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Controlled Substances

The Influence of Prescription Monitoring Programs on Chronic Pain Management

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Background: Abuse of prescribed controlled substance has become a serious social as well as health care issue over the past decade. A particularly alarming trend exists among patients aged 12 to 17. Common abuse behaviors include doctor shopping, drug theft, feigned pain symptoms to gain health care access, drug sharing, prescription forgery, and improper prescription practices. In response to this epidemic of abuse, many states have adopted prescription monitoring programs (PMPs). Such programs first originated in the early twentieth century. As of 2006, 38 states had such programs, many of which are supported by federal grants. As PMPs become more widespread, they have also increased in sophistication. By keeping a record of the prescription and dispensing of narcotics, these programs are able to build a comprehensive data network for tracking prescription medications. These databases aid law enforcement agencies in investigations of narcotic trafficking; they also help state regulatory boards to monitor improper prescription practices.

Objective: This manuscript examines the basic structure of a PMP, including the way the data are collected and the way these data are stored and used. It also looks at the organizational differences amongst state programs. NASPER and Harold Rogers are two federal programs that provide funding to the state PMPs, and the current study examines the differences as well as similarities between these 2 programs. This study also compares the results of 2 reports: the U.S. General Accounting Office Study and the Twillman study. Both studies have evaluated the efficiency of the PMPs.

Discussion: The U.S. General Accounting Office Study showed that while considerable differences exist among the state PMPs, these programs not only reduce the time and effort for law enforcement agencies to conduct investigations, but also cut the supply of prescription medications. However, the Twillman report suggests that prescription programs caused a shift in prescription practice, while the actual rate of abuse may not have been reduced. These 2 studies both point to the challenges the PMPs face. However, more recent data suggest that proactive use of the PMPs results in the decreased growth of prescription medication sales. Finally, a number of states have also begun to objectively evaluate the efficiencies of the system.

Conclusion: Many states have developed PMPs to help regulatory agencies as well as physicians detect prescription drug abuse. Limited data so far suggest that such programs reduce abuse practices. In addition, proactive usage of the data further prevents abuse.

Key words: Prescription monitoring programs, drug abuse, National All Schedules Prescription Electronic Reporting Act, Government Accountability Office, Health Insurance Portability and Accountability Act

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Americans, who constitute 4.6% of the world's population, consume approximately 80% of the global supply of opioids (1-4). Between 1997 and 2006, retail sales of methadone have increased by 933%, and sales of oxycodone have increased by 588% (4). The prescriptions of hydromorphone, morphine, and hydrocodone have also more than doubled (4). This increase reflects a recognition within the medical community of an alleged under-treatment of post-operative pain, cancer pain, pain related to AIDS, and other forms of chronic pain (1,2,5-8). Unfortunately, accompanying this high rate of use is the abuse of prescription medications, in particular the abuse of opioids (1-4). The abuse comes in the form of either non-medical (9-28) or medical abuse (29-47). A number of studies have looked at the concurrent prevalence of abuse and prescription medications, and a consensus is that it is well above 20% (1,48). A particularly alarming trend exists among teenage patients. A recent report by the Office of National Drug Control Policy showed that prescription medications rank second only to marijuana as a substance used by teenagers to achieve psychogenic effects. In 2005, 2.1 million teenagers abused prescription drugs, accounting for almost one third of the abuse in the whole country (1). The reason for this increasing prevalence of prescription medication abuse is manifold. For instance, it has been argued that due to the tightening control of street drugs, more teenage abusers are relying upon prescription medications to abuse. In addition, there is a false perception among abusers that prescription medications are safer than street drugs (49). At the same time, medical drug abuse is likely the result of over-prescription. Because pain is subjectively defined, it is difficult to diagnose and treat. Even studies trying to define the prevalence of chronic pain provide widely divergent data, from as low as 2% to as high as 40% (50,51). Since the 1990s, a number of initiatives have been developed by both patient advocacy groups and professional medical organizations to address the issue of under-treatment of pain (52-59). Meanwhile, there is only limited data available that opioids are useful for both cancer and non-cancer chronic pain (9,10,29,50,60-65). Consequently, physicians in the last decade have often been more inclined to treat chronic pain with opioids, with exploding therapeutic use (66-84). Unfortunately, and perhaps not surprisingly, there has been a concurrent increase in the number of visits to the emergency room for opioid toxicity, and in the rate of opioid related morbidity and mortality (20-28).

Pain physicians, including interventional pain physicians, treat a unique patient population. Studies have shown that in pain management clinics, 90% of the patients receive opioids, and the prevalence of opioid abuse ranges from 20% to greater than 50% (29-47). Therefore, the risk associated with prescription medication abuse is of particular concern for pain medicine specialists.

