

SUPPORTING STATEMENT DRUG ABUSE WARNING NETWORK

A. JUSTIFICATION

1. Circumstances of Information Collection

The Substance Abuse and Mental Health Service Administration's (SAMHSA), Office of Applied Studies, is requesting OMB approval for a revision for the Drug Abuse Warning Network (DAWN) (OMB No. 0930-0078), which expires 12/2008. DAWN proposes to make minor changes in the reporting forms for its DAWN emergency department (ED) and Medical Examiner/Coroner (ME/C) components.

DAWN is an on-going national public health surveillance system that monitors drug-related medical emergencies and deaths. DAWN relies on a national probability sample of non-Federal, short-stay, general hospitals that operate 24-hour emergency departments (EDs). Hospitals are oversampled in selected metropolitan areas and divisions, and a remainder sample covers hospitals in the rest of the U.S. Based on data from sampled hospitals, national estimates of drug-related emergency department visits for the U.S. are produced annually.

The DAWN mortality component collects data on drug-related deaths from participating death investigation jurisdictions across the U.S. administered by medical examiners and coroners (ME/Cs). The death investigation jurisdictions that participate in DAWN do not constitute a statistical sample nor is every jurisdiction within a metropolitan area necessarily a participant. As a result, extrapolation of drug-related deaths to the Nation as a whole is not possible, and metropolitan area totals are only possible if all jurisdictions within the area participate. The number of jurisdictions that participate in DAWN varies from year to year. Currently, 442 jurisdictions in 11 States with centralized death investigation systems and 131 jurisdictions in an additional 29 metropolitan areas participate in DAWN. Profiles are published annually.

DAWN was initiated in 1972 by the White House Special Action Office for Drug Abuse Prevention and the Drug Enforcement Administration (DEA) [as authorized in 42 U.S.C. (290 aa-2,11)]. In November 1981, the National Institute on Drug Abuse (NIDA) assumed responsibility for the continued operation of DAWN. Upon the establishment of SAMHSA by an act of Congress in October 1992, the administration of DAWN passed to SAMHSA. SAMHSA is required to collect DAWN data under Section 505(c)(1)(A,B) of the Public Health Service Act (42 U.S.C. 290aa-4).

Additionally, the White House Office of National Drug Control Policy (ONDCP) is directed under 21 U.S.C. 1705(a)(4)(E)(iv) to use information from DAWN to measure the impact of the National Drug Control Strategy on reductions in ED visits related to drug abuse.

DAWN's major objectives are to:

- \$ Measure drug-related morbidity and mortality, based on visits to hospital EDs and deaths investigated by ME/Cs;
- \$ Monitor drug misuse and abuse patterns and trends for specific substances;
- \$ Detect new drugs of abuse and new drug combinations;
- \$ Assess the health hazards associated with drug misuse and abuse; and
- \$ Provide information for Federal, State, and local drug abuse policy and program planning.

Since its inception, DAWN has tracked the number of emergency department (ED) visits and deaths induced by or related to abuse of illegal drugs and nonmedical use of legal drugs. In 2003, DAWN began collecting data on all drug-related ED visits and deaths. This approach has not only enabled DAWN to do a better job of capturing ED visits and deaths that involved drug misuse (that frequently were not captured previously), but has also resulted in the ability to capture adverse reactions to prescription and over-the-counter medications, ED visits resulting from the accidental use of drugs, and intentional drug poisonings with malicious intent. DAWN also now collects data on underage drinking.

The two primary sources of DAWN data are:

- \$ A national probability sample of non-Federal, short-term, general hospitals with 24-hour emergency department services; and
- \$ Medical examiner/coroner offices.

The design of the DAWN hospital ED sample makes it possible for DAWN to produce estimates of drug-related ED visits for the U.S. and for a selection of over-sampled (OS) areas. Under this design, DAWN collects data on emergency department visits related to recent drug use for patients of all ages, regardless of the motive for using the drug(s); demographic characteristics of those patients; up to 16 substances plus alcohol; ED visits involving alcohol only for patients under age 21 (underage drinking); and detailed information about the diagnoses and the disposition of the ED visits.

The mortality (ME/C) component of DAWN has never been based on a probability sample. Instead, participation is voluntary and, as a result, participating jurisdictions vary somewhat from year to year. For the 11 states participating in DAWN in 2008 (Maine, Maryland, Massachusetts, New Hampshire, New Mexico, Oklahoma, Oregon, Utah, Vermont, Virginia, and West Virginia), all 442 jurisdictions reported to DAWN. In the metropolitan areas located outside these States, however, 131 jurisdictions in 29 metropolitan areas are reporting drug-related deaths to DAWN, with participation of all jurisdictions in only 6 of the 29 areas. No extrapolation to a larger universe was possible from data supplied by participating jurisdictions.

DAWN collects data on drug-related deaths investigated by Medical Examiner/Coroner jurisdictions, regardless of the motive for using the drug(s). Data are collected on decedent demographic characteristics, the place of death, manner of death, cause of death, up to 16

substances plus alcohol, and deaths involving alcohol only for decedents under age 21 (underage drinking).

One of the goals of DAWN is to include all death investigation jurisdictions within selected metropolitan areas and selected States. DAWN continues to recruit ME/C jurisdictions in the metropolitan areas that are oversampled for the ED component. Enrolling all ME/Cs in each of the metropolitan areas will obviate the need for a sample, which is not feasible. This approach is intended to provide measures of drug-related morbidity (estimates from the ED sample) and mortality (a census) for the same geographic units. DAWN also collects data on drug-related deaths from states with centralized ME systems, which is an efficient way to achieve a census of drug-related deaths for metropolitan areas within the states. It has the added advantage of providing data for some non-metropolitan areas that DAWN never included before.

DAWN data are abstracted from a retrospective review of ED medical records and ME case investigation files according to specified case selection criteria.¹ Each facility that participates in DAWN has one or more DAWN Reporters to review charts and collect data on its behalf.² The DAWN Reporter reviews ED medical records or ME/C death investigation files to find those that are drug-related (DAWN cases), and then submits data items electronically on each DAWN case.

Changes to DAWN that began in 2003 have helped to obtain more consistent and reliable data on drug abuse cases. The previous age restriction has been lifted, and cases involving alcohol as the only substance have been reportable for minors, for whom alcohol is an illegal drug. Revisions and additions to the data elements collected on DAWN cases have facilitated new approaches to categorize and subset cases for different audiences and have, for the first time, allowed analysis of the health condition of ED patients and the cause(s) of death for ME/C cases.

DAWN data are as important now as when the system was first instituted in the early 1970s. The pervasiveness of drug abuse in American society, the ever-changing nature of the drug abuse problem, and the paucity of other data all support the continuing need for DAWN data. Recent improvements in content and presentation of DAWN findings have been met with expressions of greater demand for the information DAWN can produce. Additionally, DAWN is now able to provide real-time data on an on-going basis to identify adverse drug reactions as well as the health consequences of drug use, misuse, and abuse.

¹ DAWN data are collected from hospitals and ME/C jurisdictions under the DAWN Operations Contract (DOC). The DOC is also responsible for recruiting hospitals, processing the data and producing analysis-ready data files, and managing IT needs. Responsibility for drawing the sample of hospitals, producing estimates for the ED data, and preparing the ED estimates and mortality data for publication is under the DAWN Analytic Contract (DAC).

² Depending on the needs of the facility, the DAWN Reporter may be one of three types: (a) Staff Reporter, (b) Field Reporter, or (c) Remote Reporter. Staff Reporters are members of the facility's staff who conduct DAWN data collection on behalf of their facility. Field Reporters and Remote Reporters are employees of the DAWN operations contractor who conduct DAWN data collection for the facility. Field Reporters perform their data collection functions at the DAWN participating facility (i.e., in the field). Remote Reporters perform their data collection functions at the contractor's home office, by remote access to electronic medical records of participating facilities.

All data are submitted electronically using programs developed specifically for DAWN. Emergency department data are submitted via eHERS (electronic Hospital Emergency Reporting System) and ME/C data are submitted via eMERS (electronic Medical Examiner Reporting System). Data collection forms proposed for use beginning January 1, 2009 (Attachment A) include:

- \$ ED: eHERS case report (Attachment A.1)
- \$ ME/C: eMERS case report form (Attachment A.3)

No changes are proposed for the Emergency Department Activity Report or the Medical Examiner Activity Report (Attachments A.3 and A.6).

2. Purpose and Use of Information

DAWN provides information in support of SAMHSA's drug abuse surveillance, prevention, and treatment objectives. SAMHSA's Center for Substance Abuse Treatment (CSAT) is responsible for certifying opioid treatment programs (OTPs) and uses DAWN data to monitor buprenorphine and methadone, the drugs used to treat opioid dependence. CSAT uses DAWN ED data to track misuse/abuse, adverse reactions, and accidental ingestions involving methadone or buprenorphine and the nonmedical use of prescription pain medications, and uses the DAWN mortality data to track and investigate deaths associated with methadone or buprenorphine.

ONDCP uses findings from DAWN, in conjunction with other drug-related data sets, to formulate strategy for the reduction of illegal drug use and its consequences in the United States, and to measure the impact of that strategy in terms of reductions in ED visits related to drug abuse.

The Food and Drug Administration (FDA) uses DAWN to monitor the abuse potential of prescription drugs and to assist them with scheduling of controlled substances under the Controlled Substance Act (CSA), in coordination with the Drug Enforcement Administration (DEA). FDA uses DAWN data in conjunction with other sources to assist in drug labeling decisions, such as the labeling of sustained-release opioids, and for post-marketing surveillance and risk assessment of new drugs.

The Centers for Disease Control and Prevention (CDC) uses DAWN ED data to monitor adverse reactions to medications used to treat influenza, ED visits related to the nonmedical use of prescription opiates, and deaths associated with the use of prescription and over-the-counter medications.

DAWN data are used at the State and local level and by the medical community to direct the allocation of resources and to promote the planning and design of drug abuse treatment and prevention activities. The members of the Community Epidemiology Work Group (CEWG) are intensive and regular users of metropolitan-area findings from DAWN data. The CEWG is a network of epidemiologists and researchers supported by NIDA to provide community-level surveillance of drug abuse for 21 separate areas. On a semi-annual basis, the CEWG members update and report on drug abuse profiles for each of their communities, using OS-area

information from DAWN in conjunction with locally available treatment data, special surveys, and ethnographic findings. Other active users include the health departments in Boston, Denver, Detroit, New York City, and San Francisco and State health agencies in Illinois, Maine, Massachusetts, Michigan, and New York.

DAWN collects very specific drug information at a level of detail unmatched by any other source. As a result, DAWN can be used as an indicator of emerging trends in new drugs of abuse and new drug combinations and their potential threat to public health. DAWN is particularly valuable for detecting emerging trends, especially those involving prescription drugs. Another important feature of DAWN is its ability to provide a measure of the trends and impact of identified drug abuse on the emergency departments of the Nation's hospitals. DAWN also provides important information about the health consequences of drug misuse and abuse.

Proposed Changes in Data to be Collected

Besides formatting changes, DAWN proposes making 3 changes to reporting forms:

- \$ Remove "Beginning with the presenting complaint" from the instructions for Item (8) on the ED form.
- \$ Add a response category, "Transdermal," to data item (9) on the ED form and to data item (12) on the mortality form.
- \$ Add a case description field to the ME/C reporting form. This will permit Reporters to document why the death is a DAWN case in a dedicated field. Additional detail about the case will be especially valuable in deaths where drugs were not the primary cause of death.

Instructions that will be provided to DAWN Reporters are provided in Attachment B and will be revised to reflect the approved reporting forms.

It is DHHS policy that all national surveys are reviewed by the Office of the Assistant Secretary for Planning and Evaluation (ASPE). The review for the 2009 survey was conducted in August 2008.

3. Use of Information Technology

DAWN benefits from modern information technology applied to electronic data submission. All current DAWN participants (ME/Cs and hospitals) submit data electronically. DAWN's use of information technology was reviewed and approved by the Information Technology Investment Review Board (ITIRB) on April 29, 2002.

DAWN makes extensive use of the Internet, with data security a high priority, through the electronic Medical Examiner Reporting System (eMERS) and the electronic Hospital Emergency Reporting System (eHERS). eMERS and eHERS originated as web-based data entry applications that used participants' own hardware, software (a standard Internet browser), and connectivity. Data submitted via eHERS or eMERS are encrypted during transmission, and

the systems are accessible only with valid user ID and password. Data are stored in access-controlled facilities and are accessible only to authorized users.

In addition, there are separate versions of eMERS and eHERS that run on laptop computers not connected to the Internet at the time of data entry. These stand-alone versions have the same look and feel as the web-based systems, but provide a portable option for DAWN Reporters. This is essential, for not all DAWN data collection occurs in a fixed location or at a location within the facility with the necessary computer setup. For facilities where computer or web access is unavailable, DAWN offers assistance by providing computers and/or web access, depending on which assistance is most effective for the location. Data stored on laptop computers are encrypted, so that theft or loss of a computer will not jeopardize data security. During transmission from the portable device, the data remain encrypted, and the data are deleted from the device once no longer needed. DAWN's electronic reporting systems mean that data reach DAWN more rapidly; errors are reduced because automated checks identify invalid responses upon entry; and DAWN Reporters receive immediate feedback about invalid or incomplete data entry.

Because DAWN data are submitted electronically, in 2004 DAWN was able to establish a secure, internet-based query system, *DAWN Live!* This system gives members access to de-identified, real-time DAWN data. Authorized hospital staff may use *DAWN Live!* to track drug-related ED visits in their hospital; local public health authorities may use it to identify new drugs of concern in their jurisdiction, confirm recent patterns identified in other metropolitan areas; and run special inquiries on new public health priorities. Participating ME/Cs can use *DAWN Live!* to track drug-related deaths in their jurisdictions. FDA in particular relies on *DAWN Live!* to track adverse events associated with drugs approved for marketing and to monitor misuse of drugs. It also enables DAWN staff to provide more timely data to the public.

