

Leveraging other data: Linking and benchmarking

Cynthia Kornegay, Ph.D. Lead, Prescription Drug Abuse Team Office of Surveillance & Epidemiology. Center for Drug Evaluation and Research US Food and Drug Administration



Introduction

- Meeting began with a discussion of data resources for evaluating ADF opioids
 - Identification Metrics/Measures
 - Sampling Analyses
 - Study Designs
 Confounders
- This session will focus on ideas for leveraging those and other data resources together to enhance ADF opioid investigations



Overview

- Linking or benchmarking existing data to other data resources can serve several purposes
 - Providing additional statistical power for rare outcomes (i.e., Claims/EMR→NDI)
 - Providing additional risk factor and/or confounder information for a more comprehensive assessment (e.g., NPDS→Claims/EMR→NDI)
 - Providing additional context to address sampling and generalization issues (i.e., TEDS→N-SSATS)



Additional Statistical Power

- Large collections of healthcare information have a large number of individuals at low risk of abuse-related overdose or death
 - Individuals still participating in society
- Smaller practices that include pain and addiction management have wider variety of patients but data are less accessible



Additional Statistical Power - Example

- Study examining risk of misuse, abuse, and addiction in patients treated with extendedrelease and long-acting opioids for chronic pain
 - Prospective cohort study
 - Multiple complementary data resources used to
 - Enhance target population of individuals on long-term therapy for chronic pain
 - Ensure adequate participation of individuals perceived to be at high, medium, and low risk of misuse, abuse, and/or addiction



Additional Risk Factors

- Prescription drug abuse has a variety of risk factors, and outcomes may not be predictable
- Not all of these potential confounders available in health care data
 - BRFSS YBRFSS
 - NFLIS drug testing data
- Possible to link abuse-related data to behavioral/laboratory/law enforcement data?
- Example: FDA supporting pilot project in state of CT

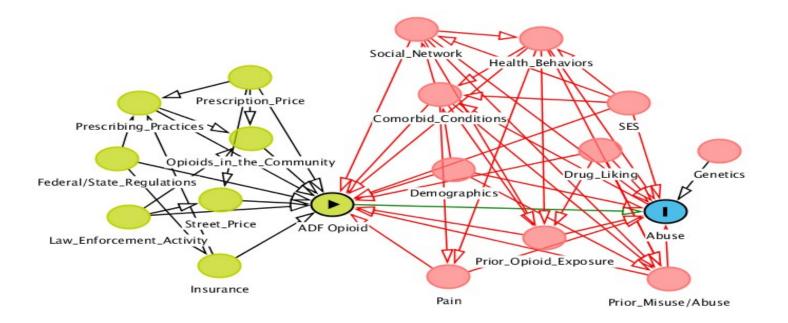


Additional Risk Factors - Example

- Effort to link exposure, treatment, and outcome information statewide
 - Proof of concept will link clinical and non-clinical data resources
 - Goal is also to determine if products prescribed to patients (specifically opioids) are the same ones involved overdoses



Additional Risk Factors





Additional Context

- Goal would be to benchmark convenience sample to enhance generalizability
- Would need to find data sources with welldefined base population of interest, and determine important variables to estimate
- Unclear that census data most appropriate
 - No drug-related data
 - Key census characteristics?



Additional Context - Example

- Outcome-based evaluation of methodology to obtain U.S.-based inpatient drug utilization levels
 - ICD9 codes and drug utilization from a large convenience sample of acute care hospitals in the US
 - Compared to National Hospital Discharge Survey
 - Nationally projected discharges
 - ICD9 codes but no drug use
 - Able to compare demographics, diagnoses, and procedures between the two samples
 - Facilitated understanding of representativeness of convenience sample
- Did not require actual linkage of data



Challenges Specific to Leveraging Data

- Even within sphere of clinical data, many and varied complications in linking data resources:
 - Technical Update frequency
 - Confidentiality Contractual restrictions
 - Consistency
- As a result, most linkages use data collected for similar reasons
- Linking dissimilar data will be even more difficult



Discussion Question

- Discuss potential data sources and considerations for linking to additional data sources to increase study size and power
 - Misuse and abuse definitions
 - Outcomes of interest
 - Data granularity



Discussion Question

- Discuss potential data sources and considerations for linking to additional data sources to provide additional risk factors and insights
 - Confidentiality concerns
 - Time-dependent variables



Discussion Question

- Discuss potential data sources and considerations for benchmarking to other data sources to enhance generalizability
 - Use of contextual variables (e.g., census data)