National addictions vigilance intervention and prevention program (NA VIPPRO™): a real-time, product-specific, public health surveillance system for monitoring prescription drug abuse

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SUMMARY

Purpose The National Addictions Vigilance Intervention and Prevention Program (NA VIPPRO™) is a scientific, comprehensive risk management program for scheduled therapeutics. NA VIPPRO™ provides post-marketing surveillance, signal detection, signal verification and prevention and intervention programs. Here we focus on one component of NA VIPPRO™ surveillance, the Addiction Severity Index-Multimedia Version¹ (ASI-MV¹) Connect, a continuous, real-time, national data stream that assesses pharmaceutical abuse by patients entering substance abuse treatment by collecting product-specific, geographically-detailed information.

Methods We evaluate population characteristics for data collected through the ASI-MV¹ Connect in 2007 and 2008 and assess the representativeness, geographic coverage, and timeliness of report of the data. Analyses based on 41,923 admissions to 265 treatment centers in 29 states were conducted on product-specific opioid abuse rates, source of drug, and route of administration.

Results ASI-MV¹ Connect data revealed that 11.5% of patients reported abuse of at least one opioid analgesic product in the 30 days prior to entering substance abuse treatment; differences were observed among sub-populations of prescription opioid abusers, among products, and also within various geographic locations.

Conclusions The ASI-MV¹ Connect component of NA VIPPRO™ represents a potentially valuable data stream for post-marketing surveillance of prescription drugs. Analyses conducted with data obtained from the ASI-MV¹ Connect allow for the characterization of product-specific and geospatial differences for drug abuse and can serve as a tool to monitor responses of the abuse population to newly developed “abuse deterrent” drug formulations. Additional data, evaluation, and comparison to other systems are important next steps in establishing NA VIPPRO™ as a comprehensive, post-marketing surveillance system for prescription drugs. Copyright © 2008 John Wiley & Sons, Ltd.
INTRODUCTION

Misuse, abuse, and addiction to prescription medications are increasingly important public health concerns. The Substance Abuse Mental Health Services Administration (SAMHSA) reported, in 2002, that prescription medication abuse, particularly abuse of pain relievers, was second only to marijuana abuse but also that prescription opioid abuse had, for the first time, surpassed marijuana for initiation into drug use. Various studies suggest that a dramatic increase in prescription abuse began in the late 1990s, and that efforts to better understand this rapid increase in abuse have been hampered by a lack of data. A report by the Government Accountability Office (GAO) in 2003 noted the lack of risk management plans in the evaluation of drugs with increased abuse potential, such as OxyContin, and the inability to comprehensively assess the current situation because “the data on abuse and diversion are not reliable, comprehensive, or timely” (emphasis added). The resultant ambiguity in data collection surrounding the potential abuse of prescription medications fostered a lag in the authorities’ ability to respond. Consequently, the Food and Drug Administration (FDA) has developed guidelines for pharmaceutical companies interested in submitting new drug applications (NDAs) for substances with potential for abuse or addiction. Within these guidelines, the FDA calls for the creation of Risk Evaluation and Mitigation Strategy plans (called REMS), previously known as risk minimization action plans, or RiskMAPs, that include post-marketing surveillance to monitor, on an active, ongoing basis, indicators that might suggest the occurrence of adverse events, such as an emerging trend of abuse. Such a surveillance system would meet other public health needs and would include the development of “an early warning and response system” to detect the emergence of new drugs (street drugs and pharmaceuticals) into the drug abuse “community” in addition to being able to monitor trends in the consumption and trafficking of illegal drugs and diverted pharmaceuticals.

While several systems are currently in place to monitor patterns of both illicit and prescription drug abuse, each of the existing systems has potential shortcomings when it comes to assessing patterns of prescription drug abuse. Although no single data stream is likely to cover all populations or regions, we sought to address some of the limitations of existing approaches to a national surveillance of abusable substances, including pharmaceuticals, through the development of the National Addictions Vigilance Intervention and Prevention Program (NAVIPPRO). This article briefly introduces the system, its rationale, and its major components. The primary focus of this article is to describe the ASI-MV® Connect, one of the system’s continuous, real-time data streams and to demonstrate its ability to effectively monitor product-specific prescription opioid abuse within a sentinel population.