4. Efforts to Identify Duplication

No data collection systems duplicate or can be adapted to supply the information contained in DAWN. DAWN was developed in the 1970s to fill a need for information that is ongoing, national and local in scope, and specific in nature regarding abused drugs and their health consequences that manifest in medical emergencies and deaths. The metropolitan-area component of DAWN recognizes that local patterns of illicit drug availability, purity, use and therefore, the consequences of drug abuse, vary widely. Furthermore, many aspects of drug abuse policy, control, prevention, and treatment also occur at a local level, and would not be served by data that are solely national in scope.

The **National Electronic Injury Surveillance System** (NEISS), administered by the Consumer Product Safety Commission (CPSC), collects data on consumer product-related injuries from a nationally representative sample of hospitals with a minimum of 6 beds and a 24-hour ED. Data are abstracted from medical records and reported electronically to CPSC. NEISS surveillance data are available to the public online in various computer formats and by request.

In 2000, NEISS expanded to collect data on all injuries (both intentional and unintentional) in the All-Injury Program (NEISS-AIP). Subsequently, in 2003, CDC, in collaboration with CPSC and FDA, created the Cooperative Adverse Drug Event Surveillance (NEISS-CADES) project

by adding active surveillance of adverse drug events to the NEISS-AIP. NEISS-CADES is a nationally representative subsample of 64 of the 98 NEISS hospitals. Trained data collectors review ED charts for adverse drug events, which are then submitted electronically to CPSC.

NEISS and DAWN use similar methodologies, with a reporter at each participating facility reviewing ED charts to identify cases, and submitting case reports to their respective agencies. However, there are several important differences between the NEISS systems (AIP and CADES) and DAWN (**Tables 1a and 1b**). The key differences include:

- \$ DAWN is designed to produce estimates for the Nation and for a selection of oversampled metropolitan areas. NEISS produces national estimates only; its sample cannot support sub-national estimates for any geographic unit.
- \$ DAWN collects data on all ED visits related to substance misuse/abuse. NEISS captures data on unintentional pharmaceutical misuse (CADES) and poisonings involving children under age 5.
- \$ DAWN collects data on all types of drugs: illicit drugs, prescription and over-the-counter pharmaceuticals, dietary supplements, non-pharmaceutical inhalants, and alcohol. NEISS does not collect data on illegal drugs or alcohol.
- \$ To meet its objective of protecting consumers from faulty products, NEISS performs follow-up investigations on certain cases, an activity that requires access to individually identifiable patient information. DAWN does not collect direct identifiers and does not conduct investigations related to individual cases.

Although there are similarities between the DAWN and NEISS methodologies, only DAWN has the geographic and population coverage essential for both national and local users, DAWN includes complete coverage of drug abuse ED visits, and only DAWN collects substantial detail about the drugs involved and about the circumstances of each case.

Table 1a. Comparison of DAWN and NEISS Systems			
	DAWN	NEISS-AIP	NEISS-CADES
Sample	Non-Federal, general hospitals with 24-hr EDs (n=300)	Hospital with 24-hr ED and >=6 beds (n=98)	Hospital with 24-hr ED and >=6 beds (n=64)
Representation	Representative of US and OS metropolitan areas	Representative of US	Representative of US
Case criteria	ED visit related to recent drug use -Directly caused by drug(s) -Drug(s) contributed to the ED visit	All consumer product-related emergency visits; poisonings to children under age 5	Injury related to the outpatient use of a drug and resulting from allergic reaction, side effect, unintentional overdose, or secondary effect
Patient demographics	All ages	Ages 0 to 5 only	All ages

Table 1b. Comparison of DAWN and NEISS-CADES		
	DAWN	CADES
Reason for Drug Use/ED Visit		
Drug abuse	Yes	No
Suicide attempt	Yes	No
Accidental/unintentional	Yes	Yes
Adverse drug reaction	Yes	Yes
Nonmedical use of pharmaceuticals	Yes	Some
Malicious poisoning/assault	Yes	No
Seeking detox	Yes	No
Withdrawal	Yes	No
Types of Drugs Included		
Illicit Drugs	Yes	No
Prescription and OTC pharmaceuticals, dietary supplements, vaccines	Yes	Yes
Inhalants (nonpharm.)	Yes	No
Alcohol	Yes if patient under age 21 If patient 21 or older, included only if present with another drug	No
Presence of other drugs	All other drugs	Pharmaceuticals only
Toxicology testing	Confirmation by toxicology (individual drugs)	Tests conducted in ED
Drug information	Brand name, route	Brand name, dose, frequency, duration, route

The **National Hospital Ambulatory Medical Care Survey** (NHAMCS, OMB No. 0920-0278), conducted by the Centers for Disease Control and Prevention (CDC), National Center for Health Statistics, collects nationally representative data on visits to hospital emergency and outpatient departments. The differences between DAWN and NHAMCS include:

- \$ NHAMCS relies not only on a sample of hospitals but also on a sample of visits occurring during a 4-week reporting period. Therefore, NHAMCS does not collect drug-related cases in sufficient numbers or detail to support the types of analyses available from DAWN, because drug abuse is a relatively rare phenomenon even in EDs.
- \$ A relatively small sample of visits from a limited timeframe is adequate and efficient for the purposes for which NHAMCS was designed, that is, to track ambulatory medical care that is delivered in hospitals. However, such a small sample is inadequate for making estimates about drug-related ED visits or estimates about specific drugs, even at a national level.
- \$ Further, NHAMCS cannot support any metropolitan-area estimates of the type that local users of DAWN depend upon. These estimates are not available from any other sources. In fact, NCHS has relied on DAWN for estimates of substance abuse-related ED visits for publication in *Health, United States*.

The **Healthcare Cost and Utilization Project** (HCUP), sponsored by the Agency for Healthcare Research and Quality (AHRQ), is composed of a group of health care databases of

patient-level health care data. Contributors to HCUP include State data organizations, hospital associations, private data organizations, and the Federal government. One of the components of HCUP, the **State Emergency Department Databases (SEDD)**, includes data on ED visits that did not result in admission to the hospital. Data organizations in 25 states participate in SEDD. There are several important differences between DAWN and SEDD:

- \$ DAWN is able to produce estimates for the Nation and for a selection of oversampled metropolitan areas. Because SEDD does not sample hospitals, it is unable to provide National estimates.
- \$ SEDD does not include ED visits where the patient was admitted to the hospital; therefore, information about the most severe drug-related ED visits is not available.
- \$ While there is a comorbidity measure for drug abuse and for alcohol abuse, detailed information about drugs is not included in SEDD. Case descriptions that could be used to make the link between a drug (if reported) and the ED visit are not available.
- \$ The SEDD databases do not have the detailed drug information or geographic and population coverage that is essential for DAWN's national and local users.

BioSense, administered by CDC, is a national initiative to enhance the Nation's capability to rapidly detect, quantify, and localize public health emergencies, particularly biologic terrorism, by accessing and analyzing diagnostic and prediagnostic health data. BioSense enables receipt, analysis, and visualization of electronic health-care data for public health use. Data are available simultaneously to local, State, and Federal public health officials and hospital personnel through BioSense, which can be accessed through the CDC Secure Data Network. Hospitals are included in the system based on their ability to supply appropriate electronic data and their willingness to participate. In October 2007, data were being received from EDs at 413 nonfederal hospitals in the United States. Data received by BioSense included age, sex, free-text patient-reported chief complaints, and diagnosis codes (usually International Classification of Diseases, Ninth Revision, Clinical Modification [ICD-9-CM] codes). There are several critical differences between Biosense and DAWN:

- \$ DAWN must be capable of producing national estimates of drug-related ED visits and therefore requires a probability sample of hospitals from across the Nation. DAWN also oversamples hospitals in selected areas to produce area estimates. BioSense relies on data submitted by a voluntary group of hospitals, which do not constitute a statistical sample. Therefore, Biosense cannot be used to produce estimates for the Nation or for local areas.
- \$ BioSense does not collect the data necessary to find DAWN cases from all patients treated in hospital emergency departments. DAWN cases are identified through retrospective direct medical record review. BioSense data come from laboratory findings, ICD-9-CM diagnosis codes, and CPT medical procedure codes. When screening based on ICD-9-CM methods was evaluated as part of the DAWN redesign, it showed that this method was clearly inferior to direct chart review for finding DAWN cases (i.e., drug-related ED visits). DAWN cases also cannot be reliably found based on laboratory findings, because not all drug-related cases receive such tests and not all drugs of interest to DAWN can be detected through laboratory tests.

\$ BioSense does not collect the detailed data necessary to characterize drug-related ED visits. DAWN collects more detailed information on drugs than any other substance abuse data collection system. Again, such information cannot come from laboratory findings.

The design of BioSense enables it to collect data rapidly for public health emergencies, but its findings are not generalizable to the Nation. Because its ability to detect and describe drug-related ED visits is limited, BioSense could not meet the needs of DAWN's national and local users.

The **Adverse Event Reporting System (AERS)** is a computerized database designed to support FDA's post-marketing safety surveillance program for all approved drug and therapeutic biologic products. Data for AERS come from adverse drug reaction reports sent to FDA by manufacturers, as required by regulation. AERS also includes reports of serious adverse events for medical products sent voluntarily by health care professionals and consumers through the **MedWatch** program. The goal of AERS is to protect the public's health by providing tools for storing and analyzing drug safety reports. The AERS reports on adverse drug events are evaluated by clinical reviewers in the Center for Drug Evaluation Research to detect safety signals and to monitor drug safety sentinel events; they also form the basis for further epidemiological studies when appropriate. The information provided by AERS may be used by FDA for regulatory actions and re-evaluating drug approval decisions.

Although DAWN collects data on adverse drug events, the DAWN and AERS systems are quite different:

- \$ AERS is a passive surveillance system, relying on manufacturers, health care providers, and the public to submit reports. DAWN is an ongoing, active surveillance system.
- \$ The detail that DAWN collects on adverse events is unlikely to match that available from AERS reports.
- \$ DAWN does not collect direct identifiers for individuals, so adverse drug events collected by DAWN, although useful to FDA, will not provide an opportunity for follow-up investigations.
- \$ Unlike DAWN, AERS data are not drawn from a sample, so representative estimates at the National or local level are not possible.
- \$ AERS only covers approved drugs, and does not collect data on drug abuse and misuse. Therefore, the data collected by DAWN are not duplicative of that collected by AERS.

Other drug abuse data collection efforts operated by SAMHSA and other agencies typically provide information by general categories rather than by specific drugs of abuse or, if specific drug information is available, it typically involves only the most frequent such drugs; on a periodic rather than a continual basis; and/or in insufficient quantity to produce valid estimates or extrapolations.

5. Involvement of Small Entities

The information requested from all participants (both small entities and otherwise) has been kept to the absolute minimum required to meet DAWN=s objectives. The DAWN operations contractor provides training, supplies, and technical assistance through liaisons in the field and staff in the home office. A toll-free telephone number, help desk, and facility relations staff are available to assist DAWN participants and answer their questions. DAWN offers participants with staffing constraints the option of data collection by a Field Reporter or Remote Reporter, an individual provided by the operations contractor with the participant=s approval, on a permanent basis.

6. Consequences If Information Collected Less Frequently

Section 505 of the Public Health Service Act requires that information provided by DAWN be collected on an annual basis. The use of DAWN by the Office of National Drug Control Policy to develop and monitor progress for the National Drug Control Strategy also requires estimates on an annual basis.

DAWN provides the Federal Government with the only ongoing data collection system that documents specific trends in the consequences of drug misuse and abuse that manifest in medical emergencies and deaths nationally and for selected areas of the country. It was designed to function as an early warning indicator of emerging problems and changing patterns of drug abuse. In 2004, DAWN introduced *DAWN Live!*, the secure, Internet-based query system that provides de-identified, real-time DAWN data to authorized public health users. In addition to providing data to participating hospitals and local public health authorities, *DAWN Live!* is used by authorized staff at FDA, CDC, ONDCP and SAMHSA, and members of NIDA's Community Epidemiology Work Group. Pharmaceutical companies use *DAWN Live!* to monitor their own products and to provide reports to FDA.

Thus, it is essential that the current schedule of reporting be maintained. Less frequent reporting would significantly diminish DAWN=s effectiveness, and could adversely affect the Federal Government=s drug abuse monitoring and prevention efforts.

7. Consistency with the Guidelines in 5 CFR 1320.5(d)(2)

The data are collected in a manner consistent with the guidelines in 5 CFR 1320.5(d)(2).

8. Consultation Outside the Agency

A notice soliciting public comment on this data collection was published in the *Federal Register* on May 5, 2008, Volume 73, Number 87, pages 24603-24604. No comments were received in response to this notice.

DAWN receives valuable and ongoing feedback from the Office of National Drug Control Policy, which is one of the principal users of DAWN data. The National Institute Drug Abuse's Community Epidemiology Work Group members also communicate frequently with DAWN staff about the data collected and the DAWN *Live!* system. The following additional experts were consulted about the proposed changes to the reporting forms:

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9. Payment to Respondents

Most DAWN facilities receive remuneration to compensate for the time spent reviewing records and reporting eligible cases. Escalating fiscal and other pressures on health care providers clearly indicate the necessity of compensating the participating facility or the data collection staff. This is especially important since maintaining the statistical sample of selected participants is essential to maintaining the validity of the DAWN estimates.

DAWN recognizes that equitable and consistent payment for the work performed is essential, but has to be part of a comprehensive strategy that includes both monetary and non-monetary incentives to encourage and recognize the importance of participation. The payment protocol includes two components: an annual access fee for each facility and, for hospitals that collect the data using their own staff (Staff Reporters), a piece-rate payment for each chart reviewed and for each DAWN case submitted (**Table 2**). Since payment varies depending on the size of the facility and the prevalence of DAWN cases, it recognizes explicitly the variation in the quantity of work across facilities.

