Tufts Health Care Institute

EXECUTIVE SUMMARY

Tufts Health Care Institute Program on Opioid Risk Management

Summit Meeting on

Prescription Monitoring Research Update

April 2-3, 2009

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List of Abbreviations

DOJ: Department of Justice
EDT: Electronic Data Transfer
HIPAA: Health Insurance Portability and Accountability Act
KASPER: Kentucky All Schedule Prescription Electronic Reporting
NASPER: National All Schedules Prescription Electronic Reporting Act of 2005
PM: Prescription Monitoring
PMP: Prescription Monitoring Program
TEDS: Treatments Episode Data Set

Despite the widely acknowledged efficacy of prescription opioids in pain management, the ready therapeutic availability of these powerful analgesics for therapeutic use has erupted in a number of public health and societal problems, including death from overdose, non-fatal overdosing, accidental pediatric ingestion, abuse and addiction, initiation of drug misuse, suicide, crime, and exponentially increasing costs associated with co-morbidities, issues of law enforcement, and loss of workplace productivity related to abuse/misuse of prescription opioids. Use of prescription monitoring programs (PMPs) is one among a number of solutions being developed to address these problems. PMPs have two overarching goals: public safety (via support of law enforcement), and public health, both of which need to be addressed in parallel. *The meeting on **Prescription Monitoring Research Update was organized by Tufts Health Care Institute in April 2009.** Participants discussed the public health impact of PMPs, primarily in relation to targeting individuals who have problems of abuse and addiction, and to identifying activities that indicate diversion of prescription opioids at the level of the individual (doctor/pharmacy shopping) and of the prescriber (inappropriate or criminal prescribing/dispensing).*

State and Federal PMPs

Prescription monitoring (PM) is currently operational in 32 states and not yet, or no longer, operational in six states (AK, WA, KA, MN, NJ); PM legislation is under consideration in four states (AR, FL, MI, OR) while the bill for instituting PMPs has failed once in the GA senate. Three states have unique approaches to PM: since the 1970's, WI has been integrating information from various sources, including crime labs, the ARCOS system, and state Medicaid databases; MD has created an Advisory Council, which in turn makes recommendations regarding PM; and in SD, pharmacists have taken the lead with regard to PM, and the state expects to enact a PMP for 2010. DE, NH and NB do not have operational PMPs, nor are any legislative initiative(s) pending.

At the federal level, funding is appropriated this year (2009) for two programs: i) the Hal Rogers Prescription Drug Monitoring Program, created in 2001, is administered by the DOJ ($7M appropriated for 2009-2010); funds are awarded to states via a competitive process, which means that they are not guaranteed. ii) NASPER ($2M appropriated for 2009) is a formula grant (all states meeting criteria and submitting an application receive funds, according to a formula), with a mission to approach PM from the public health (rather than from the law enforcement) standpoint. Both PMPs are widely acknowledged as being effective in limiting specific types of diversion.

PM and legislative issues

The lack of homogeneity across states in terms of data collection and data access makes comparison and analyses of information gathered in different states a challenge. The recent availability of the federal funds to support PMPs has made possible the setting of some regulations that facilitate interstate sharing of information, and is aimed at preventing and detecting abuse and diversion of controlled substances. Hal Rogers permits states to have considerable flexibility in what drug Schedules each state chooses to monitor, in providing access to PMP data, and in the methodologies used to collect/share/transmit data; NASPER funding, on the other hand, mandates the collection of prescription data for Schedule II-IV drugs and the sharing of information among states, to enable targeting of diversion across state lines. Both programs permit disclosure of PM reports to health care providers, and both encourage the use of data for identifying and treating patients at risk of substance abuse.