THE NAVIPPRO SYSTEM

NAVIPPRO is a comprehensive, risk management system for prescription opioids and other Schedule II or III therapeutic agents. Risk management is viewed as a cyclic process that includes surveillance, signal detection capabilities, signal verification processes and targeted prevention and intervention strategies.

Figure 1. Cyclic process involved in pharmaceutical risk management

(Figure 1). Continuous and “real-time” data streams are subjected to temporal and spatiotemporal signal detection strategies. Detected signals are followed up with signal verification. Signal verification is a critical step that considers both the statistical performance of measures as well as field verification. Before an intervention is implemented, the system makes every effort to ensure that a detected signal reflects a true problem occurring in the local community (i.e., ruling out “false alarms”). Effective risk management requires not only detection and verification of a signal, but also interventions that can address the health concern that has been identified. Finally, continued surveillance helps to determine whether the implemented interventions were effective, and maintains the search for new signals. NAVIPPRO\textsuperscript{TM} addresses each of the stages in this cycle.

A complete presentation of all these activities is beyond the scope of this article. Therefore, in the current study, we focus only on the surveillance component of NAVIPPRO\textsuperscript{TM}, the ASI-MV\textsuperscript{R} Connect, one of NAVIPRO\textsuperscript{TM}’s primary data streams. Signal detection, signal verification, and prevention/intervention components of NAVIPPRO\textsuperscript{TM} will be addressed in a future publication.

**NAVIPPRO\textsuperscript{TM} surveillance**

The surveillance component of NAVIPPRO\textsuperscript{TM} integrates multiple data streams to monitor drug abuse both temporally and spatially at a product-specific level. Two proprietary data sources are monitored: the ASI-MV\textsuperscript{R} Connect and Web Informed Services (WIS): Internet Monitoring and Surveys on Prescription Drug Misuse. Several publicly available data sources are also monitored within NAVIPPRO\textsuperscript{TM}: the FDA-AERS, DAWN Live!, and AAPCC’s New Core System database (NCSBeta). Collectively, these data streams offer a comprehensive perspective on the use and abuse of drugs, including prescription medications. Since the goal of this study is to describe the ASI-MV\textsuperscript{R} Connect component of NAVIPPRO\textsuperscript{TM}, the characteristics of WIS will be described in a future publication.

**ASI-MV\textsuperscript{R} Connect**

ASI-MV\textsuperscript{R} Connect collects data from a national network of substance abuse treatment centers on substances used and abused by adult individuals (18 years or older) entering treatment. The ASI-MV\textsuperscript{R} Connect was originally developed and tested in English and has since been adapted to Spanish. The system is built on a modified version of the Addiction Severity Index (ASI), which is a standard intake assessment designed for use on admission to drug and alcohol treatment that has demonstrated reliability and validity.\textsuperscript{13} The ASI assesses severity of addiction and the need for treatment\textsuperscript{14,15} by measuring patients’ medical, employment, drug, alcohol, legal, family and social relationships, and psychiatric problems.

The Addiction Severity Index-Multimedia Version\textsuperscript{R} (ASI-MV\textsuperscript{R}) is a computer-administered CD-ROM version of the traditional ASI interview that has demonstrated good reliability and validity.\textsuperscript{16–18} The ASI-MV\textsuperscript{R} is a commercial product, purchased by treatment facilities for efficient and cost-effective patient evaluation and treatment planning purposes. The ASI-MV\textsuperscript{R} has been modified to include questions regarding patients’ use of specific branded and generic pharmaceutical drug products. Patients whose responses indicate the possible use/abuse of pharmaceuticals are directed to screens containing names (brand, generic, and slang names) and pictures of the pharmaceutical products (see Figure 2). Respondents select the picture(s) of drugs they have used and follow-up questions are asked regarding route of administration and source of drug. Questions about pain and pain treatment are also included. The system currently tracks 64 branded and generic prescription opioids. A “fake” drug helps track the extent of error due to patient inattention, fabrication, or other misidentification issues.

