

Strengths and Limitations of Drug Abuse Warning Network Data Used in a Surveillance Study

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ABSTRACT

Background: Surveillance of possible abuse and misuse of a product is an important component of pharmacovigilance activities for prescription narcotic analgesics. This requires the use of specialized data sources that can provide reliable and complete data on these events. The Drug Abuse Warning Network (DAWN), operated by the Substance Abuse and Mental Health Services Administration, has been used for monitoring abuse and misuse of many narcotic analgesics. DAWN captures drug-related emergency department (ED) visits from a sample of US hospitals by retrospective review of ED records. ED visits are weighted to the US population to provide national estimates, and if that number is <30 or if the standard error exceeds 50% of its value, the estimate is not provided.

Objectives: To evaluate the impact of DAWN estimate suppression rules on the completeness of data obtained as part of a narcotic analgesic surveillance program.

Methods: Tabulations of DAWN ED visit estimates for overmedication, nonmedical use, accidental ingestion, and suicide attempt reported for a specific narcotic analgesic of interest and separately for all prescription narcotic analgesics for 2004 were requested. In addition, estimates of the above mentioned ED visit categories stratified on demographics were requested for the specific narcotic analgesic of interest. We examined the proportion of the total requested ED visit estimates that were available from DAWN.

Results: An estimated 71.2 million patients were exposed to all prescription narcotic analgesics in 2004 and of these, about 1.2 million patients were exposed to the specific narcotic analgesic of interest. Of the 32 total ED visit estimates requested, 88% were provided, including 100% of the estimates related to all prescription narcotic analgesics and 50% of estimates related to the specific narcotic analgesic of interest. Of the 100 total estimates requested to describe DAWN case demographics for the specific narcotic analgesic of interest, only 22% were returned.

Conclusions: Based on the results of this analysis, DAWN data appear to be more complete for larger product groupings compared to a specific product and may be less useful for describing demographic characteristics related to a specific product because of a lower return of ED visit estimates.

CONFLICT OF INTEREST

RTI Health Solutions (RTI-HS) and Johnson & Johnson PRD employees contributed to the analysis and interpretation of the findings. Employees of RTI HS, a nonprofit research organization, conducted the safety surveillance study from which the data for this analysis originated. The safety surveillance study is fully funded by Johnson & Johnson PRD. RTI-HS has an independent right to publish.

BACKGROUND

- Surveillance of possible abuse and misuse of a product is an important component of pharmacovigilance activities for narcotic analgesics.
- It is difficult to obtain data on narcotic misuse and abuse from traditional data sources, such as health care claims databases.
- Specialized data sources, such as the Drug Abuse Warning Network (DAWN), can provide reliable data for monitoring abuse and misuse events.
- DAWN captures data from medical records of drug and alcohol-related emergency department (ED) visits and provides data weighted to the US population (by age and gender) for different types of visits, including overmedication, accidental ingestion, and attempted suicide.

OBJECTIVE

To describe the effect of DAWN estimate suppression rules on the completeness of data obtained as part of a narcotic analgesic surveillance program.

DAWN

DAWN is an active public health surveillance system administered by the Substance Abuse and Mental Health Services Administrations (SAMHSA). DAWN collects information on drug-related ED visits and drug-related deaths from a national sample of approximately 500 nonfederal hospitals operating 24-hour EDs through retrospective review of medical records. SAMHSA publishes weighted summary-level estimates annually. Manufacturers may obtain weighted estimates on specific narcotic agents upon special request to SAMHSA.

History

DAWN and DAWN Live!

- DAWN was established in the 1970s but was redesigned in 2003. The redesign affected the sampling frame and case eligibility criteria.¹ As a result, comparisons cannot be made between old DAWN data (2002 and earlier years), data from the transitional year of 2003, and new DAWN data from 2004 and beyond.² Weighted estimates are representative of the entire US, including all 50 states and the District of Columbia.
- Unweighted data can be obtained via DAWN Live!, a real-time online query system that can be accessed upon approval and appropriate training by SAMHSA. Raw, unweighted data can be used for detecting sentinel events and emerging trends for specific brand-name drugs.³

Case Definition and Ascertainment

- Cases are identified through retrospective review of all medical records in each hospital in the DAWN system. An ED visit becomes a DAWN case if, based on clinician documentation, the visit is judged to be for a condition induced by or related to recent drug use.
- Cases are classified into one of eight case types (i.e., suicide attempt, seeking detoxification, alcohol only in patients under age 21, adverse reaction, overmedication, malicious poisoning, accidental ingestion, and other) in the DAWN data set according to a hierarchical decision tree approach.