At the state level, regulations about PM focus on the use of data for assisting law enforcement to target and prosecute diversion and abuse, but the great diversity in PM that exists among the different state programs can sometimes hamper such efforts. PM in CA has been implemented since 1940: early experience led to the introduction of state-issued, serialized, triplicate forms for providers to prescribe Schedule II medications; legislative changes over the years have led to the current mandate to use state-issued, tamper-resistant prescription forms for recording use of Schedule II-IV drugs, and weekly electronic transmission of reports to the DOJ as well as to a third party vendor. On the other hand, NC's

PMP was approved as recently as 2005, and led the creation of a reporting system that focuses more on identifying and treating individuals that abuse scheduled substances, and on stopping diversion of prescription drugs without causing a chilling effect; it provides web-access to data for authorized users including medical examiners, facilitates discussion of trends and findings among authorized users, and requires weekly reporting by dispensers.

The public health impact of PM

The impact can be assessed from unpublished as well as published studies. Early use of serialized, government-issued, multiple (usually triplicate)-copy forms for prescribing Schedule II controlled substances has revealed some information about the impact of PM on public health, though the lack of timeliness in compiling these data makes them of limited utility. PM is associated with a reduced availability of Schedule II drugs, and financial savings for states (see below); The move to use of electronic data transfer (EDT) forms, and the requirements to record use of medications from multiple Schedules, further limit tampering and restricts the choice of effective pain medications outside the PM umbrella.

Separating the economic consequence of a potential chilling effect (i.e., prescribers avoid the use of these medications for valid medical purposes and instead substitute other, non-Schedule II drugs) remains a challenge. Such potentially inappropriate prescribing has generated much debate, since PM is not meant to hinder prescribing for legitimate medical purposes. And while descriptive as well as quantitative empirical studies confirm that PM is associated with a decrease in prescribing or use of controlled substances, the extent to which a substitution effect contributes to this reduction has yet to be established. Nevertheless, introduction of PMPs is correlated with decreased pharmacy shopping. Also, although no direct relationship between PM and decreased diversion has yet been documented, adoption of PM does appear to shift diversion activity out of the state, as has been reported for Kentucky. An unpublished report from 2006 concludes that PMPs are also associated with decreased prescription opioid use (assessed via ARCOS data on drug distribution), and that PM is associated with higher rates of treatment admissions (as indicated via TEDS data); furthermore, these changes are detected to a greater extent in states that have proactive PMPs (i.e., they provide unsolicited reports to providers, on a periodic basis) as compared to states that have reactive programs (that provide reports only in response to practitioners' request).

Collectively, empirical studies indicate a positive influence of PMPs on abuse and diversion, but few systematic evaluations have been published, pointing to an urgent need for further work in evaluating these programs.

Physician use of PM data

Physicians utilizing PM data in their practice should be alerted to the challenges of balancing privacy/data security and regulation of medical practice and of regulation of prescribing practices via state as well as federal governments. Programs such as KASPER mandate that PM data received by physician must be shredded or destroyed after use; they should not be disclosed to patient (or suspect). PM reports are most useful for targeting doctor shopping, via identification of overlapping prescriptions for same/similar drugs. However, PM should be used as one of several tools in a multi-faceted program of risk management for abuse/misuse, along with patient screening for aberrant behaviors and risk stratification, compliance monitoring (urine screening, pill/patch counts), education about not sharing drugs and safe drug storage, highly structured approaches and psychotherapy, and abuse deterrent formulations.

Allaying fears about PM

Apprehension associated with use of PM is based on misperceptions about its potential impact on health care – these include that ***i) PM will have a chilling effect on the use of controlled substances for pain,*** as a result of associated bureaucratic requirements and law enforcement activities. While likely during

earlier years, prescribing of opioid analgesics continues to rise annually, even in states using electronic PMPs. ***ii) PM violates HIPAA***. In fact, HIPAA does permit sharing of Protected Health Information, but sets specific requirements for such disclosures; sharing of PM information is also subject to these requirements. ***iii) PM incurs exorbitantly high costs.*** In reality, PM in most states is estimated to cost less than a million dollars/yr, while savings in health care and societal costs may be significant. ***iv) Compliance with PMP requirements will be inordinately time-consuming for pharmacists.*** In reality, data required for PM are the same as those already recorded by pharmacists; thus, except for the need for about 10-15 minutes more per prescription, little additional time is required to consolidate the information and submit it to the PMP. Further facilitation of reporting will be realized with anticipated increases in homogeneity of data collection across states.