From the supply perspective, there are a few common mechanisms for prescription medication abuse. First, a patient may receive multiple medications from multiple physicians. This is known as "doctor shopping." A majority of physicians believe that doctor shopping represents the major source of opioid diversion. Second, some patients may feign symptoms of pain in an effort to deceive physicians and obtain opioids for abusive purposes. A third mechanism of abuse is related to drug theft, which includes theft from other patients as well as theft from pharmacies. A corollary of drug theft is prescription forgery and obtaining prescriptions without a physician's approval through fraudulent telephone calls to pharmacies. Fourth, family members and friends may share a patient's prescription medications, leading to abuse. Finally, a small number of physicians have been involved in illegal prescribing practices, providing controlled substances either for themselves or for their patients (1).

A number of initiatives have been instituted both at the national and state level to control prescription medication abuse. These include educational and outreach programs aimed at preventing drug abuse, rehabilitating facilities to help treat drug abuse, and, importantly, prescription monitoring programs (PMPs) (2,5,85).

Prescription Monitoring Programs

PMPs originated in the early twentieth century. The initial goals of these programs focused on detecting and prosecuting diversion as well as the abuse of controlled substances. PMPs collect statewide prescription information that can track the flow of prescriptions of controlled medications. There are 3 key components of a PMP. First, prescription medication data need to be collected from physicians who prescribe medications and pharmacies which fill these prescriptions. Whereas most states require mandatory reporting from pharmacies, physicians often are only encouraged, rather than required to report the

data. The type of data may differ from state to state, but generally the prescriber's name and DEA number, the prescription date, the name and dose of the medication, the drug schedule code, and the patient's name, address, date of birth, and gender are included on each prescription. Second, these data need to be stored and centrally processed. This is usually accomplished by a state government agency founded within the department of health and/or the bureau of narcotic enforcement. Third, a set of rules are established to regulate how these data should be made available to authorized persons and agencies. There is considerable variability among different states on the disclosure of the prescription information. In general, however pharmacists and prescribers can access the system for information regarding their own patients only. Licensure boards may use the information for investigations they are conducting. Law enforcement officials can access the data, but often only through the Attorney General's Office by subpoena for a case they are currently investigating. Finally, individual patients may access the system to receive information about themselves. The availability of prescription data for pharmacists and physicians is a relatively new component of a PMP, and its aim is to prevent, rather than prosecute the abuse of prescription medications by allowing physicians and pharmacies to identify patients who are at risk for doctor shopping or diversion. This feature reflects the increased sophistication of PMPs as they strive to meet newer challenges in a complicated medical environment.

As of 2007, 38 states have developed PMPs, many of which have been created in the last 2 decades. There exist considerable differences amongst these programs. For example, New York state operates one of the earliest established PMPs, and monitors schedule II, III, IV, and V medications. In contrast, Massachusetts only monitors schedule II medications. Data collection also varies. Some states, such as New York and California collect prescription data once a month. In Maine, data are collected twice a month. Yet in other states, data collection may be less frequent. Data collection methods also differ. The PMP in California established the triplicate prescription form as early as 1940, which represented the gold standard for data collection in most states until quite recently. In 1998, however, the state senate of California replaced the triplicate prescription system with an electronic prescription system. Most states have since followed this practice.

The Role of Federal Government in State Prescription Monitoring Programs

Although states initially assumed the responsibility of monitoring prescription medications, the federal government has been taking an increasingly important economic role. Due to the large scope of operating PMPs including the collection and processing of large amount of data and disseminating this information to regulatory agencies and physicians and pharmacies, PMPs can be costly. For example, in New York State, where 4,500 controlled substance dispensers participated in the monitoring of 12 million prescription medications in 2006, the annual budget for the program was $17 million. Starting in 2002, the Congress appropriated PMP (86). This program was designed to provide funding for PMPs of individual states. In 2002, a total of $2 million was granted to 9 of the 16 states that applied for funding. In 2003, this federal program provided $7 million in funding, and in subsequent years, it has consistently provided more than that amount on an annual basis. The qualification requirements for the Harold Rogers Program are relatively simple (86). The program encourages, rather than demands the sharing of information among states. It also encourages the submission of data for prescriptions in Schedule II, III, IV and V. The only strict criterion for participation requires that a state possess a statute or regulation "that requires submission of controlled substance prescription data to a centralized database administered by an authorized state agency" (86).

In August 2005, President Bush signed into law the National All Schedules Prescription Electronic Reporting Act (NASPER) (87). This act creates an additional source of funding for states to create and improve prescription drug monitoring databases (5). NASPER has authorized the availability of $60 million through fiscal year 2010. The NASPER program is housed within the Department of Health and Human Services. NASPER requires states to collect data for prescriptions for schedules II, III, and IV medications. Furthermore, NASPER requires that states have the capability of sharing information with each other.

