



Prescription Monitoring Research: Methodological Considerations

Cindy Parks Thomas PhD

Brandeis University

April 2, 2009



Overview of Research Issues

- Design
- Data
- Data analytic / research base challenges
- Special topics
- Research / evaluation agenda



Design Decisions

- Driven by goals: Evaluation vs research
- Epidemiological studies
 - Trends analyses, case studies, case / control, predictive models (limited covariates at patient level) Outcomes to consider
 - Appropriateness is HG
 - Program impact: Questionable activity rates; diversion
 - May parallel prescription drug research: adherence, prescribing patterns, surveillance of adverse or rare events
- Link with additional data
 - Physician surveys and overall prescribing patterns (if individual physician identifier available), geographic variation analyses, other databases (household surveys, health care, addiction treatment services)
- Benchmarks
 - Opportunity for state programs to set benchmarks for outcomes and data collection e.g., questionable activity!
- Unit of analysis
 - Physician, county, population, health system, pharmacy, state or program



Data: The NAMSDL Model Act

- Establishes, as a minimum standard, the collection of information for all prescriptions issued for Schedule II - IV controlled substances
- Provides the option for states to also collect information on Schedule V controlled substances and on drugs that have a potential for abuse but are not currently scheduled
- Requires submission of minimum essential data elements to be collected for each prescription, and maintains an option for states to collect additional data elements, if needed
- Mandates that pharmacies submit data electronically
- Ensures the privacy and confidentiality of information collected by a PMP
- The designated state agency may provide data to public or private entities for statistical, research, or educational purposes after removing identifying information



Data Description

- General prescription drug database format
- Uniform variables across states, Model Act data specifies:
 - Dispenser ID
 - Date prescription filled
 - Prescription number
 - Prescription is new or is a refill
 - NDC code for drug dispensed
 - Quantity dispensed
 - Patient ID
 - Patient name, address
 - Patient date of birth
 - Prescriber identification number
 - Date prescription issued by prescriber
 - Person who receives the prescription from the dispenser
 - Source of payment for prescription



Data Considerations

- Strengths
 - Rich data source, current
 - Large n
 - Standard flat file prescription claims database (NDC) and unique patient IDs
- Limitations
 - Five states only collect CSII; issues and n differ by schedule
 - Need matching algorithm for identifying unique users
 - State regulations regarding use vary (state reviews required)
 - Privacy concerns for provider as well as patient
 - No diagnoses limit research potential
- Definitions unique to study context
 - Therapeutic class analyses
 - Long vs short acting, dosage units
 - Morphine equivalents



Data Quality

- Data cleaning process not standard across states
 - Pharmacy to vendor, vendor to state, state to evaluator or researcher
- Missing data
 - Fields
 - Data input
- Typically unreliable fields for pharmacy data claims (e.g., new rx /refill)
- Matching algorithms for identifying unique patients



Data Quality Check Examples

| Item | Definition | Values | Issues |
|-------------------------|--|--|--|
| MONTHCOVER | Month and year for which data were submitted | Month and year (e.g. 12/2007) | If one month has a much lower frequency than other months, missing data likely; check further |
| NDC | National drug code of dispensed drug | 11 digit number sometimes including leading zeroes | Negligible percent missing or invalid |
| CUST_ID (PRIOR TO 2009) | Customer Identifier | In the majority of cases, this is either the 9 digit social security number or 9 character driver's license number of the person picking up the prescription whether it be the patient or a family member of the patient | There is much variation in how the customer ID is formatted Once the customer ID is cleaned, it is combined with patient birth date to create an individual patient identifier. |
| FILLDATE | Date prescription filled | Month, day and year (e.g. 10/21/2007) | If one month has a much lower frequency than other months, missing data likely; check further |
| SEX | Gender | 1 = male 2 = Female | <6% missing |
| METRIC_QTY | Metric units # | Should be 5-digit but sometimes letter or symbol | If 5 th character is "M", replace with leading zero. If other non-numeric, set to missing. |



Data Analytic Challenges

- Beware cross sectional state comparisons
- Cross state analyses raise issues of compatibility of systems and reporting across states: same system, different versions
- Model estimation: specification with limited variables suggests linking with additional databases
- OUTCOMES: Estimating thresholds for questionable activity or other impact
- The usual statistical suspects: distribution of variables, n, comparison groups, censoring, accounting for missing data
- Cost effectiveness research limitations



Selected Special Issues for PMP Data

- Border states are critical for evaluating impact of policies
 - Identification by GIS, distance
- In integrating into electronic medical records and electronic prescribing
 - Matching prescriptions prescribed vs. reported for adherence, dropped rxs, inconsistencies
 - Unique matching issues: precise NDC of dispensed drug has to be matched to prescribed drug through generic groupers, if pharmacist gets authority to change ingredients
 - Incorporating additional medical data is not always available
- Work with policymakers to interpret data, explain trends, and avoid mis-specification of models