To protect against fraudulent inflation of workload, a census list protocol and a quality assurance system using Statistical Process Control models are used to monitor the number of cases reported and charts reviewed to identify irregularities on a flow basis. Tying payments to the number of charts reviewed is also intended to act as a performance incentive, designed to discourage short-cuts, such as reviewing ED logs to identify a minimal subset of charts for

review. A study conducted as part of the evaluation of design alternatives clearly demonstrated the inferiority of any method of case finding other than direct chart review.

Under the current payment protocols, EDs are eligible to receive annual access payments for participating in DAWN and providing access to medical records for the retrospective review required to find DAWN cases. When a hospital joins DAWN in a timely manner, it is eligible for an additional payment in addition to the annual access payment.

Hospitals that provide a staff member(s) to collect DAWN data on hospital time are eligible also for payments for data collection. Currently, these are based on a payment per ED chart reviewed and per DAWN case reported. There are two systems, standard and graduated:

- \$ In the standard system, hospitals receive \$0.10 per chart reviewed and \$2.00 per case reported within 31 days of the visit (\$1.00 per case reported after 31 days). Currently, all but 4 of the hospitals that provide a Staff Reporter are in this plan.
- \$ The graduated system is structured to reward timely reporting. Hospitals receive \$0.50 per chart reviewed and \$10.00 per case reported within 13 days of the ED visit. The piece rate decreases if data are submitted more than 13 days after the ED visit. Currently, four hospitals are in this plan.

Facilities also have the option of participating in DAWN but having the data collection performed by a Field Reporter or Remote Reporter supplied and paid by the DAWN operations contractor. In facilities that use Field Reporters or Remote Reporters, the facility still receives the access fee.

During the period covered by this requested OMB renewal, which corresponds to Year 7 of the current DAWN operations contract and Years 1-3 of the operations contract to be awarded in the fall of 2008, an estimated **\$2,690,800** will be paid to participating facilities; **\$2,049,880** to EDs and **\$640,920** to ME/Cs.

Contract Year	ED	ME/C	Total
Year 7 Feb. 2008-Feb. 2009	\$512,470	\$160,230	\$672,700
Year 1 Feb. 2009-Feb. 2010	\$512,470	\$160,230	\$672,700
Year 2 Feb. 20107-Feb. 2011	\$512,470	\$160,230	\$672,700
Year 3 Feb. 2011-Feb. 20012	\$512,470	\$160,230	\$672,700
Grand Total	\$2,049,880	\$640,920	\$2,690,800
¹ Facility payments exclude salaries for Field Reporters and Remote Reporters, who are employed by			

Table 2. DAWN Facility Payments¹			
Contract Year	ED	ME/C	Total
the DAWN operations contractor.			

The payments based on this formula approximate assume a stable number of participating EDs and ME/Cs and an approximate labor cost of \$15.50 per hour assuming that reviewing a chart to determine if it is a DAWN case takes an average of 2.5 minutes per chart. However, the time it takes to review a chart varies across facilities based on numerous factors, including the nature of record flow within the facility, the process point at which the DAWN Reporter accesses the charts and the degree of automation in the facility.

10. Assurance of Confidentiality

Health information privacy regulations issued pursuant to the Health Insurance Portability and Accountability Act of 1996 affect most, possibly all, hospital participants in DAWN. Hospitals were required to comply with these rules April 14, 2003.

Under the HIPAA Privacy Rule, hospitals may disclose individually identifiable data to DAWN under disclosures for public health activities authorized by law, 45 CFR 164.512(b)(1). These disclosures are permitted without individual consent or authorization. SAMHSA is a public health authority required by law B Section 505 of the Public Health Service Act (42 U.S.C. 290aa-4) B to collect data on:

- \$ The number of individuals admitted to the emergency rooms of hospitals as a result of the abuse of alcohol or other drugs, and
- \$ The number of deaths occurring as a result of substance abuse, as indicated in reports by coroners.

In accordance with the HIPAA Privacy Rule, SAMHSA requests only the minimum amount of information necessary to fulfill DAWN=s purpose.

HIPAA does not apply to medical examiners or coroners, who are not covered entities under the Act. State law, which varies considerably from State to State, governs the confidentiality of decedents who are the subject of medical examiner/coroner death investigation. In some States, information about decedents is publicly available.

Data submitted to DAWN from hospitals or medical examiners/coroners fall under specific protections that apply to all data collected by SAMHSA under Section 505 of the Public Health Service Act (42 U.S.C. 290aa-4). The Children=s Health Act of 2000 (P.L. 106-310) enacted in October 2000 restricts the uses and disclosures of data collected by DAWN; Section 501(n) of the Public Health Service Act (42 U.S.C. 290aa) states:

LIMITATION ON THE USE OF CERTAIN INFORMATION. No information, if an establishment or person supplying the information or described in it is identifiable Y may be used for any purpose other than the purpose for which it

was supplied unless such establishment or person has consented Y to its use for such other purpose. Such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented ... to its publication or release in other form.

Furthermore, the Confidential Information Protection and Statistical Efficiency Act (CIPSEA), Title V of the E-Government Act of 2002 (Pub. L. 107-347) applies similar restrictions to data collected for statistical purposes. In Section 512, it states:

(a) USE OF STATISTICAL DATA OR INFORMATION.—Data or information acquired by an agency under a pledge of confidentiality and for exclusively statistical purposes shall be used by officers, employees, or agents of the agency exclusively for statistical purposes.

(b) DISCLOSURE OF STATISTICAL DATA OR INFORMATION.—

(1) Data or information acquired by an agency under a pledge of confidentiality for exclusively statistical purposes shall not be disclosed by an agency in identifiable form, for any use other than an exclusively statistical purpose, except with the informed consent of the respondent.

In addition, Section 513 of the E-Government Act of 2002 provides for stiff penalties for unlawful disclosures of information by employees of SAMHSA and its sworn agents:

Whoever ... having sworn to observe the limitation imposed by Section 512, ... and, knowing that ... disclosure ... is prohibited ..., willfully discloses the information in any manner to a person or agency not entitled to receive it, shall be guilty of a class E felony and imprisoned for not more than 5 years, or fined not more than \$250,000, or both.

The Office of Applied Studies, SAMHSA, has been designated as a Federal Statistical Unit by the Office of Management and Budget (OMB). Under CIPSEA, statistical agencies and units are authorized to designate agents to acquire information and/or perform other statistical activities. DAWN statistical data are collected by a contractor (currently, Westat), that is designated as an “agent” under CIPSEA. Accordingly, the DAWN Operations contractor and its employees are bound to the same legal requirements and subject to the same penalties as agency employees under CIPSEA.

SAMHSA has developed and follows the following policies and procedures that govern DAWN data collection and prevent misuse or disclosure of DAWN data:

- \$ DAWN does not collect direct identifiers (e.g., names, Social Security number, medical record number) for patients or decedents.
- \$ Terms of participation, the document executed with DAWN facilities, contain specific clauses regarding the confidentiality of DAWN data and the obligations of each party with respect to confidentiality.

- \$ Data collected electronically are encrypted and transmitted via secure connections to the DAWN operations center. Data entered into portable devices for subsequent transmission are encrypted for storage and are removed from the device when no longer needed.
- \$ Employees of OAS/SAMHSA and its contractors sign confidentiality agreements that spell out the confidentiality requirements, how those requirements affect employees' behavior and use of data, and the penalties associated with violations.
- \$ Every individual affiliated with DAWN at SAMHSA and its contractors receives specific annual training on the confidentiality and data protection rules that apply to DAWN.
- \$ DAWN data are viewed and processed only by individuals who require access. Access to DAWN electronic data collection systems is limited to DAWN staff and facility Reporters with a valid user id and password. The central database is maintained on a secure server to which access is limited to authorized project staff only.
- \$ The most sensitive data elements, date and time of visit and patient ZIP code, are available only to authorized employees of SAMHSA and its contractors.
- \$ No facility-level data are published. A facility's own data are accessible through DAWN systems only to the individuals authorized by the facility that submitted the data.
- \$ All data produced in tabular format are reviewed for confidentiality risks before release. Published reports suppress data where necessary if the publication of such data could potentially identify an individual hospital, patient, or decedent.

11. Questions of a Sensitive Nature

Information of a sensitive nature is not solicited directly from individuals. The data collection forms do not record direct identifiers for patients or decedents. DAWN's data collection procedures involve abstraction of information from existing records; the information contained on DAWN forms is a subset of the information available in source records (medical records or case files of medical examiners/coroners).

12. Estimates of Annualized Hour Burden

Table 3 includes both a gross burden estimate that includes all DAWN Reporters and an adjusted burden estimate with the Field Reporters and Remote Reporters deducted from the total. It shows the hour and cost burden associated with the updated reporting forms, for events occurring from January 1, 2009 through December 31, 2011. The **average annual burden** for DAWN is **72,227** hours, with an annual cost of **\$1,119,510**. Estimates of response burden are based on past experience, as are the hourly cost estimates. (The assumptions underlying the burden calculations are described in Section 15).

Table 3. Annualized Reporting Burden for DAWN: 2009—2011

Activity	Number of Respondents ¹	Estimated Number of Responses per Respondent	Total Responses	Estimated Time per Response (in minutes)	Total Hour Burden	Wage Rate	Total Hour Cost ²
Emergency Departments							
ED Chart review	61	24,551	1,497,611	2.5	62,400	\$15.50	\$967,207
Case data entry	61	556	33,916	3	1,696	\$15.50	\$26,285
ED activity report	61	52	3,172	2	106	\$15.50	\$1,639
Subtotal	61				64,202		\$995,131
State Medical Examiners¹							
Death investigation records review	6	3,099	18,594	4	1,240	\$15.50	\$19,214
Case data entry	6	338	2,028	3	101	\$15.50	\$1,572
ME/C activity report	6	104	624	2	21	\$15.50	\$322
Subtotal	6				1,362		\$21,108
Individual Medical Examiners/Coroners¹							
Death investigation records review	84	1,097	92,148	4	6,143	\$15.50	\$95,220
Case data entry	84	89	7,476	3	374	\$15.50	\$5,794
ME/C activity report	84	52	4,368	2	146	\$15.50	\$2,257
Subtotal	84				6,663		\$103,270
TOTAL	151				72,227		\$1,119,509

¹ State MEs and some other ME/C offices report for multiple jurisdictions. For this reason, the number of respondents is smaller than the number of ME/C jurisdictions participating in DAWN.

² Row and column totals may differ due to rounding.

13. Estimates of Annualized Cost Burden to Respondents

Neither hospital EDs nor ME/C offices incur start-up or operational costs associated with participation in DAWN. Facilities use office and computer equipment that is in place for general operational purposes. Where necessary, DAWN provides laptop computers and Internet connections so data can be submitted electronically.

14. Estimates of Annualized Cost to the Government

The annualized cost to the Government for the DAWN operations and analytical contracts is approximately \$17 million. This includes payments to facilities (hospitals and ME/Cs), Facility Reporters, and compensation paid to Field Reporters, and takes the growth of the system into account. Government personnel costs for that period to monitor the DAWN contracts, perform programming and related tasks, and oversee the analytical report production are approximately \$600,000 per year. The total annualized cost to the Federal Government is \$17,600,000.

15. Changes in Burden

Currently, there are 111,938 burden hours in the OMB inventory. The program is requesting an estimated annualized burden of 72,227 burden hours, a decrease of 39,711 hours. Program changes resulted in a decrease of 53,769 hours and adjustments resulted in an increase of 14,508 hours.

Program Changes

Two program changes decreased DAWN's burden. First, a programmatic decision was made to reduce the number of participating hospitals in 2005. The purpose was to conserve DAWN resources without sacrificing data quality. This allowed for a more focused effort to maintain or increase participation in 13 OS areas and the remainder sample (areas outside the OS areas).

Second, participating hospitals are opting to use Field Reporters or Remote Reporters provided by the DAWN operations contractor. This has resulted in a decrease in the total number of ED respondents from 116 in 2005 to 61 in 2008. The increased reliance on contractor personnel reduces burden on respondents, particularly hospitals. Currently, approximately 81 percent of all EDs and 35 percent of all ME/C facilities that participate in DAWN use Field Reporters or Remote Reporters to perform the DAWN record review and data submission. Field Reporters and Remote Reporters are paid directly by the DAWN operations contractor, so no burden is incurred by hospitals and medical examiner offices that use them. Therefore, no burden is claimed in this submission for that portion of DAWN reporting that is carried out by the Field Reporters and Remote Reporters.

The mortality component saw an increase in participants, including centralized State ME systems and individual jurisdictions. In contrast to the ED component, most ME/C offices opt to use their own staff as Reporters, which resulted in an increase in respondents from 11 to 90 (84 individual jurisdictions and 6 State ME offices).

Adjustments

The burden calculation presented here separates the three DAWN Reporter activities: (1) review of ED charts and ME/C case files to find DAWN cases; (2) electronic submission of data items for each case found; and (3) completion of activity reports. By calculating the amount of time needed for each activity separately, a more accurate estimate of burden is reached.

Based on more extensive information about the length of time needed by Reporters to review ED charts and death investigation records, identify DAWN cases, and submit case data and new procedures for activity reports, we have revised the estimated time per response for both the ED and mortality components. Overall, we discovered that it took the Reporters slightly longer to obtain and review records, but less time to submit the case data. The separation of these three elements shows that almost the entire burden (97 percent for EDs and 92 percent for ME/Cs) is associated with the comprehensive review of source records – ED medical records and ME/C case files – that is required to find DAWN cases.

The current estimates are shown below, followed by the net difference from the estimates submitted in 2005.

Emergency Department component:

- \$ Chart review/case finding: 2.5 minutes per chart (increase of .5 minute).
- \$ Data entry for DAWN cases: 3 minutes per case (decrease of 7 minutes). This is probably due to the modifications to the ED reporting form that were implemented in 2006 (i.e., deletion of data elements).
- \$ Data entry for Activity Report: 2 minutes per report. This value has not changed; however, reporters are now required to submit a weekly activity report. This has resulted in an increase from 1 activity report per month to a 1 activity report per week.