The ASI-MV\textsuperscript{R} Connect is the next generation of the ASI-MV\textsuperscript{R}. It is web-enabled so that upon completion of an assessment, aggregate, de-identified patient-level data are automatically uploaded to a secure central server. New screens or questions can be installed on the local computer as needed (i.e., to allow for the addition of new products). Uploaded aggregate data serve a surveillance function and assessment data (not product-level data) are available online to participating treatment agencies. A Web site called the ASI-MV\textsuperscript{R} Connect Data Center allows treatment providers to manipulate and analyze their own patients’ data and to make comparisons with similar treatment sites. Although secondary to the goal of post-marketing surveillance, the ASI-MV\textsuperscript{R} Connect Data Center is important to the treatment centers and will ensure long-term viability of the ASI-MV\textsuperscript{R} Connect system for collecting ongoing surveillance data collection. The seamless integration of the ASI-MV\textsuperscript{R} Connect assessment into the flow of clinical tasks further ensures that data collection is essentially invisible to clinicians and not an added burden for staff.
Since the ASI-MV Connect system captures patient-level data, the HIPAA (Health Insurance Portability and Accountability Act) regulations are a consideration. The research reported here is exempt from IRB policy since it uses de-identified patient data collected under a Business Associate Agreement and Limited Data Set Use Agreement with participating treatment facilities around the country under conditions specified under the Code of Federal Regulations.\(^1\)

The disadvantage of de-identified data, however, is that it prevents longitudinal analysis of cases. To address this issue, the ASI-MV Connect utilizes an algorithm which assigns each case a unique, 14-character identifier that is a concatenation of data entered by patients and are unlikely to change (e.g., gender, year of birth, mother’s name, etc.). Using cryptographic techniques, the identifier is converted into a unique linking code at upload and is maintained in the dataset but no longer reveals any elements of the personally identifying information. The nature of the ID permits identification of an individual who completes the ASI-MV Connect assessment at different times and even at different places. Testing of a similar system with census data found an unduplicated rate of 99.845\%.\(^2\) The unique ID retains patient privacy while permitting longitudinal tracking of patients within and across treatment centers.

Results from ASI-MV Connect

For purposes of illustration, we present the capacity of ASI-MV Connect to differentiate characteristics of this abuse population in terms of abusers, products, and geography. Recruitment of treatment sites to use the ASI-MV Connect began in 2007. Currently, 265 treatment sites from 29 states have contributed data to the system. New sites are joining the network at a rate of approximately 15 per month. The network has representation across the four U.S. Census Regions. However, the distribution of treatment sites varies across these regions, with the greatest number of sites in the West (48% of cases, 126 sites) and South (31%, 83 sites). By state, New Mexico has the greatest representation (88 sites) followed by Michigan (33 sites) and Oklahoma (21 sites). Given the importance of geographic coverage in a post-marketing surveillance system, it is important to note that the ASI-MV Connect substance abuse treatment facility network is a growing entity with new sites being added regularly and plans to add new treatment sites indefinitely.

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\(^1\) ASI-MV Connect (2008). NAVIPPRO, 1145.

Figure 3. ASI-MV® Connect Network: active and committed sites

Figure 4. Coverage by patient 3-digit zip code

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Figure 3 presents a map of the treatment site locations contained in the ASI-MV® Connect network.

As a testament to the geographic specificity of the ASI-MV® Connect as a post-marketing surveillance system, the ASI-MV® Connect collects the 3-digit home zip code of each patient as shown in Figure 4. Currently, the patient sample is drawn from 417 unique 3-digit zip codes (47% of 886 U.S. 3-digit zip codes 2007) representing a geographic coverage of 59% of the U.S. population.

The following analyses utilize data on 41,923 patient assessments uploaded from the 265 treatment facilities in 29 states collected by the ASI-MV® Connect system through 1 July 2008. Six to 21,648 cases per state have been uploaded. Three states had less than 20 assessments, eight states had between 21 and 100 assessments, nine states had between 101 and 1000 assessments, and the remaining nine had more than 1000. Currently, the most well represented geographic areas in this dataset are New Mexico (21,648 cases, 88 facilities in 52 unique zip codes), Michigan (5008 cases, 33 facilities in 23 zip codes), eastern Tennessee (3247 cases, 11 facilities in nine zip codes), and Florida (2324 cases, 10 facilities in nine zip codes).