DAWN Data

- DAWN data, weighted to the US population to provide national estimates of ED visits, are provided to the requestor by SAMHSA in the form of populated data tables. Weighted data are not available until 6 to 12 months or more after the close of each annual data collection period.
- DAWN suppression rules are based on the size and stability of the calculated national estimate. The estimate is not provided if the estimated number of ED visits is <30 or if the standard error exceeds 50% of its value.

METHODS

Design

- We requested tabulations of DAWN ED visit estimates for overmedication, nonmedical use, accidental ingestion, and suicide attempt reported for a specific narcotic analgesic of interest, and separately for all prescription narcotic analgesics, for 2004 and 2005 (2005 data became available after the original abstract was submitted and have been included).
- We also requested ED visits stratified on demographic characteristics for the fentanyl transdermal system of interest.
- We conducted analyses examining the proportion of estimates returned out of the total requested ED visit estimates that were available from DAWN.

Reporting Source

US nonfederal hospitals with 24-hour EDs across the US and District of Columbia:

- For 2004, 417 hospitals submitted data that were used for estimation by DAWN.
- For 2005, 355 hospitals submitted data that were used for estimation by DAWN.

Study Variables

- ED visit types: overmedication, nonmedical use (i.e., DAWN "other" case type), accidental ingestion, and suicide attempt;
- Exposure variables: all narcotic analgesics, fentanyl transdermal system of interest, all fentanyl transdermal systems, all fentanyl products including nontransdermal systems, hydromorphone/combinations, hydrocodone/combinations, oxycodone/combinations, and methadone;
- Patient characteristics: gender, age, number of drugs involved, patient disposition, and race/ethnicity.

Analysis

We conducted an analysis to compare the percentage of ED visit estimates requested to those returned overall and by product group and ED visit type. The number of estimates requested corresponds to the number of cells in each table. A completed cell is one that contains a numerical value. Incomplete cells are indicated by three dots (...) and refer to suppressed estimates (i.e., one with a relative standard error greater than 50% or with a count less than 30).

Main Study Measures

- Percentage of cells returned overall,
- Percentage of cells returned by ED visit type,
- Percentage of cells returned by product group.

RESULTS

Description of Estimates Requested and Returned

Table 1. Example of Data Table Received from DAWN (32 Estimates Requested)^{1,2}
2004 DAWN National Estimates of Emergency Department Visits by Product Category and Visit Type: Fentanyl Transdermal System of Interest Versus Other Products

| Opioid Product Category* | Over-medication | Nonmedical Use | Accidental Ingestion | Suicide Attempt |
|---|-----------------|----------------|----------------------|-----------------|
| All narcotic analgesics | 49,642 | 82,390 | 2,490 | 15,133 |
| Fentanyl transdermal system of interest | 2,131 | 3,427 | ... | ... |
| All fentanyl transdermal systems | 2,310 | 4,810 | ... | 30 |
| All fentanyl products, including nontransdermal systems | 2,626 | 5,374 | ... | ... |
| Hydromorphone/combinations | 738 | 2,043 | ... | ... |
| Hydrocodone/combinations | 21,396 | 21,062 | 1,012 | 7,325 |
| Oxycodone/combinations | 12,679 | 23,759 | 563 | 3,324 |
| Methadone | 5,854 | 25,976 | 236 | 1,207 |

¹These are national estimates of emergency department visits based on a national probability sample of nonfederal short-stay hospitals with 24-hour emergency departments in the US.

²Three dots (...) indicate that an estimate with a relative standard error greater than 50% or an estimate less than 30 has been suppressed.

³All pharmaceutical opioids, excluding illicit opioids (e.g., heroin).

Note: Table represents the total number of emergency department visits by DAWN case type for an opioid group.

Table 2. Example of Data Table Received from DAWN (32 Estimates Requested)^{1,2}
2005 DAWN National Estimates of Emergency Department Visits by Product Category and Visit Type: Fentanyl Transdermal System of Interest Versus Other Products

| Opioid Product Category* | Over-medication | Nonmedical Use | Accidental Ingestion | Suicide Attempt |
|---|-----------------|----------------|----------------------|-----------------|
| All narcotic analgesics | 61,328 | 98,827 | 2,968 | 15,944 |
| Fentanyl transdermal system of interest | 2,312 | 2,338 | ... | ... |
| All fentanyl transdermal systems | 4,245 | 4,051 | ... | ... |
| All fentanyl products, including nontransdermal systems | 4,728 | 4,432 | ... | ... |
| Hydromorphone/combinations | 1,697 | 3,646 | ... | 197 |
| Hydrocodone/combinations | 26,468 | 24,862 | 1,223 | 8,320 |
| Oxycodone/combinations | 15,039 | 27,771 | 840 | 3,014 |
| Methadone | 8,380 | 32,658 | 252 | 1,628 |

¹These are national estimates of emergency department visits based on a national probability sample of nonfederal short-stay hospitals with 24-hour emergency departments in the US.