Mortality component

- \$ Chart review/case finding: 4 minutes per death investigation record (increase of 1.5 minutes).
- \$ Data entry for DAWN cases: 3 minutes per case (decrease of 1 minute).
- \$ Data entry for Activity Report: 2 minutes per report. This value has not changed; however, reporters are now required to submit an activity report on a weekly (individual jurisdictions) or monthly (State offices) basis for each day they collect data. This has resulted in an increase from 1 activity report per month to a maximum of 8 per month.

Using these revised assumptions, the burden per case for the ED component is 114 minutes and the burden per case for the mortality component is 51 minutes. These increases are primarily the result of increased time allocated for chart review/case finding compared to 2005.

16. Time Schedule, Publication, and Analysis Plan

Data are submitted by participating hospital EDs and ME/Cs on a continuous basis. Because data collection is completely electronic, a secure web-based query system (DAWN *Live!*) was

developed to allow real-time queries of de-identified DAWN data. This system was originally developed to allow participating facilities access to their own de-identified data. With this capability, SAMHSA is able to respond to a wide range of special requests as well. Biweekly data files are also delivered by the DAWN Operations contractor to allow for additional ad hoc analyses.

The production of annual data files at the end of the data period supports the development of annual ED and ME/C publications as well as reports on special topics. The time from the end of the data period to the publication of annual reports varies. Normally, data are available for publication about 6-9 months from the close of the data period for EDs and ME/Cs. The release of the annual ED estimates were delayed for 2006 because of problems identified with the ED estimation methodology for 2004 and 2005, which necessitated a detailed review of procedures. OAS plans to release 2006 ED estimates in the summer of 2008; this publication will include the revised estimates for 2004 and 2005. DAWN will produce an annual series of ED reports to include:

- An overview of estimates for the United States, and
- An overview of estimates for selected OS metropolitan areas.

SAMHSA publishes annual estimates from the DAWN ED data for the U.S. and selected OS areas. The publication *Drug Abuse Warning Network, 2006: National Estimates of Drug-Related Emergency Department Visits* will be available on the Internet at <http://dawninfo.samhsa.gov/pubs/edpubs/>.

The ED report series includes the following types of information in tables and figures for both the United States and for selected OS metropolitan areas:

- \$ Response rates of the DAWN ED sample,
- \$ Estimates and population-adjusted rates for:
 - ED visits for major illicit drugs and therapeutic classes of drugs
 - Component drugs within selected drug groups
 - Patient demographic characteristics, and
- \$ Estimates for visit characteristics (type of case, single- vs. multi-drug, and disposition).

Annually, SAMHSA publishes mortality data from participating State and local ME/C jurisdictions. The focus of the mortality component of DAWN has been to have full participation of all ME/C jurisdictions in the OS metropolitan areas included in the ED component of DAWN.

Later this year, the publication *Drug Abuse Warning Network, 2004: Area Profiles of Drug-Related Mortality*, will be available on the Internet at <http://dawninfo.samhsa.gov/pubs/mepubs/>. Changes implemented in 2008 will enable more rapid production of the annual publication.

The publication of mortality data includes for each State and metropolitan area:

- \$ Participation of jurisdictions and population, by county;
- \$ Summary of drug-related deaths, by county;

- \$ Demographic characteristics of decedents in drug-related deaths;
- \$ Death characteristics (manner of death, place of death, single- vs. multi-drug);
- \$ Most frequently reported drugs, and
- \$ Trends in drug deaths for major illicit drugs and selected categories of drugs.

Periodically, SAMHSA also publishes *The DAWN Report*, which focuses on topics of special interest in a brief publication format. Inquiries from the public, the press, and other entities are used as a gauge of important topics that are then addressed in these reports. Topics are also developed in consultation with others in the Agency and in the field. This report series can be found on the DAWN website at <http://dawninfo.samhsa.gov/pubs/shortreports/>. Methodology reports are also published periodically as topics of interest arise.

DAWN provides feedback to participating facilities in several ways. Quarterly facility-specific reports are sent to ED directors and ME/Cs. These reports include summarized information about the number of cases reported in the facility. Additionally, at the end of the reporting period for the year, ME/Cs are provided with a year-end summary of cases reported for their facility. This allows ME/Cs to comment on the validity of their data prior to the development of the annual publication. Each facility may authorize individuals to have access to *DAWN Live!* These individuals are encouraged to access the de-identified raw data for their own facility, and OS area tabulations are provided for comparison.

17. Display of Expiration Date

All DAWN forms will display the OMB expiration date.

18. Exceptions to Certification Statement

The certifications are included in this submission.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

1. Respondent Universe and Sampling Method

Emergency Department Component

The universe for the DAWN ED sample is all non-Federal, short-stay, general medical and surgical hospitals in the United States that operate one or more EDs 24 hours a day, 7 days a week. Specialty hospitals, hospital units of institutions, long-term care facilities, pediatric hospitals, hospitals operating part-time EDs, and Federal hospitals such as those operated by the Veterans Health Administration and the Indian Health Services are excluded.

The universe of EDs is identified from the American Hospital Association's Annual Survey Database. The AHA Survey Database (AHASDB) includes both American Hospital Association member and non-member hospitals. The AHASDB is created annually and includes virtually all hospitals in the United States, except for a very small number of nonparticipating hospitals (less than 1 percent). The AHASDB is updated every year to reflect new, closed, merged, and demerged³ hospitals.

DAWN stratifies the universe of eligible hospitals by geographic area (Metropolitan Statistical Areas⁴ and Divisions⁵) by ownership (public/private) and by size (measured by the number of annual ED visits) (**Table 4**).

DAWN's target sample frame consists of all non-Federal, short-stay, general medical and surgical hospitals in the United States that have one or more EDs open 24 hours per day. For that population of inference, DAWN estimates the annual number of drug-related ED visits for multiple domains of interest at the national and subnational level. Any one ED visit may have multiple drugs associated with it; separate estimates are produced for each of the drugs reported.

The sample employs a single-stage cluster design where the cluster is a hospital and all of the ED visits in the hospital are used. Stratified simple random sampling with oversampling is used

³ A demerged hospital is a hospital that is split into at least two other hospitals.

⁴ The information for the counties that make up the MSAs or Metropolitan Divisions within an MSA are based on the County File available from the Census Bureau and located at <http://www.census.gov/population/estimates/metro-city/03mfips.txt>. The file header is: Metropolitan and Micropolitan Statistical Areas and Components, 2003, With Codes. The Metropolitan and Micropolitan Statistical Areas were defined by OMB on June 6, 2003. The source of the information is the Population Division, U.S. Census Bureau. The Internet release date was June 10, 2003, and it was last revised on July 10, 2003. The file contains Core Based Statistical Area (CBSA) Division Code, Federal Information Processing Standards (FIPS) State Code, FIPS County Code, CBSA Title, CBSA Division Title, county name, and state postal abbreviation. Because DAWN only uses MSAs, any reference to CBSA should be interpreted as MSA.

⁵ The four MSAs where samples were drawn for divisions are Los Angeles, Miami, New York, and San Francisco. The division definitions used by DAWN follow Census Bureau definitions of Metropolitan Divisions, except in New York where the three submetropolitan areas were defined uniquely based on local input.

to select the hospitals. The stratum sample sizes are determined through the optimum allocation process, and the sampling weight is the inverse of the probability of selection (POS).

Table 4. DAWN Emergency Department Component: Universe of Hospitals				
Stratum*	Region	Ownership	Size†	Frame Count
All				4,568
Atlanta-Sandy Springs-Marietta, GA				40
2311		Public	Largest	3
2325		Private	Largest	9
2326		Private	Large	9
2327		Private	Medium	9
2328		Private	Small	10
Austin-Round Rock, TX				13
3411		Public	Largest	1
3425		Private	Largest	2
3426		Private	Large	3
3427		Private	Medium	3
3428		Private	Small	4
Baltimore-Towson, MD				21
2425		Private	Largest	5
2426		Private	Large	5
2427		Private	Medium	5
2428		Private	Small	6
Birmingham-Hoover, AL				16
2911		Public	Largest	2
2912		Public	Large	2
2925		Private	Largest	2
2926		Private	Large	3
2927		Private	Medium	3
2928		Private	Small	4
Boston-Cambridge-Quincy, MA-NH				40
111		Public	Largest	2
125		Private	Largest	9
126		Private	Large	10
127		Private	Medium	10
128		Private	Small	9
Bridgeport-Stamford-Norwalk, CT				6
225		Private	Largest	3
226		Private	Large	3
Buffalo-Cheektowaga-Tonawanda, NY				13
611		Public	Largest	1
625		Private	Largest	3
626		Private	Large	3

Table 4. DAWN Emergency Department Component: Universe of Hospitals

Stratum*	Region	Ownership	Size†	Frame Count
627		Private	Medium	3
628		Private	Small	3
Chicago-Naperville-Joliet, IL-IN-WI				90
1311		Public	Largest	6
1325		Private	Largest	20
1326		Private	Large	19
1327		Private	Medium	25
1328		Private	Small	20
Cincinnati-Middletown, OH-KY-IN				20
3011		Public	Largest	2
3025		Private	Largest	4
3026		Private	Large	4
3027		Private	Medium	5
3028		Private	Small	5
Cleveland-Elyria-Mentor, OH				26
1411		Public	Largest	1
1425		Private	Largest	6
1426		Private	Large	6
1427		Private	Medium	6
1428		Private	Small	7
Columbus, OH				13
1511		Public	Largest	2
1512		Public	Large	3
1525		Private	Largest	2
1526		Private	Large	2
1527		Private	Medium	2
1528		Private	Small	2
Dallas-Fort Worth- Arlington, TX				55
3511		Public	Largest	3
3512		Public	Large	3
3525		Private	Largest	10
3526		Private	Large	11
3527		Private	Medium	10
3528		Private	Small	18
Denver-Aurora, CO				15
3911		Public	Largest	2
3925		Private	Largest	3
3926		Private	Large	3
3927		Private	Medium	3
3928		Private	Small	4
Detroit-Warren-Livonia, MI				37
1625		Private	Largest	9

Table 4. DAWN Emergency Department Component: Universe of Hospitals

Stratum*	Region	Ownership	Size†	Frame Count
1626		Private	Large	9
1627		Private	Medium	11
1628		Private	Small	8
Hartford-West Hartford-East Hartford, CT				10
311		Public	Largest	1
325		Private	Largest	2
326		Private	Large	2
327		Private	Medium	2
328		Private	Small	3
Honolulu, HI				10
4425		Private	Largest	3
4426		Private	Large	7
Houston-Baytown-Sugar Land, TX				47
3611		Public	Largest	3
3612		Public	Large	6
3625		Private	Largest	8
3626		Private	Large	11
3627		Private	Medium	10
3628		Private	Small	9
Indianapolis, IN				15
1711		Public	Largest	2
1712		Public	Large	2
1713		Public	Medium	2
1714		Public	Small	3
1725		Private	Largest	3
1726		Private	Large	3
Kansas City, MO-KS				33
1811		Public	Largest	2
1812		Public	Large	2
1813		Public	Medium	2
1814		Public	Small	2
1825		Private	Largest	6
1826		Private	Large	6
1827		Private	Medium	6
1828		Private	Small	7
Las Vegas-Paradise, NV				13
4011		Public	Largest	1
4025		Private	Largest	4
4026		Private	Large	8
Los Angeles-Long Beach-Santa Ana, CA[#]				108
3110011		Public	Largest	3
3110012		Public	Large	5
3110025		Private	Largest	20

Table 4. DAWN Emergency Department Component: Universe of Hospitals

Stratum*	Region	Ownership	Size†	Frame Count
3110026		Private	Large	23
3110027		Private	Medium	27
3110028		Private	Small	30
Los Angeles division				82
4511		Public	Largest	3
4512		Public	Large	4
4525		Private	Largest	18
4526		Private	Large	20
4527		Private	Medium	17
4528		Private	Small	20
Orange County division				26
4725		Private	Largest	6
4726		Private	Large	7
4727		Private	Medium	6
4728		Private	Small	7
Louisville, KY-IN				16
3111		Public	Largest	2
3112		Public	Large	2
3125		Private	Largest	3
3126		Private	Large	3
3127		Private	Medium	3
3128		Private	Small	3
Memphis, TN-MS-AR				12
3225		Private	Largest	2
3226		Private	Large	3
3227		Private	Medium	4
3228		Private	Small	3
Miami-Fort Lauderdale-Miami Beach, FL[#]				52
3310011		Public	Largest	2
3310012		Public	Large	2
3310013		Public	Medium	2
3310014		Public	Small	2
3310025		Private	Largest	10
3310026		Private	Large	9
3310027		Private	Medium	12
3310028		Private	Small	13
Miami-Dade County division				22
2611		Public	Largest	1
2625		Private	Largest	5
2626		Private	Large	5
2627		Private	Medium	4
2628		Private	Small	7
Fort Lauderdale division				30
2511		Public	Largest	3
2512		Public	Large	3

Table 4. DAWN Emergency Department Component: Universe of Hospitals

Stratum*	Region	Ownership	Size†	Frame Count
2525		Private	Largest	5
2526		Private	Large	5
2527		Private	Medium	6
2528		Private	Small	8
Minneapolis-St. Paul-Bloomington, MN-WI				27
1911		Public	Largest	2
1925		Private	Largest	6
1926		Private	Large	6
1927		Private	Medium	7
1928		Private	Small	6
Nashville-Davidson-Murfreesboro, TN				25
3311		Public	Largest	2
3325		Private	Largest	5
3326		Private	Large	5
3327		Private	Medium	5
3328		Private	Small	8
New Haven-Milford, CT				7
425		Private	Largest	3
426		Private	Large	4
New Orleans-Metairie-Kenner, LA				17
3711		Public	Largest	3
3712		Public	Large	3
3725		Private	Largest	3
3726		Private	Large	3
3727		Private	Medium	2
3728		Private	Small	3
New York-Newark-Edison, NY-NJ-PA				134
3562011		Public	Largest	4
3562012		Public	Large	4
3562013		Public	Medium	4
3562014		Public	Small	5
3562025		Private	Largest	31
3562026		Private	Large	29
3562027		Private	Medium	29
3562028		Private	Small	28
New Jersey division				46
711		Public	Largest	1
725		Private	Largest	12
726		Private	Large	11
727		Private	Medium	12
728		Private	Small	10
New York Suburban division				38