Evaluation of State Prescription Monitoring Programs

Because many of the state PMPs are relatively young, there have been very few studies that evaluate the effectiveness of these programs. One study

was conducted by the U.S. General Accounting Office in 2002 (85). This study examined 15 state PMPs and focused on 3 newly founded programs in Kentucky, Nevada, and Utah. This study reviewed information from the DEA and the National Alliance for Model State Drug Laws. PMP administrators, licensure boards, state attorneys general, as well as manufacturers of OxyContin (Pharma L.P.) were interviewed in the evaluation process. All 15 programs in the study distributed prescription information to medical practitioners, pharmacies, and state law enforcement and regulatory agencies. The study found that programs differed dramatically in their objectives, design, and operations. In terms of objectives, some states placed specific emphasis on educational initiatives, whereas others did not include them. In terms of design, programs varied widely in the type of specific drugs covered and the kind of government agencies that regulated data collection and distribution. Finally, some programs used the data proactively to identify high risk patients, whereas many programs only used the data to respond to regulatory investigations.

Despite program variability, the U.S. General Accounting Office Study cited 2 prime outcomes that suggested the effectiveness of state PMPs. First, states with PMPs have considerably reduced the time and effort required by the regulatory agencies to investigate drug diversion cases. In Kentucky, for example, the state has documented a reduction from an average of 156 days of investigation to only 16 days following the institution of its PMP. Similar rates of reduction were also reported in Utah and Nevada. Secondly, PMPs have reduced the supply of controlled substances. For example, 8 of the 10 states with the highest number of prescriptions for OxyContin did not have PMPs, whereas 6 of the 10 states with the lowest number of OxyContin prescriptions had instituted such monitoring programs.

Some problems remain from the U.S. General Accounting Office Study. First, shorter investigation time does not necessarily mean fewer investigations. Second, the simple reduction in supply of drug does not necessarily produce a reduction in abuse. A reduction in supply may also signal under-treatment of pain as physicians strive to "play it safe" in order to avoid investigations by regulatory agencies. Third, this study revealed the troubling finding that border states actually experienced an increase in the supply of prescriptions, implying a shift in doctor shopping behavior. The study, however, did not address the nature and the extent of this shift. A study by Twillman provides a partial explanation to some of the dilemmas raised by the U.S. General Accounting Office Study (88,89). The 2 questions of the Twillman study were: 1) how do state programs alter prescription patterns, and 2) what is the evidence for reduced substance abuse in states with these programs? In order to address their first objective, the authors used data from Automation of Reports and Consolidated Orders System (ARCOS), a nationwide database that tabulates retail distribution of prescription opioids. The authors found a significant reduction in Schedule II opioids, covered by all PMPs, but a concurrent increase in Schedule III opioids such as codeine and hydrocodone, which are covered only in a subset of these programs. In order to answer their second question about substance abuse, the authors reviewed the Treatment Episode Data Base (TEDS), which provided data for treatment admission for non-heroin opioid abuse, and the National Survey on Drug Use and Health (NSDUH), which provided survey data on non-medical use of prescription opioids in 2003. The authors discovered no statistically significant difference in TEDS and NSDUH data between states with PMPs and those without them. Therefore, the Twillman study highlights the possibility that PMPs result in a shift in the pattern of prescribing, and that the actual rate of abuse may not actually decrease.

The Challenges Facing Prescription Monitoring Programs

In reality, the U.S. General Accounting Office Study (85) and the Twillman studies (88,89) both exposed challenges that PMPs encounter in the ever-changing environment of medical science and ethics. The first study exposed the problem of border state diversion. For example, not every state has developed a PMP, and all states do not administer identical programs; therefore, abusers have the opportunity to obtain prescriptions from a physician's office in a bordering state. In a way, it is an inherent problem of the PMP itself. Certainly, if the current trend continues, most if not all states will operate PMPs which will solve the problem of border state diversion. In an effort to address the risk of border state diversion, the federal government instituted a unique provision in the NASPER that requires the sharing of information between states, especially bordering states.