²Three dots (...) indicate that an estimate with a relative standard error greater than 50% or an estimate less than 30 has been suppressed.

³All pharmaceutical opioids, excluding illicit opioids (e.g., heroin).

Note: Table represents the total number of emergency department visits by DAWN case type for an opioid group.

Table 3. Example of Data Table Received from DAWN (100 Estimates Requested)^{1,2}
2004 DAWN National Estimates of Emergency Department Visits for Fentanyl Transdermal System of Interest: Demographics and Patient Disposition by Visit Type

| Characteristic | Overmedication N = 2,133 n (%) | Nonmedical Use N = 3,427 n (%) | Accidental Ingestion N = ... n (%) | Suicide Attempt N = ... n (%) |
|---------------------------------|--------------------------------|--------------------------------|------------------------------------|-------------------------------|
| Gender | | | | |
| Male | 497 (23.3) | 1,548 (45.2) | ... | ... |
| Female | 1,634 (76.6) | 1,879 (54.8) | ... | ... |
| Unknown | ... | ... | ... | ... |
| Age | | | | |
| 0-5 | ... | ... | ... | ... |
| 6-11 | ... | ... | ... | ... |
| 12-17 | ... | ... | ... | ... |
| 18-20 | ... | ... | ... | ... |
| 21-24 | ... | 246 (7.2) | ... | ... |
| 25-29 | ... | ... | ... | ... |
| 30-34 | ... | 356 (10.4) | ... | ... |
| 35-44 | ... | 961 (28.0) | ... | ... |
| 45-54 | 182 (8.5) | 695 (20.3) | ... | ... |
| 55-64 | 397 (18.6) | 385 (11.2) | ... | ... |
| 65 and older | 1,051 (49.3) | ... | ... | ... |
| Unknown | ... | ... | ... | ... |
| Number of drugs involved | | | | |
| Single drug | 900 (42.2) | 1,478 (43.1) | ... | ... |
| Multiple drugs | 1,231 (57.7) | 1,948 (56.8) | ... | ... |
| Patient disposition | | | | |
| Admitted to hospital | 1,200 (56.3) | 934 (27.3) | ... | ... |
| Died | ... | ... | ... | ... |
| Other | 931 (43.6) | 2,493 (72.7) | ... | ... |
| Race/ethnicity | | | | |
| White | 1,670 (78.3) | 2,924 (85.3) | ... | ... |
| Black | ... | ... | ... | ... |
| Hispanic | ... | ... | ... | ... |
| Race/ethnicity NTA | ... | ... | ... | ... |
| Unknown | ... | 353 (10.3) | ... | ... |

¹These are national estimates of emergency department visits based on a national probability sample of nonfederal short-stay hospitals with 24-hour emergency departments in the US.

²Three dots (...) indicate that an estimate with a relative standard error greater than 50% or an estimate less than 30 has been suppressed.

Note: The denominator for percentage is the total number of emergency department visits for the fentanyl transdermal system of interest for a given event of interest.

NTA = Not tabulated above.

Table 4. Example of Data Table Received from DAWN (100 Estimates Requested)^{1,2}
2005 DAWN National Estimates of Emergency Department Visits for Fentanyl Transdermal System of Interest: Demographics and Patient Disposition by Visit Type