Table 4. DAWN Emergency Department Component: Universe of Hospitals

Stratum*	Region	Ownership	Size†	Frame Count
811		Public	Largest	2
825		Private	Largest	9
826		Private	Large	9
827		Private	Medium	11
828		Private	Small	7
New York City, 5 Boroughs division				50
911		Public	Largest	3
912		Public	Large	3
913		Public	Medium	3
914		Public	Small	4
925		Private	Largest	9
926		Private	Large	10
927		Private	Medium	9
928		Private	Small	9
Omaha-Council Bluffs, NE- IA				12
2011		Public	Largest	1
2025		Private	Largest	2
2026		Private	Large	2
2027		Private	Medium	3
2028		Private	Small	4
Philadelphia-Camden- Wilmington, PA-NJ-DE- MD				53
1025		Private	Largest	14
1026		Private	Large	13
1027		Private	Medium	14
1028		Private	Small	12
Phoenix-Mesa-Scottsdale, AZ				28
4111		Public	Largest	1
4125		Private	Largest	6
4126		Private	Large	8
4127		Private	Medium	6
4128		Private	Small	7
Pittsburgh, PA				30
1125		Private	Largest	8
1126		Private	Large	8
1127		Private	Medium	9
1128		Private	Small	5
Portland-Vancouver- Beaverton, OR-WA				15
4811		Public	Largest	1
4825		Private	Largest	3
4826		Private	Large	4

Table 4. DAWN Emergency Department Component: Universe of Hospitals

Stratum*	Region	Ownership	Size†	Frame Count
4827		Private	Medium	4
4828		Private	Small	3
Providence-New Bedford-Fall River, RI-MA				14
525		Private	Largest	3
526		Private	Large	3
527		Private	Medium	4
528		Private	Small	4
Riverside-San Bernardino-Ontario, CA				32
4911		Public	Largest	2
4912		Public	Large	2
4913		Public	Medium	2
4914		Public	Small	2
4925		Private	Largest	6
4926		Private	Large	6
4927		Private	Medium	5
4928		Private	Small	7
Rochester, NY				11
1225		Private	Largest	3
1226		Private	Large	3
1227		Private	Medium	3
1228		Private	Small	2
Sacramento-Arden-Arcade-Roseville, CA				14
5011		Public	Largest	1
5025		Private	Largest	2
5026		Private	Large	3
5027		Private	Medium	3
5028		Private	Small	5
Salt Lake City, UT				9
4211		Public	Largest	2
4225		Private	Largest	3
4226		Private	Large	4
San Antonio, TX				20
3811		Public	Largest	2
3812		Public	Large	2
3825		Private	Largest	3
3826		Private	Large	3
3827		Private	Medium	4
3828		Private	Small	6

Table 4. DAWN Emergency Department Component: Universe of Hospitals

Stratum*	Region	Ownership	Size†	Frame Count
San Diego-Carlsbad-San Marcos, CA				16
5111		Public	Largest	2
5112		Public	Large	3
5125		Private	Largest	3
5126		Private	Large	3
5127		Private	Medium	3
5128		Private	Small	2
San Francisco-Oakland-Fremont, CA				36
4186011		Public	Largest	3
4186012		Public	Large	4
4186025		Private	Largest	5
4186026		Private	Large	8
4186027		Private	Medium	10
4186028		Private	Small	6
Oakland division				18
4611		Public	Largest	4
4625		Private	Largest	3
4626		Private	Large	3
4627		Private	Medium	4
4628		Private	Small	4
San Francisco division				18
5211		Public	Largest	2
5225		Private	Largest	4
5226		Private	Large	4
5227		Private	Medium	4
5228		Private	Small	4
St. Louis, MO-IL				36
2111		Public	Largest	3
2125		Private	Largest	7
2126		Private	Large	8
2127		Private	Medium	9
2128		Private	Small	9
Seattle-Tacoma-Bellevue, WA				24
5311		Public	Largest	3
5312		Public	Large	5
5325		Private	Largest	3
5326		Private	Large	5
5327		Private	Medium	4
5328		Private	Small	4

Table 4. DAWN Emergency Department Component: Universe of Hospitals

Stratum*	Region	Ownership	Size†	Frame Count
Tampa-St. Petersburg-Clearwater, FL				29
2711		Public	Largest	1
2725		Private	Largest	7
2726		Private	Large	7
2727		Private	Medium	7
2728		Private	Small	7
Tucson, AZ				9
4311		Public	Largest	1
4325		Private	Largest	3
4326		Private	Large	5
Washington-Arlington-Alexandria, DC-VA-MD-WV				34
2825		Private	Largest	8
2826		Private	Large	8
2827		Private	Medium	9
2828		Private	Small	9
Wichita, KS				6
2211		Public	Largest	2
2225		Private	Largest	2
2226		Private	Large	2
Remainder				3,209
9901	Northeast	Public	Large	3
9902	Northeast	Public	Medium	3
9903	Northeast	Public	Small	2
9904	Northeast	Private	Large	94
9905	Northeast	Private	Medium	92
9906	Northeast	Private	Small	93
9907	Midwest	Public	Large	102
9908	Midwest	Public	Medium	105
9909	Midwest	Public	Small	107
9910	Midwest	Private	Large	236
9911	Midwest	Private	Medium	237
9912	Midwest	Private	Small	241
9913	South	Public	Large	148
9914	South	Public	Medium	150
9915	South	Public	Small	158
9916	South	Private	Large	287
9917	South	Private	Medium	293
9918	South	Private	Small	329
9919	West	Public	Large	62
9920	West	Public	Medium	67
9921	West	Public	Small	68
9922	West	Private	Large	107
9923	West	Private	Medium	112

Table 4. DAWN Emergency Department Component: Universe of Hospitals				
Stratum*	Region	Ownership	Size†	Frame Count
9924	West	Private	Small	113
* In the numeric strata the last digit is the size, the next to last digit is the ownership, and any digits that precede the ownership digit are geography. †Size categories were calculated independently for each OS area. #Indicates an OS area with oversampled divisions.				

Adequacy of the Sampling Frame

Health Forum, the organization that prepares the AHA file works on an ongoing basis with the American Hospital Association field staff, State hospital associations, and governmental agencies (both Federal and State) to identify new or missing hospitals. Based on those efforts, Health Forum believes that the AHA file has coverage for over 99% of all hospitals in the United States and territories.

Not all hospitals in the United States and its territories are eligible for inclusion in the DAWN sample frame. As mentioned before, to be eligible for DAWN, a hospital must be a non-Federal, short-stay general medical and surgical hospital that operates an emergency department providing services 7 days a week, 24 hours a day. In about 10% of the hospitals, the AHA file fails to provide information about the presence of an emergency department in hospitals that would otherwise be eligible. This omission is rectified, though, for all but a few hospitals by looking to other information provided on the AHA file (i.e., a hospital recorded as not having an ED may have data present for the number of ED visits per year) or by looking to other sources of information, e.g., the hospital's web site. In the end, eligibility is determined for all but about 20 cases out of 6000. The AHA file, in conjunction with added effort to resolve missing data, does provide an excellent frame from which to determine the DAWN-eligible hospital sample.

Mortality Component

Drug-related deaths may be among the most important sentinel events for the surveillance of the consequences of drug abuse and misuse in the Nation and in its major cities. The DAWN mortality component provides this important information on deaths related to drug use, misuse, and abuse based on data collected from death investigation jurisdictions.

Respondent Universe and Sampling Method

The universe for the DAWN mortality component includes all the death investigation jurisdictions in the U.S. All types of death investigation offices (Medical Examiners, Coroners, Sheriff-Coroners, Justices of the Peace) within the U.S. are eligible to participate. As a matter of convention, the basic ME/C reporting unit is referred to as a jurisdiction, which generally corresponds to a specific county. In some instances, one office covers multiple counties or an entire State.

Unlike the ED component, the mortality component is not based on a statistical sample. The possibility of developing a national sample of death investigation jurisdictions received thorough consideration during the redesign of DAWN. However, no viable or practical means for developing such a sample could be found. Even if a national sample were feasible, the types of deaths subject to official investigation differ across the States. This would result in incomparable data being combined, with potentially misleading estimates of drug-related deaths.

In lieu of a sample, the mortality component focuses on achieving a census of death investigation jurisdictions within selected geographic areas. However, the results cannot be aggregated across geographic areas. The usefulness of the mortality data is primarily in its ability to provide information at the OS area. OS-level counts of drug-related fatalities are produced annually (based on unweighted data).

In some States, the ME/C reporting procedures are organized so that all death reports in the State are funneled through one office. Eleven states with centralized ME systems are currently participating in the mortality component and are expected to continue to do so in future years. Data from these States allow for the formulation of counts not only for the State as a whole but also for each MSA in the State and for each county. Each MSA and jurisdiction in each of these States has 100% coverage of its population.

2. Information Collection Procedures

Emergency Department Component

DAWN is an ongoing national public health surveillance system that monitors drug-related medical emergencies. DAWN relies on a sample of hospitals to generate representative national and subnational estimates of drug-related ED visits. The current DAWN survey and sample design went into effect January 1, 2004, and is substantially different than DAWN's previous design. As a result, DAWN estimates for 2004 forward cannot be compared to those for earlier years.⁶ For DAWN, 2003 represented a transition year between old and new samples. Estimates for 2003 cannot be compared to those for earlier or later years and are not addressed in this Report.

DAWN was initiated in 1972 by the White House Special Action Office for Drug Abuse Prevention and the Drug Enforcement Administration. In 1992, the administration of DAWN was passed to SAMHSA.

DAWN's major objectives in regard to the ED component are to

- measure drug-related morbidity, based on visits to hospital EDs;
- monitor drug misuse and abuse patterns and trends for specific substances;
- detect new drugs of abuse and new drug combinations;
- assess the health hazards associated with drug misuse and abuse; and
- provide information for Federal, State, and local drug abuse policy and program planning.

The White House Office of National Drug Control Policy (ONDCP) is directed by statute to use information from DAWN to measure the impact of the National Drug Control Strategy on reductions in ED visits related to drug abuse.

DAWN data are abstracted from a retrospective review of ED medical records according to specified case selection criteria. Each facility⁷ that participates in DAWN has one or more DAWN reporters to review charts and collect data on its behalf. The reporter reviews ED medical records to find those that are drug-related (DAWN cases). The reporters submit data on DAWN cases electronically via eHERS (electronic Hospital Emergency Reporting System).

Since its inception, DAWN has reported on ED visits induced by or related to abuse of illegal drugs or legal drugs. As part of the design changes introduced in 2003, DAWN dropped the requirement that the visit be a result of abuse and began collecting data on all drug-related ED visits and deaths. This approach enables DAWN to capture not only a broader spectrum of ED visits that involve drug misuse and abuse, but also to include ED visits associated with adverse reactions to prescription and over-the-counter pharmaceuticals taken for therapeutic purposes,

6 Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (September 2005). The DAWN Report: New DAWN: Why It Cannot Be Compared with Old DAWN. Rockville, MD.

7 A facility is synonymous with an ED. A hospital may have multiple EDs. All eligible EDs within a hospital are included if the hospital is sampled.

accidental ingestion of drugs, and drug-facilitated assaults. Since 2003, DAWN has collected data on all ED visits related to recent drug use for patients of all ages. Data items for each case include the age, gender, and race/ethnicity of the patient; up to 16 substances plus alcohol; and detailed information about the diagnoses and the disposition of the ED visits. Since 2003, DAWN has collected data on underage drinking when no other drug is involved. For adults, alcohol-related visits are collected only if the visit involves another reportable substance.

Sample Design

The redesign of the DAWN system introduced in 2003 altered most of the major features of the DAWN data collection and included a new sample of hospitals that constituted the DAWN. The new sampling plan, fully implemented for the first time for the 2004 estimates, formed a nationally representative panel of hospitals to be followed longitudinally for the indefinite future.

The current sample design is a probability-based stratified one-stage sample. A complete and accurate list of all hospitals in the United States was drawn and, from that, all hospitals meeting the criteria for the target sample frame were identified. Samples were drawn to provide the capability to make estimates for the Nation as well as OS areas.

The stratified design called for drawing oversamples of hospitals in 48 Metropolitan Statistical Areas (MSAs); in four of those 48 MSAs, additional oversamples were drawn for a total of nine divisions. In effect, there are 53 non-overlapping geographic areas (44 whole MSAs and nine divisions). (See **Table 5** for list of MSAs and divisions where oversamples were drawn.) In this document and future writing, these areas are collectively referred to as oversample areas, or OS areas. In the redesign, two goals guided the selection of the OS areas. The first was to preserve the ability to represent the 21 areas that had been part of DAWN since its inception. The second was to improve population and geographic coverage beyond the 21 legacy areas. Accordingly, the design ensured representation of the five most populous MSAs in each of the nine Census divisions. That brought the net total number of MSAs to 48 and necessitated the splitting of four MSAs into divisions.⁸

Sampled hospitals in each of the OS areas were stratified by hospital size (up to four categories based on ED visits) and ownership type (public and private). Size categories were determined independently for each OS area.

