diagnosed Opioid “Abuse”

Publication	Data Source	Prevalence/ 1,000	Comment
Baser et al Pain Practice 2014;14(5):437-445	National VHA	11.1 (2006-2010)	5-year prevalence. ICD-9 codes of opioid abuse, dependence, or poisoning.
McAdam-Marx et al J Pain Palliative Care Pharmacotherapy 2010;24(1):5-18	Medicaid MAX Data	8.7 (2002–2003)	Included 47 states. ICD-9 codes of opioid abuse, dependence, or poisoning.
Roland et al J Opioid Management 2013;9:161-175	Thomson MarketScan Commercial and Medicare Supplemental Database	1.95 (2005-2010)	6-year prevalence. ICD-9 codes of opioid abuse, dependence, or poisoning.
White et al Am J Pharmacy Benefits 2011;3(4):e59-e70	Florida Medicaid and Ingenix	5.0 (Medicaid) 1.6 (Ingenix)	Year 2006. ICD-9 codes of opioid abuse, dependence, or poisoning.
Rice et al Postgraduate Medicine 2014;126(4):53-58	Truven MarketScan Commercial Claims and Encounters	1.58 (2009) 2.66 (2012)	ICD-9 codes of opioid abuse or dependence.
Rice et al Applied Health Economics and Health Policy 2014;12:435-446	OptumHealth Reporting and Insights	1.18 (2009) 1.86 (2011)	ICD-9 codes of opioid abuse or dependence.

**No publications identified for stimulant or sedative abuse using claims data.**

# Example of Using Claims Data to Assess Change in Prevalence

- Rossiter et al reported relative reductions in diagnosed abuse among continuous users of ER opioids following the introduction of reformulated ER oxycodone
  - 22.7% decrease among commercially-insured ( $p=0.001$ )
  - 18.0% decrease among Medicaid patients ( $p=0.034$ )
- Conclusion: Study provides evidence that reformulated ER oxycodone has been associated with reductions in abuse rates
  - Need to consider time factor; i.e., how do changes in environment impact findings over time?
  - Population – this was not community at large, but continuous users of ER opioids (as defined in study)

Source: J Med Econ 2014;17(4):279-87

# How Claims Data Compare with Other Data Sources

Data Source	Behavior/Outcome Measured							
	Method of misuse/abuse	Product Specificity	Fatal Overdose	Non-Fatal Overdose	Addiction	Misuse	Abuse	Diversion
ASI-MV® Connect/CHAT®	Y	Y	N	N	Y	N	Y	Y
RADARS® System - Poison Center Program	Y	Y	Y	Y	N	Y	Y	N
<b>Claims</b>	<b>N</b>	<b>Y</b>	<b>Y</b>	<b>Y</b>	<b>Y</b>	<b>Y</b>	<b>Y</b>	<b>N</b>
DAWN	N	N	Y	Y	Y	Y	Y	N
MTF	N	N	N	N	N	N	Y	N
NFLIS	N	N	N	N	N	N	N	Y
NSDUH	N	N	N	N	Y	Y	Y	Y
TEDS	Y	N	N	N	N	N	N	N
WIS™	N	N	N	N	N	N	N	N

DAWN: Drug Abuse Warning Network; Claims: Third-Party Payer Claims Databases; RADARS®: Researched Abuse, Diversion, and Addiction-Related Surveillance; ASI-MV: Addiction Severity Index-Multimedia Version; TEDS: Treatment Episode Data Set; MTF: Monitoring the Future; NSDUH: National Survey on Drug Use and Health; CASA: National Center on Addiction and Substance Abuse; NFLIS: National Forensic Laboratory Information System; CHAT®: Comprehensive Health Assessment for Teens; WIS® = Web-Informed Services.

**\*Results in the table are specific to the ADF discussed at the Joint meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee held in Gaithersberg, MD on October 21-22, 2010; a similar assessment must be conducted for each product being evaluated.**

# Abuse Prevalence across Data Sources

Data Source	Per 1,000
NSDUH 2012 Substance Dependence	6
TEDS <sup>1</sup> 2012 (Primary non-heroin opiates/synthetics admissions)	0.64
NHWS <sup>2</sup> 2012 (Abuse “to get high” <b>among opioid users</b> )	13.1
EMR <sup>3</sup> 2006 – 2012 (“Problem Opioid Use” <b>chronic opioid treatment</b> )	94
Claims 2002-2003 (Medicaid)	8.7
Claims 2010 (VHA)	7.3
Claims 2011 (Commercial – Optum)	1.9
Claims 2010 (Commercial - MarketScan)	1.5

1. These drugs include codeine, hydrocodone, hydromorphone, meperidine, morphine, opium, oxycodone, pentazocine, propoxyphene, tramadol, and any other drug with morphine-like effects. Non-prescription use of methadone is not included.

2. Pain Medicine 2014;15:2064-2074

3. Pain 2015 (e-pub. DOI: 10.1097) COT defined as 70+ days supply of opioid in a calendar quarter

# Claims: Advantages

- Large numbers of patients – more generalizable – external validity
- Less lag time
- Inexpensive
- Most are reliable since used for adjudication
- Standard variables collected



# Claims Data: Limitations

- Set up for reimbursement – NOT epidemiology/economic studies
- Some utilization may not be captured
  - e.g., OTC use, non-plan services, may have exceeded cap
  - Drug may be missing if drug purchased out of pocket or through diversion
- Drug Specificity/Association
  - Drugs listed as dispensed at retail level
  - Drug association – presence of drug and diagnosis code assumes association
- ICD-9 codes rely on clinician recognition and training; the extent of this recognition and training is unknown
  - Misclassification potential
  - May under-report extent of abuse or misuse
- Eligibility – results are limited by the period of eligibility chosen for study
- Does not provide route of abuse

# Claims Data Summary

- Large number of patients – external validity
- Inexpensive and data is timely
- Many limitations that need to be considered
  - Potential for misclassification
  - Potential for under-reporting; diagnosis codes rely on clinician recognition and training
  - Need to consider impact of eligibility requirements
  - May lack drug specificity
  - Does not provide route of abuse
- Many studies with opioids, none found for other drugs
- Prevalence for opioids varies depending on population and timeframe

**Terminology/Context are Important**

"Not everything that counts can be counted, and not everything that can be counted counts."



*Albert Einstein*