Demographics of the entire substance abuse treatment population revealed a mean age of 34.9 (S.D. = 11.6, median = 33). Sixty-two per cent were males and 53% were Caucasian, with approximately 9% African-American, and 29% Hispanic or Latino. Individuals between the ages of 21 and 34 accounted for 45% of the sample, with 61% of the patients in this age group male although individuals between the ages of 35 and 54 accounted for 41% of the sample, with 62% of the patients in this age group male. Among all admissions, 11.5% (n = 4807) indicated using at least one opioid analgesic product “in a way not prescribed by your doctor,” at least once in the 30 days prior to the assessment, compared with 6% who used heroin, 29% who used alcohol to intoxication, 13% cocaine, 5% amphetamines, and 22% marijuana. Among those reporting illicit use of opioids in the past 30 days, most (54%) were men. However, considering the sample as a whole, 14% of women abused prescription opioids in the past 30 days compared with only 10% of men (χ² = 153.4, df = 1, p < .001). Out of the entire substance abuse treatment population, Caucasians were more likely to abuse prescription opioids (15 versus 7% for non-white racial categories, χ² = 659.3, df = 1, p < .001), and younger patients were more likely than older patients to have abused prescription opioids in the past 30 days (13 younger versus 9% older patients, median split, χ² = 170.6, df = 1, p < .001).
Finally, 33% of the sample reported a chronic pain problem, and those with pain (20%) were much more likely to use prescription opioids illicitly, than those who do not report a pain problem (8%, \(\chi^2 = 1167.0, df = 1, p < .001\)).

As noted, ASI-MV Connect permits a fine grained level of product specificity for prescription products substance abusers who report using or abusing in the 30 days prior to completing the assessment. Product-specific abuse rates indicated by trade name and grouped by chemical compound among clients entering substance abuse treatment are shown in Figure 5. As can be seen, out of the entire substance abuse population, approximately 7% of patients used any hydrocodone product, with Lortab (hydrocodone bitartrate; UCB Pharmaceuticals, Atlanta, GA) reported as the most commonly abused product (4%). Abuse of oxycodone products was seen in approximately 7% of the population with 7% using an immediate release version of oxycodone and approximately 7% using any oxycodone extended release, most of which (approximately 4%) was OxyContin. Abuse of morphine was largely the extended release formulations, with all such products abused at about the same level (1% Avinza; 1% MS Contin). Methadone abuse was primarily of the pill (2%), compared to the wafer formulations (0.2%). Abuse of any fentanyl in the past 30 days was seen in 0.7% of the total substance abuse population.

Finally, ASI-MV Connect data are capable of examining geographic differences in abuse at the 3-digit zip code level. While 11.5% of the sample abused prescription opioids in the past 30 days, there was considerable variation across the states. For instance, examining only states with at least 100 assessments in the database (n = 18), the rates of prescription opioid abuse differed significantly across these states, ranging from a low of 1% in Nebraska to a high of 53% in Nevada (\(\chi^2 = 4,683, df = 17, p < .001\)).

Two areas in which the ASI-MV Connect has reasonably good geographic coverage are eastern Tennessee (rate of prescription opioid abuse = 44% of admissions) and New Mexico (rate of prescription opioid abuse = 7% of admissions). Percentage of admissions abusing prescription opioids within the past 30 days was calculated for patient 3-digit zip code areas within these two states. The average number of assessments for these 3-digit zip codes was 239 admissions (SD = 826, median = 2). Figures 6a and Figure 6b present these proportions mapped at the 3-digit zip code level for the two geographic areas.

As can be seen, in New Mexico, prescription opioid abuse is not uniform across the state. In most of the 3-digit zip code areas, a small percentage of prescription opioid abusing patients were observed. Twelve zip codes yielded 5% or fewer admissions claiming prescription opioid abuse; two zip codes reported between 5 and 10%. A higher level of abuse (13%) was seen in one zip code area in central New Mexico (Figure 6a). Eastern Tennessee has a much higher level of prescription opioid abuse and as was observed in New Mexico, abuse rates are also not uniformly distributed across this state. Figure 6b reveals that three of the 3-digit zip codes in eastern Tennessee had proportions of prescription opioid abuse similar to areas in New Mexico (i.e.,1% to 5%). Another three
Tennessee zip codes report higher proportions of patients taking these opioids (between 5.1% and 10%), while a single area in eastern-most Tennessee had a rate higher than 30%. These data suggest that abuse of prescription opioids varies geographically. Thus, the ability of a surveillance system to precisely localize where these medications are being abused is critical in being able to implement intervention programs.

Figure 7 presents route of administration data for four opioid analgesic compounds: hydrocodone, oxycodone, morphine, and fentanyl. Distinct differences between these drugs in the routes of administration among this population are reported. Hydrocodone is more likely to be taken orally (swallowing, chewing, or sublingually) than the other drugs (significantly different from the morphine, $t = 29.47$, df = 3838, $p < .001$). Oxycodone formulations are more likely to be snorted (difference with morphine is significant, $t = 7.98$, df = 3695 $p < .001$). Fentanyl is much more likely to be smoked (significantly different from methadone, $t = 6.98$, df = 638, $p < .001$). Finally, morphine is more likely to be injected (significantly different from fentanyl, $t = 7.34$, df = 1142, $p < 0.001$).