⁸ When metropolitan areas were redefined in June 2003 based on data from the 2000 decennial Census, several legacy MSAs were merged with other MSAs to form new, much larger MSAs. However, a strong constituency of DAWN data users still needed estimates for the pre-merger areas. Because of this, four of the 48 metropolitan areas—Los Angeles, Miami, New York, and San Francisco—were subdivided into a total of nine divisions, corresponding to the constituents' areas of interest.

Table 5. Oversample (OS) Areas in DAWN Sample Design

Atlanta-Sandy Springs-Marietta, GA*
Austin-Round Rock, TX
Baltimore-Towson, MD*
Birmingham-Hoover, AL
Boston-Cambridge-Quincy, MA-NH*
Bridgeport-Stamford-Norwalk, CT
Buffalo-Cheektowaga-Tonawanda, NY*
Chicago-Naperville-Joliet, IL-IN-WI*
Cincinnati-Middletown, OH-KY-IN
Cleveland-Elyria-Mentor, OH
Columbus, OH
Dallas-Fort Worth-Arlington, TX*
Denver-Aurora, CO*
Detroit-Warren-Livonia, MI*
Hartford-West Hartford-East Hartford, CT
Honolulu, HI
Houston-Baytown-Sugar Land, TX
Indianapolis, IN
Kansas City, MO-KS
Las Vegas-Paradise, NV
Los Angeles-Long Beach-Santa Ana, CA*
Los Angeles-Long Beach-Santa Ana, CA – Los Angeles division (contains Los Angeles-Long Beach-Glendale, CA Metropolitan division)
Los Angeles-Long Beach-Santa Ana, CA – Orange County division (contains Santa Ana-Anaheim-Irvine, CA Metropolitan division)
Louisville, KY-IN
Memphis, TN-MS-AR
Miami-Fort Lauderdale-Miami Beach, FL*
Miami-Fort Lauderdale-Miami Beach, FL – Fort Lauderdale division (contains Fort Lauderdale-Pompano Beach-Deerfield Beach, FL, and West Palm Beach-Boca Raton-Boynton Beach, FL, Metropolitan divisions)
Miami-Fort Lauderdale-Miami Beach, FL – Miami-Dade County division (contains Miami-Miami Beach-Kendall, FL Metropolitan division)
Minneapolis-St. Paul-Bloomington, MN-WI*
Nashville-Davidson—Murfreesboro, TN
New Haven-Milford, CT
New Orleans-Metairie-Kenner, LA*
New York-Newark-Edison, NY-NJ-PA*
New York-Newark-Edison, NY-NJ-PA – New Jersey division (contains Middlesex, Monmouth, Ocean, Somerset, Essex, Hunterdon, Morris, Sussex, Union, Bergen, Hudson, Passaic Counties, NJ, and Pike County, PA)
New York-Newark-Edison, NY-NJ-PA – New York Suburban division (contains Nassau, Putnam, Rockland, Suffolk, Westchester Counties, NY)
New York-Newark-Edison, NY-NJ-PA – New York City, 5 Boroughs division (contains Bronx, Kings, New York, Queens, Richmond Counties, NY)

Table 5. Oversample (OS) Areas in DAWN Sample Design
Omaha-Council Bluffs, NE-IA
Philadelphia-Camden-Wilmington, PA-NJ-DE-MD*
Phoenix-Mesa-Scottsdale, AZ*
Pittsburgh, PA
Portland-Vancouver-Beaverton, OR-WA
Providence-New Bedford-Fall River, RI-MA
Riverside-San Bernardino-Ontario, CA
Rochester, NY
Sacramento-Arden-Arcade-Roseville, CA
Salt Lake City, UT
San Antonio, TX
San Diego-Carlsbad-San Marcos, CA*
San Francisco-Oakland-Fremont, CA*
San Francisco-Oakland-Fremont, CA – Oakland division (contains Oakland-Fremont-Hayward, CA Metropolitan division)
San Francisco-Oakland-Fremont, CA – San Francisco division (contains San Francisco-San Mateo-Redwood City, CA Metropolitan division)
Seattle-Tacoma-Bellevue, WA*
St. Louis, MO-IL*
Tampa-St. Petersburg-Clearwater, FL
Tucson, AZ
Washington-Arlington-Alexandria, DC-VA-MD-WV*
Wichita, KS
* Denotes a legacy area. Two separate legacy areas (New York and Newark) are contained in the New York-Newark-Edison, NY-NJ-PA Metropolitan Statistical Area

The stratification plan included an additional geographic construct for the remainder of the United States outside the OS areas. Hospitals in the remainder area were stratified into 24 remainder strata based on four regions (Northeast, South, Midwest, West), hospital size (three size categories based on ED visits), and ownership type (public and private).

The DAWN national estimates are the sum of the estimates for OS areas and the remainder area. Using a formula, the national estimate is depicted as:

$$\sum_{i=1,n} a_i + b$$

where a_i is the estimate for OS area i , n is the number of OS areas, and b is the remainder area estimate.

It was never expected that DAWN would be able to expand data collection into all 53 OS areas. Instead, the expectation was that DAWN would build up gradually to the number of OS areas its budget could support. The DAWN sample design was conceived to provide the flexibility to change gradually over time in terms of the number of OS areas where data were collected, while

providing the statistical infrastructure to enable the production of reliable and representative estimates for the Nation and select OS areas, regardless of their number.

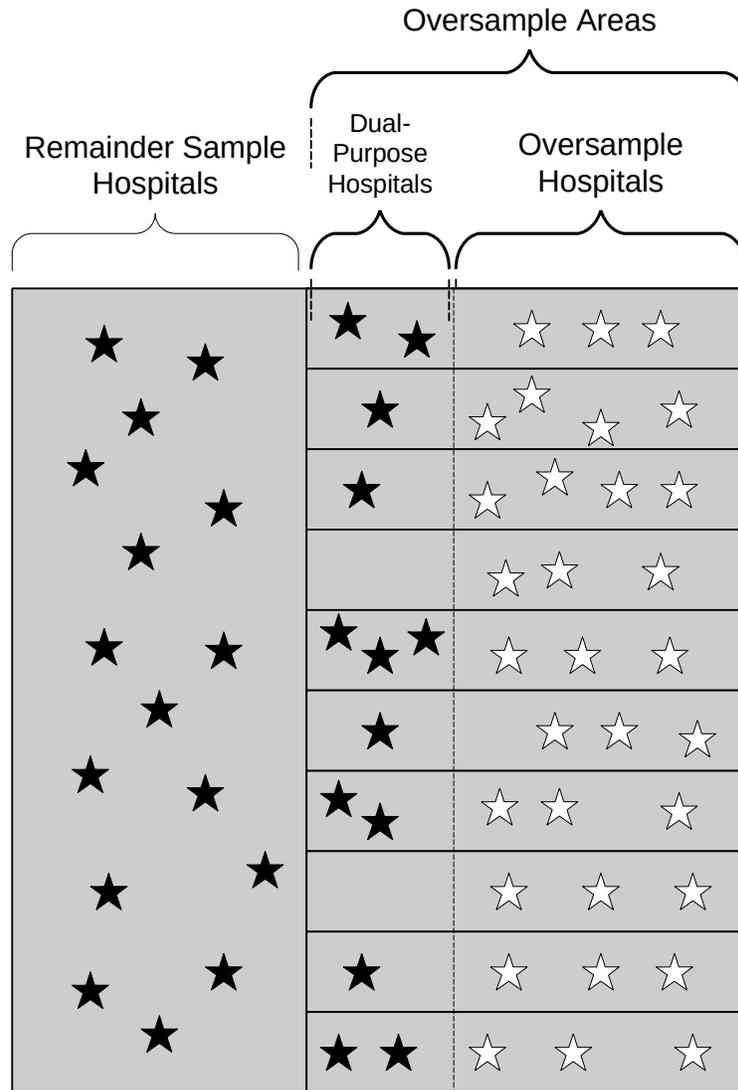
To accomplish this, the design incorporates an approach in which a subset of the hospitals within the OS areas were identified *a priori* as having a dual-purpose in estimation. Referred to as “dual-purpose hospitals,” these designated hospitals can contribute to an estimate for the OS area in which they are located or they can contribute to the estimate for the remainder area. Dual-purpose hospitals carry two POS and two stratum identifiers. One POS/stratum is associated with membership in an OS-area sample and the other is associated with membership in the remainder-area sample.⁹

Figure 1 depicts the initial sample as it was drawn to provide:

- individual samples from a series of OS areas,
- dual-purpose hospitals within those areas, and
- a remainder sample to represent the rest of the country.

⁹ In addition, a portion of hospitals in the nine oversampled divisions were identified *a priori* to serve in their MSA-level oversample and were assigned an OS area level POS/stratum for that third purpose. Therefore, hospitals in the four MSAs with division-level oversampling can have up to three nonzero POS/strata: (1) a POS/stratum for membership in the MSA; (2) a POS/stratum for membership in the division; and (3) a POS/stratum for membership in the remainder area.

Figure 1. Original DAWN Sample Design



For estimation for each data year, the first step is to determine which role each sampled hospital will play in that year’s estimates. To do this, the response rates and nonresponse patterns for each OS area are reviewed to determine data quality. Those OS areas with acceptable data quality are allowed to stand on their own as the basis for separate estimates. These are referred to as “stand-alone OS areas.” All hospitals in stand-alone OS areas, including those originally designated as being in the dual-purpose subsample, are considered to be “oversample hospitals” in the OS areas, and they contribute to the OS-area estimate using their OS-area POS/stratum.

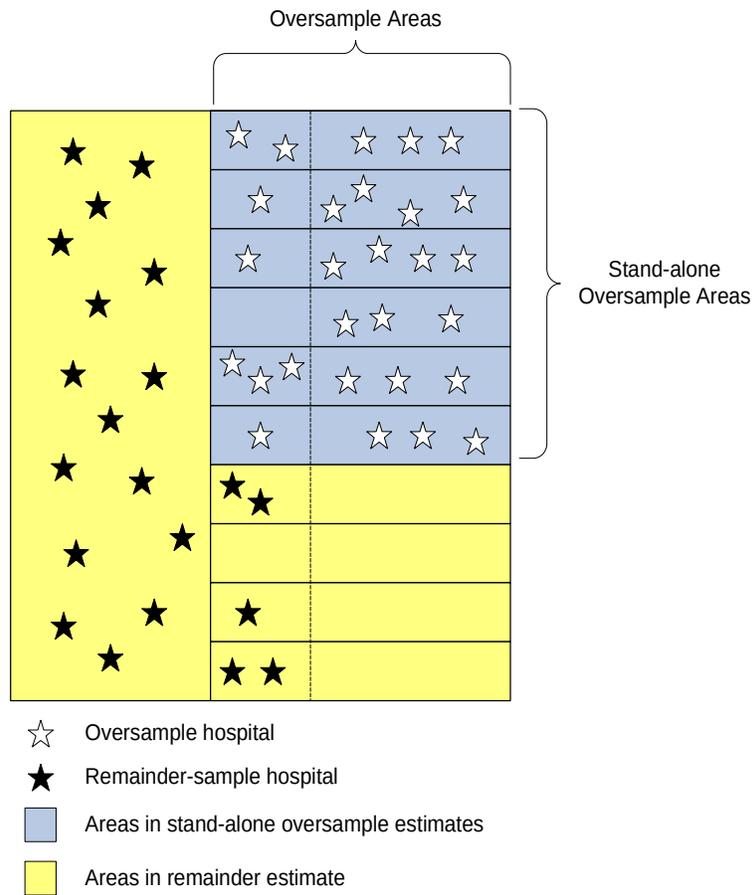
If it is determined based on response rates and bias analyses that an OS area cannot stand alone, the design provides that the OS area is eliminated as a separate area but becomes part of the remainder area. In this instance:

- only those dual-purpose hospitals that are designated *a priori* to contribute to the remainder-area estimate are retained in the remainder-area subset;

- these hospitals contribute to the remainder-area estimate using their remainder-area POS/stratum; and
- data from any other hospitals in the OS area are excluded from the remainder-area estimates.

Figure 2 depicts graphically the assignment of dual-purpose hospitals to either an OS area or the remainder area and the exclusion of OS hospitals outside of stand-alone OS areas that are not designated as dual-purpose.

Figure 2. DAWN Design in Practice



It is important to note that the definition of the remainder area and the remainder sample of hospitals is designed to be fluid; hospital membership in the remainder sample changes from year to year depending on the response rates and data quality within the OS areas.

Sample Maintenance

Because DAWN is a longitudinal survey, the sampling frame must be updated every year. The frame is updated using the most recent AHASDB to reflect new, closed, merged, and demerged hospitals. To allow DAWN to capture hospitals that are ineligible one year and then become eligible in another year, the DAWN survey eligibility status of each sampled hospital is not be used in the frame construction process.

The frame construction process includes all potentially eligible hospitals to allow the review of hospitals previously found ineligible. Such hospitals have the opportunity to be sampled the year in which they again become eligible, which is the same treatment for newly added hospitals. The DAWN Operations contractor is responsible for any steps performed in determining or confirming hospital eligibility.

For selecting new hospitals on the AHA frame in 2008 and beyond, DAWN uses a random, systematic approach. This is consistent with the method used to draw the original sample from the 2003B frame and allows control over the actual sample size. The benefit of this approach is greater ease of tracking the sample as it changes over time.

Response Rates

Hospitals face continuing pressures on resources, which poses a challenge to DAWN when recruiting new facilities. To ensure that DAWN can take full advantage of the data from participating EDs, estimation processes have been revised. **Table 6** provides response rates for the DAWN OS and remainder sample for data year 2006 (the most recent year for which both these response rates are available).

Geographic Area*	Frame Count	Sample Count	Respondent Count	Unweighted Response Rate (%)	Design Weight Response Rate (%)	Visits Weighted Response Rate (%)
All	4,568	544	205	37.7	24.9	26.1
Boston-Cambridge-Quincy, MA-NH	40	29	17	58.6	58.5	57.3
111	2	2	1	.	.	.
125	9	9	6	.	.	.
126	10	8	5	.	.	.
127	10	7	3	.	.	.
128	9	3	2	.	.	.
Chicago-Naperville-Joliet, IL-IN-WI	90	74	27	36.5	37.7	36.2
1311	6	5	3	.	.	.
1325	20	20	7	.	.	.
1326	19	19	4	.	.	.
1327	25	16	6	.	.	.
1328	20	14	7	.	.	.