Meanwhile, the Twillman study (89) uncovers a problem associated with the wealth of information created by state PMPs. Given the nebulous nature of

the rules and standards connected to prescription practice, physicians may feel uncomfortable participating in a prescription data network. PMPs aid the investigation by the state licensure board of physicians who have inadequate and improper prescription practices. Fearing the risk of investigation, litigation, or censure, many physicians may simply choose to "play it safe" by decreasing pain medication prescriptions or altering prescription patterns. This phenomenon may have led to the observed decrease in schedule II prescriptions, and the increase in schedule III prescriptions, particularly in states that monitor schedule II but not schedule III medications. An equally dangerous effect of "playing it safe," that the Twillman study (89) did not address relates to the real potential for under-treatment of pain (90-92). However, several strategies can alleviate this threat. First, PMPs should provide proactive use of the database. Since the publication of the Twillman study (89), increasing numbers of PMPs have made their data more readily available to physicians, allowing them to identify high risk patients to assist in their medical decision making. Second, some states have also begun to create prescription education curricula for physicians and pharmacists. These programs orient professionals to the rules and regulations associated with controlled medications. Clearly, a comprehensive solution to the alleged threat of inadequately treated pain focuses on the establishment of practice guidelines. However, more data evaluating prescription practices and the successes and failures of PMPs are needed before establishing practice guidelines. As more data are collected, pain societies such as the American Society of Interventional Pain Physicians will take an active role in creating useful practice guidelines for ensuring adequate treatment of pain (50).

Another challenge facing the PMPs concerns Health Insurance Portability and Accountability Act (HIPAA) compliance. HIPAA was established in 1996 under the jurisdiction of the U.S. Department of Health and Human Services to protect the privacy of a patient's health information (93-95). Because state PMPs essentially collect data regarding a patient's prescription history without specific consent from that patient, a potential HIPAA violation exists. However, HIPAA provides exceptions to specific provisions. For instance, "an oversight agency" may supersede HIPAA if it is designed to "address controlled substances." A health oversight agency represents an agency or authority of a State, or a person or entity acting under a grant of authority, a public agency that is authorized by law to oversee the health care system (96). Hence, a state agency that regulates the PMP is considered "an oversight agency" with jurisdiction that supersedes HIPAA. However, PMPs cannot operate entirely outside the scope of HIPAA. A PMP must access a minimal amount of information that is required for data collection including only the prescription information aforementioned. Moreover, government agencies and individual medical professionals can access the data on a "need to know basis" only.

Finally, there are technical challenges for PMPs. Because these programs are still relatively new, technical failures and difficulties cannot be completely avoided. For instance, a number of states have moved from a paper recording system to an electronic record system. Other states collaborate with a surrogate company for the collection and processing of vast amount of prescription data. Consequently, there are reports of misinformation due to minor problems with a computer system's algorithm. As computer technology becomes more sophisticated, these mistakes will be minimized.

Future Direction of the Prescription Monitoring Programs

Two recent updates on PMPs demonstrate encouraging signs for their effectiveness. The first study, utilizing sophisticated mathematical models that integrated data from ARCOS and TEDS showed that proactive prescription monitoring and the dissemination of this data to physicians and pharmacists achieved an approximately 10% decrease in the growth of prescription sales (97). This decrease resulted in a reduction in the abuse of prescription drugs. A second study showed that 8 PMPs provided data to health care providers within one hour of request. Three states have developed provider PMP usage guidelines. Eight states have developed or are developing educational programs for physicians, pharmacists, as well as, patients. Two states completed or are conducting evaluations of the public health impact of PMPs. Furthermore, 5 states have begun to utilize data from their PMPs as an epidemiological tool for studies of prescription practices and addiction (98). Specialty practices also have reported a decrease in drug abuse (48).

The data from these 2 studies are compelling. The policy changes and improvements documented by these investigations reflect a critical path for state PMPs. Such as path will make data readily available to providers in an effort to prevent the improper use of

controlled substances, develop educational programs for prescribers, analyze each state's program for effectiveness, establish practice guidelines for clinicians, and incorporate data from PMPs into the academic study of medication abuse. More specific guidelines and educational programs foster better communication and collaboration between regulatory agencies and patient management communities. These efforts along with facilitated accessibility of data for providers can reduce improper medication prescribing, and ensures that patients suffering from pain are adequately treated. Patient privacy must be protected when these databases are accessed. For instance, Kentucky law permits the felony prosecution of practitioners who misuse data from PMPs. Many other states have adopted similar provisions to protect patient privacy (5).

Finally, federally administered program to monitor prescription medications could be considered. Such a program may eliminate many of the problems encountered by state programs, such as border state diversion and variability in program design, objectives, and operation. However, each state strives to meet its individual needs, and these needs may not be properly met by a national program.

Conclusion

PMPs have been established in response to the emerging epidemic of prescription medication abuse. These programs collect prescription data from pharmacies and physicians. The data are made available to regulatory agencies and to health care providers. Although imperfect, PMPs have demonstrated a reduction in the supply of certain scheduled drugs. In the future, implementation of NASPER, more specific practice guidelines, better educational programs, and enhanced cooperation between regulatory agencies and providers can create these programs into an efficient and effective tool for combating prescription medication abuse without the unwanted byproduct of under treating pain.

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