Figure 8 presents data from ASI-MV® Connect on the source by which each prescription opioid was obtained for each of the five drug compounds: hydrocodone, oxycodone, morphine, methadone, and fentanyl. Across all drug compounds, the majority of individuals obtained these drugs from either a family/friend or through a dealer (i.e., someone known to sell drugs). For hydrocodone and oxycodone products, a nearly equal percentage of patients reported obtaining these drugs from a dealer or through family/friends (42 and 47%, respectively, for hydrocodone; 55 and 47%, respectively, for oxycodone). Morphine, methadone, and fentanyl were primarily obtained through a dealer (68, 48, and 60%, respectively). Relatively few individuals reported obtaining drugs for illicit use from their own prescriptions (e.g., 30% for hydrocodone; 25% for oxycodone).

**DISCUSSION**

This article describes one of the surveillance components of the NAVIPPRO™ system, the ASI-MV® Connect. During the development of a post-marketing surveillance system for the monitoring of any health-related event, including illicit and/or
prescription drug abuse, it is clear that several features must be incorporated into its design in order for it to be effective. In this context, it is interesting to note efforts to create syndromic surveillance systems and methods for infectious disease and terrorism outbreaks by CDC Working Groups and others (e.g.,). These authors have proposed frameworks for surveillance systems for detecting outbreaks and propose that the ideal syndromic surveillance system: (1) is not reliant on passive, voluntary reports from the field; (2) limits requirements for additional administrative tasks for clinical staff (healthcare workers have shown poor compliance with data collection tasks); (3) acquires data automatically, preferably in the course of regular, clinical activities; (4) electronically stores and transmits data to a central database for analysis; (5) collects ongoing data in real-time or “near” real-time; (6) has sufficient demographic, geographic, and temporal coverage to support anomaly detection; (7) captures data in standard formats across treatment sites or clinical institutions; (8) is HIPAA compliant and protects private information and patient confidentiality; and (9) scans for outbreak detection (i.e., distinguishing an abnormal pattern from a normal or expected one).

Similar system characteristics are proposed for effective post-marketing of potentially abusable prescription medications. Such a system should: (1) obtain data from a network of sentinel sites, such as substance abuse treatment facilities, which would provide a picture of drug abuse patterns in a relevant population and may serve as an early indicator population (2) produce “real-time” data available for analyses immediately following the “event” (3) reflect adequate geographic coverage to identify the location of a potential “event” (i.e., increased rate of abuse) with enough precision to assist in localized interventions (4) monitor abuse of specific products; and (5) derive information from a variety of data streams rather than relying on just one data source.
of the recommended characteristics for a surveillance system. A comprehensive comparison of these systems is hampered by the fact that much of the information on the capabilities of these systems is either not publicly available or has not yet been published in peer-reviewed sources. However, based on information that is available it can be determined that, for the publicly available systems: (1) some of these data sources were not specifically established for monitoring prescription drug abuse (AAPCC, MTF, NSDUH, TEDS) and, for a variety of reasons, may not be well-suited for post-marketing surveillance; (2) some are not product-specific (TEDS) or suffer from significant time lags between an observation or event and its availability for analysis in a database (FDA-AERS, NSDUH, TEDS, DAWNLive!, MTF); (3) several rely on passive, retrospective, and anecdotal or other non-primary source data\(^2\)\(^3\) (AAPCC, FDA-AERS); (4) geographic specificity of abuse data is either lacking or not reported for some of these systems (FDA-AERS, NSDUH, MTF, TEDS, DAWNLive!) and therefore, is difficult to assess.

The RADARS\(^3\) system was developed for post-marketing surveillance of prescription opioids and is considered here separately. RADARS\(^3\) is described as a comprehensive and proactive surveillance system\(^2\)\(^4\) that relies on a variety of data streams including key informant reports and Poison Control Center data among others to track prescription drug abuse. RADARS\(^3\)’s reliance on key informants is potentially problematic, and at least, is removed some steps from the primary source. Poison control data are a potentially very valuable resource; however, like the AAPCC data described above, these data rely on passive, retrospective, and/or anecdotal sources. The RADARS\(^3\) system’s online materials\(^3\) claim product specificity in marketing materials, however the level of product specificity has not been presented in published reports.\(^2\)\(^4\) RADARS\(^3\) collects data at the 3-digit zip code level, but the extent of coverage of the RADARS\(^3\) system’s Poison Control Center data is presented differently in different sources,\(^2\)\(^4\)\(^3\) so the actual national coverage of this system is unclear.