**Table 6. Response Rate for DAWN Emergency Department Component:
OS and Remainder Sample, Data Collection Calendar Year 2006**

Geographic Area*	Frame Count	Sample Count	Respondent Count	Unweighted Response Rate (%)	Design Weight Response Rate (%)	Visits Weighted Response Rate (%)
Denver-Aurora, CO	15	15	9	60.0	60.0	68.1
3911	2	2	2	.	.	.
3925	3	3	2	.	.	.
3926	3	3	2	.	.	.
3927	3	3
3928	4	4	3	.	.	.
Detroit-Warren- Livonia, MI	37	24	16	66.7	69.7	71.2
1625	9	9	6	.	.	.
1626	9	4	3	.	.	.
1627	11	10	6	.	.	.
1628	8	1	1	.	.	.
Houston-Baytown- Sugar Land, TX	47	42	12	28.6	28.3	30.8
3611	3	3	2	.	.	.
3612	6	6	4	.	.	.
3625	8	8
3626	11	11	2	.	.	.
3627	10	10	3	.	.	.
3628	9	4	1	.	.	.
Miami-Fort Lauderdale-Miami Beach, FL – Miami-Dade County division	22	16	8	50.0	46.7	50.1
2611	1	1	1	.	.	.
2625	5	5	1	.	.	.
2626	5	3
2627	4	4	4	.	.	.
2628	7	3	2	.	.	.
Minneapolis-St. Paul- Bloomington, MN-WI	27	27	10	37.0	37.0	44.0
1911	2	2	2	.	.	.
1925	6	6	2	.	.	.
1926	6	6	3	.	.	.
1927	7	7	1	.	.	.
1928	6	6	2	.	.	.
New York-Newark- Edison, NY-NJ-PA – New York City, 5 Boroughs division	50	39	21	53.8	46.1	55.0
911	3	3	2	.	.	.
912	3	3	3	.	.	.
913	3	3	3	.	.	.

**Table 6. Response Rate for DAWN Emergency Department Component:
OS and Remainder Sample, Data Collection Calendar Year 2006**

Geographic Area*	Frame Count	Sample Count	Respondent Count	Unweighted Response Rate (%)	Design Weight Response Rate (%)	Visits Weighted Response Rate (%)
914	4	2	1	.	.	.
925	9	7	4	.	.	.
926	10	9	4	.	.	.
927	9	9	4	.	.	.
928	9	3
Phoenix-Mesa- Scottsdale, AZ	28	26	14	53.8	53.8	58.1
4111	1	1	1	.	.	.
4125	6	6	3	.	.	.
4126	8	7	5	.	.	.
4127	6	6	2	.	.	.
4128	7	6	3	.	.	.
San Diego-Carlsbad- San Marcos, CA	16	16	8	50.0	50.0	55.7
5111	2	2	1	.	.	.
5112	3	3	2	.	.	.
5125	3	3	1	.	.	.
5126	3	3	2	.	.	.
5127	3	3	1	.	.	.
5128	2	2	1	.	.	.
San Francisco- Oakland-Fremont, CA – San Francisco division	18	18	8	44.4	44.4	54.2
5211	2	2	2	.	.	.
5225	4	4	1	.	.	.
5226	4	4	2	.	.	.
5227	4	4
5228	4	4	3	.	.	.
Seattle-Tacoma- Bellevue, WA	24	22	10	45.5	45.5	55.2
5311	3	3	2	.	.	.
5312	5	4	1	.	.	.
5325	3	3	2	.	.	.
5326	5	4	2	.	.	.
5327	4	4
5328	4	4	3	.	.	.
Remainder	4,154	196	45	23.0	22.9	21.8
9901	8	8	4	.	.	.
9902	3	3	1	.	.	.
9903	2	2	1	.	.	.
9904	239	15	3	.	.	.
9905	148	5	2	.	.	.

**Table 6. Response Rate for DAWN Emergency Department Component:
OS and Remainder Sample, Data Collection Calendar Year 2006**

Geographic Area*	Frame Count	Sample Count	Respondent Count	Unweighted Response Rate (%)	Design Weight Response Rate (%)	Visits Weighted Response Rate (%)
9906	112	6	3	.	.	.
9907	132	4
9908	109	2
9909	108	3
9910	322	35	7	.	.	.
9911	268	5	1	.	.	.
9912	251	13	3	.	.	.
9913	174	7	2	.	.	.
9914	155	4	1	.	.	.
9915	160	3
9916	452	28	4	.	.	.
9917	379	10	5	.	.	.
9918	375	14
9919	86	5	2	.	.	.
9920	68	4
9921	68	2	1	.	.	.
9922	218	6	2	.	.	.
9923	173	5	2	.	.	.
9924	144	7	1	.	.	.

* In the numeric strata the last digit is the size, the next to last digit is the ownership, and any digits that precede the ownership digit are geography.

Chart Subsampling

In certain circumstances, it has not been feasible for the DAWN Reporter to review 100 percent of the ED charts. This can occur for several reasons:

Limitations imposed by hospital

- \$ The hospital limits the days or hours of the day when reporters can work, which does not allow sufficient time to review all charts.
- \$ The ED census is so large that more than 1 reporter would be required and/or the amount of space available limits the number of reporters

To address data gaps

- \$ Changes in reporters (resignations, sick leave, termination) can create data gaps that can only be filled by reviewing a portion of the ED chart in the affected month. Wherever possible, plans are underway to replace missing staff and implement procedures to reduce the need for sampling next year.
- \$ At the end of the year it becomes apparent that there is not enough time or staffing to meet the backlog.

In these facilities, the DAWN Operations contractor employs a systematic sampling approach that maximizes the amount of data that can be collected with available resources and time. To be correctly implemented, the adjustment process must know the subsampled days in a month at a facility. In order to avoid systematic bias, the subsampling rate cannot be 1 day out of 7 or 1 day out of any multiple of 7. It is necessary to know if sampling occurred, because such knowledge will explain why counts of charts or cases are lower than expected, given the number of ED visits. The number of subsampled days must be known if these sample counts are used to impute or adjust other counts. The primary method of chart sampling is to review charts on alternate days.

In 2006, charts were sampled in 60 hospitals for part of the year or the full year. In 2007, chart sampling took place in 45 hospitals. Twenty of those hospitals were sampled for the entire year; 25 hospitals had sampling for part of the year to ensure that data were collected for each month.

When sampling is required to fill data gaps, the DAWN Operations contractor will act to replace missing staff and implement procedures to reduce the need for sampling the following year. In some hospitals, however, chart sampling is the permanent procedure.

Facility Recruitment

Factors considered for targeting recruitment efforts include increasing response rates, reducing bias, and making the estimates more robust. DAWN recruitment of eligible sampled hospitals involves the following procedures:

Step One: Identification of Facilities for Recruitment

Eligible non-participating hospitals in the sample are identified. Then, recruitment goals are established based on the existing response rate in the OS areas and the remainder sample. Hospitals identified during the annual update of the sample are included for recruitment, after their DAWN eligibility has been confirmed. The recruitment history of the individual hospitals is also considered.

Step Two: Identification of Main and Alternate Hospital Contacts

The DAWN Operations contractor maintains a database with information on all hospitals in the sample, and the results of previous recruitment efforts. The ED Administrators listed in the database and verified as still at the hospital are generally considered the first contact during recruitment. However, contacts made during previous recruitment attempts or through the recommendation of an advocate may be approached directly rather than contacting the ED Administrator. The Operations recruitment team may also identify alternate contact(s) based on a review of previous recruitment communications, knowledge of the hospital and community, suggestions from community advocates, and/or researching the hospital web site (i.e., identify public relations contacts in the facility—public relations department or grant-writing/research area).

The OAS DAWN staff will identify any local public health agencies that are users of DAWN data or that may be interested in learning more about DAWN. The staff will then contact the

local agencies to introduce them to DAWN, enroll them as DAWN *Live!* users if appropriate, and identify networks between the public health community and the hospitals that can be used for recruitment efforts.

Step Three: Development/Mailing of Recruitment Package

Each year the materials included in the initial recruitment package are reviewed and updates are made based on past experience. Each hospital is sent a letter of invitation from OAS's Director of the Division of Facility Surveys (Attachment C.1). Supporting materials include a brochure about DAWN, fact sheets (Attachment C), and any recent ED publication. A business card for the primary recruiter is also included.

Step Four: Followup

If there is no response within a week, the recruiter researches prior communications with the hospital and the hospital web site to become familiar with the recruitment history, the size of the hospital, and any needs of the community that may be addressed by the hospital's participation in DAWN. The recruitment staff, in consultation with the OAS staff, will also decide how to involve the community and public health advocates in the process.

Approximately one week after the mailing of the recruitment materials, the recruiter follows up by telephone to establish whether the packet of materials has been received. Protocols have been developed to guide the recruiter, depending on the result of the phone call. The recruiter will attempt to speak with the contact directly to discuss DAWN participation, operational issues, and the content of the agreement. If the recruiter is unable to reach the contact directly, s/he will leave an introductory voicemail using the following script:

Hello, my name is [name]. I am calling on behalf of the Substance Abuse Mental Health Services Administration, an agency of the U. S. Department of Health and Human Services (HHS). I would like to talk to you about gaining your hospital's participation in the Drug Abuse Warning Network (DAWN). DAWN's mission is to improve patient care by documenting drug use and misuse that result in visits to the emergency department. You should have received a Federal Express package containing background materials explaining more about DAWN and its many benefits to your hospital. I will call again on [insert day/time] and look forward to talking more with you about DAWN. If you would like to return my call, you can reach me at [insert number].

If there is no response from the facility contact, the recruiter will attempt to telephone the contact three times a week. Calls will be made at different times of the day, and on different days of the week, and the recruiter will leave only one message a week. If there is no response from the facility contact after 2 weeks of calls, the recruiter will send a "Trying to Reach You" Letter (Attachment C.3) by fax, email, or regular mail.

It may be necessary for the DAWN recruiter to identify a new contact, if there has been no communication with the primary contact after 3 to 4 weeks. Contact with the alternate follows the same process as with the initial contact.

An in-person visit to the facility is an option if the recruiter plans to be in the area. The recruiter will bring materials to share with the facility contact and the ED staff (Attachments C.4 and C.5).

Degree of Accuracy for ED Reporting and Analyses

The response rates from the OS areas are used to determine how they will contribute to the annual estimates:

- \$ OS area strata that achieve at least a 50 percent visit-weighted hospital-level response rate will be used to provide estimates using OS area-level weights. These OS strata will stand on their own in the national estimates using their OS area-level weights.
- \$ OS strata that fail to achieve at least a 20 percent response rate will not be used to provide estimates as an OS stratum. The dual-purpose hospitals in these OS strata will be used in the national estimates using their remainder-area weights.
- \$ For OS strata achieving at least a 20 percent but less than a 50 percent response rate, an evaluation will be conducted using information from the end-of-year data quality review, a bias analysis, and any other facts and circumstances known about the data. The results of the evaluation will be used to decide how the data will be used: to provide OS area estimates or to use in the national estimates.
- A threshold of 50 percent will also be applied for reporting (publishing) DAWN OS strata as area estimates. This means that the OS strata response rates must exceed 50 percent to report (publish) the DAWN OS area estimates.

Few OS strata will not meet the lower threshold of 20 percent, but many, by exceeding the 50 percent threshold response rate, will have an opportunity to stand alone in the national estimates. For response rates between 20 and 50 percent, additional criteria based on data quality and auxiliary information serve as the basis for deciding which OS areas may stand on their own.

Visit-weighted hospital-level response rates are used to be more consistent with the sampling design, which is based in part on the ED visit size measure found on the AHA frame file. Hospitals with a greater number of visits will be weighted more heavily in the response rates than hospitals with fewer visits. The visit-weighted hospital-level response rate measures the proportion of total sampled hospital visits represented by the responding hospitals. This differs from an unweighted hospital response rate, which only measures the proportion of sampled hospitals that responded.

Suppression of Estimates

Estimates from DAWN are suppressed if the relative standard error of the estimate is greater than 50 percent or the estimate itself is less than 30 (all estimates represent totals of ED visits with certain drugs mentioned) or was based on fewer than 30 unweighted cases. The latter will guard against reporting estimates with a potential for having a higher than desired mean square error.

The DAWN suppression rules are summarized in the following four steps:

1. Any unweighted count < 30 is suppressed, as are its associated estimate, rate, RSE, and statistical tests. This suppression is applied even if the unweighted counts are not included in the final table.
2. Any estimate with an RSE greater than 50 and its associated count, rate, and statistical tests are suppressed. The RSE is not suppressed.
3. Any estimate that is less than 30 is suppressed, as are its associated count, rate, and statistical tests. The RSE is not suppressed.
4. Suppression is denoted with three dots (...) in counts, estimates, and RSEs.

The RSEs for visits for cocaine, heroin, and marijuana are expected to be less than 10 percent in the OS strata and less than 15 percent for the national estimate based on the sample design. These RSEs were incorporated in the optimization procedures that projected the needed sample sizes in the initial design.

Data Collection

DAWN ED data are collected in emergency departments through a retrospective review of ED medical records for every patient treated in the ED. Patients or families are never interviewed. Multiple visits to the ED by the same patient cannot be linked.

The review of source records is performed by a trained DAWN Reporter in each member facility. The hospital can opt to use one of their own staff members to collect the data (a “Staff Reporter”). The Staff Reporter is trained by the DAWN Operations Contractor, and DAWN provides payments for data collection, either to the hospital directly (if the staff collect data on hospital time) or to the staff member(s) directly if they collect the data on their own time.