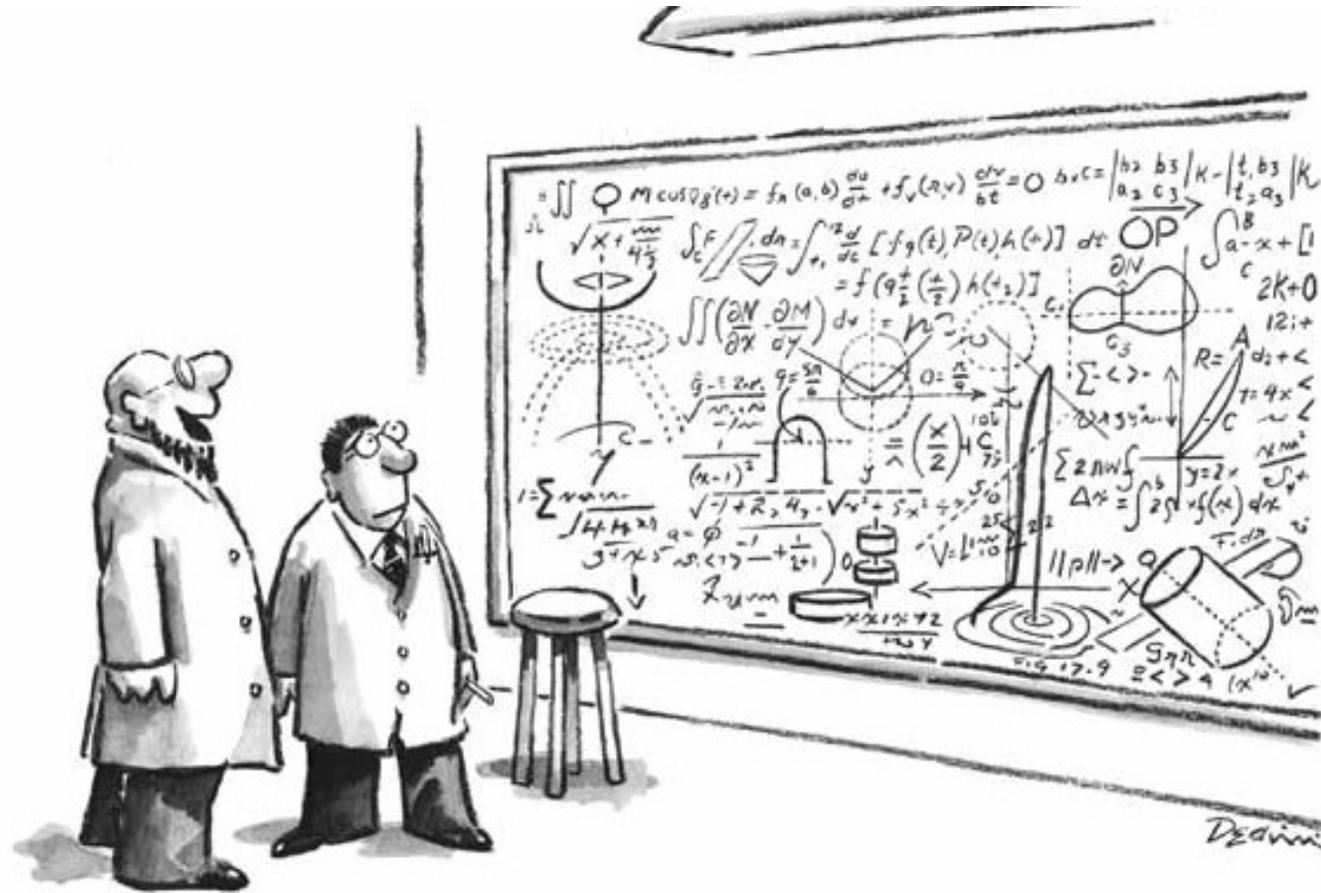


Research Opportunities

- PMP data not widely mined to date
- We have confirmed association, now explain
- Additional opportunities for treatment evaluation and treatment research: impact of targeted services over time, access to treatment
- Develop predictive models for questionable activity, and enhanced sensitivity analyses of threshold outcomes
- Assess use and misuse of emerging medications with newer treatment medications (e.g., buprenorphine)
- Combine with national survey data, facility data (N-SSATS, TEDS), state level treatment system characteristics, encounter data (DAWN, etc), even data (overdoses)
- Assess relationship between pain treatment, monitoring systems, payment systems, and diversion
- Comparative effectiveness of different treatments using PMP data-driven outcomes
- Additional technical support available through training and technical assistance center, website in development



Thank you! Discussion??



"Hey, no problem!"