The ASI-MV\(^1\) Connect system was developed specifically to address as many of the requirements of an ideal post-marketing surveillance system as possible. With regard to the general characteristics of a syndromic surveillance system, the ASI-MV\(^1\) Connect system is not passive, but collects systematic and standardized data from primary sources (i.e., those who abuse prescription products). The ASI-MV\(^1\) Connect system was specifically structured to fit into the clinical flow at substance abuse treatment centers thereby making the data collection process essentially invisible to clinical staff. The system automatically acquires consecutive admissions and electronically transmits and stores, in a standardized format, cleaned and HIPAA compliant data in real time; real time being within minutes of the event (i.e., the completion of the assessment by the patient). Finally, the ASI-MV\(^1\) Connect system produces a continuous, unbroken stream of data that permits the establishment of baselines of “normal” or “expected” levels of abuse for any specific locale making it possible to apply outbreak detection methods.

The ASI-MV\(^1\) Connect system also meets additional requirements of a post-marketing surveillance system. It monitors a sentinel population (i.e., those known to abuse substances in general and prescription drugs in particular). It has adequate geographic specificity at the patient 3-digit zip code level, allowing for targeted interventions to be tailored and directed toward local circumstances. The system monitors prescription abuse at a product-specific level, the importance of which cannot be overstated. Given the growing interest in the development of new “abuse deterrent” prescription opioid formulations, it will be essential to delineate precisely what product(s) individuals are abusing in order to help determine the effect of an abuse deterrent formulation on actual abuse rates. Furthermore, the ASI-MV\(^1\) Connect system is the only system of which we are aware that systematically collects product-specific reports of routes of administration and source of drug. The capacity to track product-specific route of administration is likely to be critical in evaluating the impact on use patterns of abuse deterrent formulations that are developed in an effort to prevent the compound from being extracted for use by alternative routes. Finally, the ASI-MV\(^1\) Connect is only one data source; therefore it does not, by itself, meet the recommendation to utilize a variety of data streams to monitor prescription drug abuse. Other data sources monitored by NAVIPPRO\(^1\) will be described elsewhere.

Illustrative data from ASI-MV\(^1\) Connect

To illustrate some of these capabilities, ASI-MV\(^1\) Connect analyses are presented to highlight the capacity of this system to differentiate prescription opioid abusers, products, and geographic locations. These analyses yield the following observations: (1) Considering the entire substance abuse treatment population, more men than women (although not significantly more) abused prescription opioids,
whereas women were proportionally more likely than men to have abused prescription opioids in the past 30 days. (2) Caucasians reported more abuse of prescription opioids than minority patients. (3) Younger patients were more likely than older ones to abuse prescription opioids. (4) Patients indicating a physical pain problem were more likely to abuse opioid analgesics than those who did not indicate pain.

Hydrocodone products were found to be the most often abused of the prescription opioids, followed by oxycodone products (both immediate-release and extended-release formulations). These observations are consistent with compound-level abuse rates reported elsewhere. The ASI-MV® Connect data, however, further demonstrates that differences in abuse rates exist at the product-specific level. Although these patterns cannot be generalized beyond the areas from which our sample was drawn, these data nevertheless illustrate the ability of ASI-MV® Connect data to clarify precisely which products are being abused. This capacity to differentiate products is essential to conduct truly product-specific surveillance.

Geographic differentiation was also demonstrated using ASI-MV® Connect data. The illustration of differences between and within New Mexico and eastern Tennessee suggest that state-level analyses are consistent with compound-level abuse rates reported elsewhere. The ASI-MV® Connect data, however, further demonstrates that differences in abuse rates exist at the product-specific level. Although these patterns cannot be generalized beyond the areas from which our sample was drawn, these data nevertheless illustrate the ability of ASI-MV® Connect data to clarify precisely which products are being abused. This capacity to differentiate products is essential to conduct truly product-specific surveillance.