| Characteristic | Overmedication N = 2,133 n (%) | Nonmedical Use N = 3,427 n (%) | Accidental Ingestion N = ... n (%) | Suicide Attempt N = ... n (%) |
|---------------------------------|--------------------------------|--------------------------------|------------------------------------|-------------------------------|
| Gender | | | | |
| Male | 672 (29.1) | 711 (30.4) | ... | ... |
| Female | 1,639 (70.9) | 1,627 (69.6) | ... | ... |
| Unknown | ... | ... | ... | ... |
| Age | | | | |
| 0-5 | ... | ... | ... | ... |
| 6-11 | ... | ... | ... | ... |
| 12-17 | ... | ... | ... | ... |
| 18-20 | ... | ... | ... | ... |
| 21-24 | ... | ... | ... | ... |
| 25-29 | ... | ... | ... | ... |
| 30-34 | ... | 266 (11.4) | ... | ... |
| 35-44 | 502 (21.7) | 669 (28.2) | ... | ... |
| 45-54 | 485 (21.0) | 617 (28.4) | ... | ... |
| 55-64 | 516 (22.3) | 324 (13.9) | ... | ... |
| 65 and older | 485 (21.0) | ... | ... | ... |
| Unknown | ... | ... | ... | ... |
| Number of drugs involved | | | | |
| Single drug | 1,138 (49.2) | 1,355 (58.0) | ... | ... |
| Multiple drugs | 1,174 (50.8) | 982 (42.0) | ... | ... |
| Patient disposition | | | | |
| Admitted to hospital | 1,028 (44.5) | 252 (10.8) | ... | ... |
| Died | ... | ... | ... | ... |
| Other | 1,284 (55.5) | 2,086 (89.2) | ... | ... |
| Race/ethnicity | | | | |
| White | 2,134 (92.3) | 1,943 (83.1) | ... | ... |
| Black | ... | ... | ... | ... |
| Hispanic | ... | ... | ... | ... |
| Race/ethnicity NTA | ... | ... | ... | ... |
| Unknown | ... | 245 (10.5) | ... | ... |

¹These are national estimates of emergency department visits based on a national probability sample of nonfederal short-stay hospitals with 24-hour emergency departments in the US.

²Three dots (...) indicate that an estimate with a relative standard error greater than 50% or an estimate less than 30 has been suppressed.

Note: The denominator for percentage is the total number of emergency department visits for the fentanyl transdermal system of interest for a given event of interest.

NTA = Not tabulated above.

Percentage of Estimates Returned

- Of the 64 total ED visit estimates requested for 2004 and 2005, 78% were provided, including 100% of the estimates related to all prescription narcotic analgesics and 50% of estimates related to the fentanyl transdermal system of interest (Tables 1 and 2).
- 100% of the 32 estimates requested were returned for ED visit types of overmedication and nonmedical use, irrespective of product category evaluated (see Figure 1).
- Of the 32 estimates requested for ED visit types of accidental ingestion and suicide attempt, 50% to 63% of the data requested was returned respectively across the different product categories evaluated (Tables 1 and 2).
- Of the 200 total estimates requested to describe DAWN case demographics for the fentanyl transdermal system of interest for 2004 and 2005, only 23% were returned (Tables 3 and 4).
- 40% to 52% of the estimates requested for ED visit characteristics for the overmedication and nonmedical use case types were returned (Figure 2).
- None of the estimates requested for ED visit characteristics for the accidental ingestion and suicide attempt case types were returned (Figure 2).

Figure 1. Percentage of National Estimates Returned of Those Requested for Fentanyl Transdermal System of Interest and All Other Product Categories Evaluated by Emergency Department Visit Type For 2004 and 2005 Combined

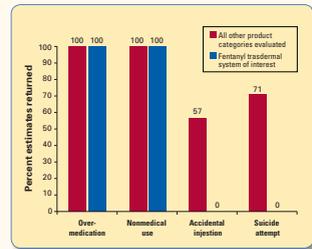
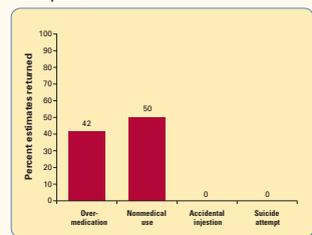


Figure 2. Percentage of National Estimates Returned of Those Requested for Fentanyl Transdermal System of Interest, by Emergency Department Visit Type for 2004 and 2005 When ED Visit Characteristics Were Requested



CONCLUSIONS

An estimated 68.9 million patients in 2005 and 71.2 million patients in 2004 were exposed to a prescription narcotic analgesic. Of these, about 1.2 million patients (1.7% in 2004 and 725,000 patients (1.1%) in 2005) were exposed to the fentanyl transdermal system of interest. Overmedication and nonmedical use were the most common ED visit types regardless of product category evaluated. IMS Health Inc. provided the number of patients exposed by product category for 2004 and 2005.)

In light of the large number of patients exposed:

- DAWN data provide some useful information for augmenting pharmacovigilance activities relating to prescription narcotic medications, but have limitations when there are small numbers within cells in the data request.

- DAWN data are more complete for larger product categories:
- Larger estimates with greater stability (smaller standard error) are more likely to result when broader product categories are requested.
- Estimates are more likely to be available for common ED visit types, such as overmedication and nonmedical use, than for accidental ingestion or suicide.
- DAWN data may be less useful for describing ED visit characteristics of patients:
- Requests for increasingly more detailed strata result in fewer estimates returned.
- Researchers should be aware of and plan for a lack of weighted estimates for more rare ED visit types, such as accidental ingestion and suicide attempts for a specific product.

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