Limitations of ASI-MV® Connect

As discussed, existing data streams are limited in their potential to provide adequate post-marketing surveillance. The ASI-MV® Connect component of NAVIPRO™ is not without its own limitations. First, it is important to emphasize that the sample of treatment centers in the ASI-MV® Connect network is not yet fully representative. The network is privately-funded and relies on the voluntary agreement of managers of substance abuse treatment facilities and systems to install and use the ASI-MV® Connect software. Recruitment of new sites will continue indefinitely in order to add as many sites as possible. Inclusion of entire states (e.g., New Mexico) and significant coverage of some high risk areas (e.g., eastern Tennessee) in the sample provides useful opportunities for studies directed toward understanding the phenomena and spread of pharmaceutical drug abuse. However, development of a truly representative system will take time.

Second, it is unclear how prescription opioid abuse data collected at intake to substance abuse treatment relate to abuse rates in the community. Clearly, findings established on a sample of adult substance abusers in treatment are not generalizable to children and adult abusers not in treatment. This question can be further broken down into two more specific questions: (1) do rates of abuse of a particular substance or product that are detected in adult substance abusers in treatment translate to what is observed in the community? And, (2) are changes in the incidence of abuse detected in the treatment population a leading (or following) indicator of abuse in the community? At this point, both of these empirical questions remain unanswered. However, it is of interest to note that the launch of Opana® (oxymorphone HCl; Endo Pharmaceuticals, Chadds Ford, PA) occurred during pilot testing of the ASI-MV® Connect system. Opana® was added to the list of drugs queried, and the first endorsement of abuse of this drug by a patient taking the ASI-MV® Connect occurred within a few weeks of its being monitored. Counselors at the site confirmed the presence of Opana® in the community at the time. Thus, while the prevalence of Opana® abuse in the community remains unknown, the ASI-MV® Connect provides, at least, an early, sensitive indicator that abuse of this product is occurring in a given community. Given the sensitivity and relevance of the substance abuse treatment population in issues related to drug abuse, it is possible that substance abuse treatment facilities can serve as important sentinel surveillance sites in establishing patterns of prescription opioid abuse. This is particularly important when considering the need to determine rates of abuse for upcoming “abuse-deterrent” prescription opioid medication.

Finally, a current limitation of ASI-MV® Connect is that this is a new data stream with limited evaluation and empirical validation. Outbreak detection is defined by the Center for Disease Control and Prevention (CDC) as an increased frequency of disease above background occurrence of the disease. Thus, the NAVIPRO™ system is currently engaged in the process of establishing baseline data that can be used for signal detection efforts for the various prescription medications. Currently, studies are underway that examine these data streams and test the performance of various temporal and spatiotemporal techniques for detecting possible clusters of abuse or emerging trends in prescription medication abuse.
CONCLUSIONS
To our knowledge, ASI-MV® Connect data represent the first, product-specific abuse data to be collected and reported on for a population of individuals in substance abuse treatment. Because no current standard or coordinated system exists for post-marketing surveillance for prescription drug abuse, it is important to consider multiple and complementary data sources as a means of monitoring diverse abuse populations. We agree with Arfken and Cicero3 (p. S104) who noted, “The importance of using multiple methods of surveillance cannot be over-emphasized. Even when a chosen method is based upon best available data and thoughtful review of prior experience, one single design may miss the target population or region where abuse is first localized”. ASI-MV® Connect provides an additional source of data on prescription drug abuse and should be considered part of a spectrum of existing resources available for prescription drug abuse surveillance in the United States. Major advantages of this data stream include the provision of geographically localized product-specific information in real-time. Results from the ASI-MV® Connect highlight the value of NAVIPPROTM as a potentially effective tool for public health surveillance. Further data evaluation and comparison to other sources are important next steps to establishing NAVIPPROTM as a comprehensive post-marketing surveillance system for prescription drugs.

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KEY POINTS
- A new system, NAVIPPROTM, has been developed to address post-marketing surveillance of abuse of scheduled pharmaceutical products.
- The ASI-MV® Connect, a component of NAVIPPROTM, provides product-specific data on scheduled pharmaceutical products, allowing for analyses of product differences with respect to abusers, route, source of drug, and geospatial distribution.
- Results from the ASI-MV® Connect highlight the value of NAVIPPROTM as an effective tool for public health surveillance.
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20. FHOP. Family health outcomes project unique identifiers, discussion, recommendations and testing; 1995.
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