Most hospitals opt to use a reporter provided by the DAWN Operations contractor, which is responsible for hiring, supervising, and paying these reporters. The majority of reporters employed by the Operations contractor work on site in the hospital (“Field Reporter”), but for hospitals that agree to provide secure, online access to electronic ED medical records, “Remote Reporters” will access hospital ED records electronically from the contractor’s home office.

Within each facility that participates in DAWN, the designated DAWN Reporter reviews all medical records to identify ED visits related to drug use. The DAWN Reporter submits an electronic case report to the DAWN system for each ED patient who meets specific case selection criteria. DAWN Reporters also track, on a copy of the ED registration log, their progress in reviewing ED visits.

Emergency Department Cases

To be considered a DAWN case, the patient must meet the following criteria:

- The patient was treated in the ED, and
- The ED visit was related to recent drug use.

For patients under age 21, visits with alcohol as the only drug are reportable. This recognizes that, for minors, alcohol is an illegal substance and a significant public health problem. For

adult patients 21 and older, alcohol is reportable only if it is present in conjunction with another reportable drug.

Each case is assigned to one of the following case types:

- Suicide attempt
- Seeking detoxification
- Underage drinking
- Adverse reaction
- Overmedication
- Malicious poisoning
- Accidental ingestion
- Other

In addition to type of case, data collected on up to four diagnoses captures information about the health status of the patient. A case narrative taken verbatim from the patient's medical record captures the chief complaint and supplies additional, detailed information for verification of case identification, quality assurance, and, possibly, for special studies.

Demographic information about the patient (age, sex, race/ethnicity, and ZIP code) is collected. There is also a ZIP code data item to designate patients who are not residents of the U.S. Date and time of the visit and disposition of the ED patient will be retained.

The number of fields for the drugs involved in the ED visit will be increased in response to a demonstrated need and to prevent DAWN Reporters from recording additional drugs in the "Comments" section. Although route of administration is frequently undocumented, it will be retained because it is essential for identifying inhalants and distinguishing different formulations of a few prescription and over-the-counter pharmaceuticals. A new category for transdermal route of administration is being added to distinguish this type of delivery system from other topical drugs.

A screenshot of the revised ED case report is shown in Attachment A.1.

Activity Report

In addition to the data submitted on each DAWN case, DAWN Reporters maintain running totals of the ED census of visits and the number of charts they were able to locate and review (associating charts with the date of the ED visit).

The purpose of the Activity Report is to assist DAWN Reporters in recording the total number of monthly ED visits (the census) and the number of charts they review each month. Reporters are encouraged to submit an Activity Report for each week that they submit data. In some facilities the census counts are available daily; in others, only weekly counts are available; and in others, monthly counts are the standard. In most instances, the monthly ED census number will be greater than the total number of charts obtained for review, but the increasing implementation

of electronic medical records in EDs has improved the ability of reporters to review 100 percent of the charts.

A screen shot of the ED Activity Report is provided in Attachment A.3. The information captured in the Activity Report is necessary for quality control, payment, and estimation:

\$ Quality control. Direct chart review is the standard for identifying DAWN cases, but in some instances the number of charts available for review is less than the total number of charts. Therefore, it is essential to know how many charts were located and reviewed by the DAWN reporter and the relationship of that number to the total number of patients treated in the ED for the same period.

\$ Payment. The performance-based per-piece payment is calculated from the actual number of charts reviewed and the number of DAWN cases identified.

\$ Estimation. Census counts of ED visits are essential for the production of sampling weights. In addition, census counts from EDs are measures against which measures of drug-related ED visits are compared.

Quality Control for ED Data Collection

DAWN's many users require information that is timely, complete, and accurate. Quality control procedures have been incorporated into DAWN systems at multiple levels and locations, including:

\$ Data collection

- Recruitment of DAWN Reporters familiar with ED environment and records, skill in computer and Internet use, dependability, and ability to meet DAWN objectives for timeliness.
- Direct review of each patient chart by DAWN Reporters.
- Creation of ED tracking lists in each facility to identify records that the DAWN Reporter has reviewed and those which remain to be reviewed.
- Electronic reporting with built-in edits and alerts that question DAWN Reporters about possibly incorrect or inconsistent data.
- Ongoing training of DAWN Reporters in person and through a computer-based training tutorial.
- Monitoring of data collection performance measures with regular feedback to DAWN Reporters.
- Site visits by contractor's facility liaisons for problem resolution and quality control (including data re-abstraction and evaluation of each DAWN Reporter's work).
- Routine contact between DAWN Reporters and regional monitors at the DAWN operations office.
- Help Desk hot line where DAWN Reporters can seek technical assistance.

\$ Data management and processing

- Generation of standard periodic reports on preparation, process, and quality assurance by the decision support system/management information system.
- Incorporation of quality assurance tools in data processing (e.g., procedures to identify duplicate records and nonspecific drug codes).
- Additional automated editing and internal consistency checking.

- Statistical process control methods to monitor DAWN Reporter performance and data quality (by identifying unusual events).
 - Quarterly review of facility data quality indicators.
- \$ Maintenance and updating of Drug Reference Vocabulary (DRV) and analysis file. The DRV is the *Alanguage@* of DAWN, providing names and categories of illicit, prescription and over-the-counter drugs. It is based on the *Multum Lexicon*,¹⁰ an externally maintained code set and database of drug brand (trade) names, generic names, therapeutic categories, and ingredient information. Maintenance of the DRV includes:
- Bimonthly updates from the Multum website,
 - Verification and incorporation of new drugs reported in DAWN cases.
 - Quality assurance checks for errors and data corruption, and
- \$ Delivery of analytic files shortly after the end of the reporting period, in an agreed-upon format.

10 The classification of drugs used in DAWN is derived from the *Multum Lexicon*, © 2007, Multum Information Services, Inc. The classification was modified to meet DAWN's unique requirements (2007). The Multum Licensing Agreement governing use of the *Lexicon* is provided in Appendix A and can be found on the Internet at <http://www.multum.com>.

Mortality Component

DAWN is an ongoing national public health surveillance system that monitors drug-related medical emergencies. DAWN relies on a sample of hospitals to generate representative national and subnational estimates of drug-related ED visits. The current DAWN survey and sample design went into effect January 1, 2004, and is substantially different than DAWN's previous design. As a result, DAWN data for 2004 forward cannot be compared to those for earlier years.¹¹

DAWN's major objectives in regard to the mortality component are to

- measure drug-related mortality, based on deaths investigated in participating ME/C jurisdictions;
- monitor drug misuse and abuse patterns and trends for specific substances;
- detect new drugs of abuse and new drug combinations, and
- provide information for Federal, State, and local drug abuse policy and program planning.

Data are abstracted from a retrospective review of death investigation records according to specified case selection criteria. Each ME/C office that participates has one or more DAWN reporters to review charts and collect data on its behalf. The reporter reviews death investigation records to find those that are drug-related (DAWN cases). The reporters submit data on cases electronically via eMERS (electronic Medical Examiner Reporting System).

Since shortly after its inception, DAWN has reported on deaths induced by or related to abuse of illegal drugs or legal drugs. As part of the design changes introduced in 2003, DAWN dropped the requirement that the death be a result of abuse and began collecting data on all drug-related deaths. This approach enables DAWN to capture not only a broader spectrum of deaths that involve drug misuse and abuse, but also to include deaths associated with adverse reactions to prescription and over-the-counter pharmaceuticals taken for therapeutic purposes, accidental ingestion of drugs, and drug-facilitated assaults. Since 2003, DAWN has collected data on all deaths visits related to recent drug use for patients of all ages. Data items for each case include the manner and cause of death; the age, gender, and race/ethnicity of the decedent, and information about up to 16 substances plus alcohol. Beginning in 2003, DAWN has collected data on deaths resulting from underage drinking when no other drug is involved. For adults, alcohol-related deaths are collected only if another reportable substance was involved.

Response Rates

The MSAs and Divisions that are contributing mortality data for the 2008 calendar year are listed in **Table 7**.¹² To indicate population coverage within each MSA, the proportion of the population covered by the participating jurisdictions in each MSA is also reported.

11 Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (September 2005). The DAWN Report: New DAWN: Why It Cannot Be Compared with Old DAWN. Rockville, MD.

12 DAWN only publishes metropolitan or county-level counts if there are sufficient numbers of deaths to protect the confidentiality of the decedents. Therefore, detailed results are not published for every metropolitan area or county in States with statewide reporting.

Table 7. Universe and Response Rates for Areas in DAWN Mortality Component, 2007

Name	Total jurisdictions	Number of Participating Jurisdictions	Percent of Jurisdictions Participating	Coverage of Population
Total, Eleven States	442	442	100	100
Total Metropolitan Areas	311	180	58	76
Metropolitan Areas				
Albuquerque, NM*	4	4	100	100
Baltimore-Towson, MD*	7	7	100	100
Burlington-South Burlington, VT*	3	3	100	100
Charleston, WV*	5	5	100	100
Eugene-Springfield, OR *	1	1	100	100

Manchester-Nashua, NH*	1	1	100	100
Ogden-Clearfield, UT*	3	3	100	100
Oklahoma City, OK*	7	7	100	100
Portland-South Portland, ME*	3	3	100	100
Provo-Orem, UT*	2	2	100	100
Salt Lake City, UT*	3	3	100	100
Springfield, MA*	3	3	100	100
Tulsa, OK*	7	7	100	100
Atlanta-Sandy Springs-Marietta, GA	28	8	29	56
Birmingham-Hoover, AL	7	1	14	60
Boston-Cambridge-Quincy, MA-NH	7	7	100	100
Buffalo-Cheektowaga-Tonawanda, NY	2	2	100	100
Chicago-Naperville-Joliet, IL-IN-WI	14	9	64	92
Cleveland-Elyria-Mentor, OH	5	1	20	62
Dallas-Fort Worth-Arlington, TX	12	2	17	21
Denver-Aurora, CO	10	7	70	98
Detroit-Warren-Livonia, MI	6	5	83	98
Fargo, ND-MN	2	2	100	100
Houston-Baytown-Sugar Land, TX	10	1	10	70
Indianapolis, IN	10	2	20	60
Kansas City, MO-KS	15	4	27	53
Los Angeles-Long Beach-Santa Ana, CA	2	1	50	77
Louisville, KY-IN	13	2	15	60
Miami-Fort Lauderdale-Miami Beach, FL	3	2	67	67
Milwaukee-Waukesha-West Allis, WI	4	1	25	61
Minneapolis-St. Paul-Bloomington, MN-WI	12	9	75	84
New Orleans-Metairie-Kenner, LA	7	4	57	54
New York-Newark-Edison, NY-NJ-PA	23	11	48	60
New Jersey division.	13	3	23	18
New York Suburban division	5	3	60	45
New York City, 5 Boroughs division	5	5	100	100
Philadelphia-Camden-Wilmington, PA-NJ-DE-MD	11	5	45	60
Phoenix-Mesa-Scottsdale, AZ	2	1	50	93
Portland-Vancouver-Beaverton, OR-WA	7	5	71	80
San Diego-Carlsbad-San Marcos, CA	1	1	100	100

San Francisco-Oakland-Fremont, CA	5	4	65	80
Seattle-Tacoma-Bellevue, WA	3	3	100	100
Sioux Falls, SD	4	1	25	77
St. Louis, MO-IL	16	9	56	85
Washington-Arlington-Alexandria, DC-VA-MD-WV	21	21	100	100
States				
Maine	16	16	100	100
Maryland	24	24	100	100
Massachusetts	14	14	100	100
New Hampshire	10	10	100	100
New Mexico	33	33	100	100
Oklahoma	77	77	100	100
Oregon	36	36	100	100
Utah	29	29	100	100
Vermont	14	14	100	100
Virginia	134	134	100	100
West Virginia	55	55	100	100
*Metropolitan area located within a participating State				
Bolded entries signify areas that are oversampled in DAWN's ED component				

As reported in **Table 7**, a census is achieved in 20 of the 45 (44%) OS areas/divisions and other metropolitan areas. In addition, in over 90 percent of the areas, a majority of the population is covered. Only 3 areas have coverage of less than half the population.

At the local level, the mortality data provide an important complement to the ED estimates and help create a fuller picture of the impact of drug use, misuse, and abuse. Even in areas where less than 100 percent of the population is covered by the mortality component, the participating jurisdictions can use the mortality data to detect drug-related fatalities and monitor changes over time.

Facility Recruitment

Recruitment of eligible Medical Examiner/Coroner offices involves the following procedures:

Step One: Identification of Facilities¹³ for Recruitment

Areas in the mortality component with incomplete coverage are identified. These include jurisdictions in ED OS areas, other metropolitan areas, and States with centralized ME systems. Recruitment goals are established based on the level of coverage in each area.

Based on their past experience with the ME/C office, as well as contacts with local government and advocates, the DAWN Operations contractor's recruitment team apprises the Project Officer

¹³ In the mortality component, a facility is synonymous with Medical Examiner/Coroner's office.

on any past recruitment efforts and on the degree of willingness of individual jurisdictions to join DAWN.

Step Two: Identification of Main and Alternate ME/C Contacts

The Operations contractor maintains a database with information on death investigation jurisdictions in the ED OS areas and in other areas covered by DAWN (**Table 7**) and the results of previous recruitment efforts. The entry for the Chief ME/C in the database is verified and updated if necessary. The Chief ME/C is the initial contact for recruitment, but contacts made during previous recruitment attempts, at conferences, and through the recommendation of an advocate can be useful advocates for DAWN in the office. The OAS DAWN team builds support for DAWN with local public health agencies and works with local and State contacts to assist with recruitment of ME/Cs.

Step Three: Development/Mailing of Recruitment Package

Each year the materials included in the initial recruitment package are reviewed and updates are made based on past experience. ME/Cs are sent a letter of invitation from OAS's Director of the Division of Facility Surveys (Attachment C.6). Supporting materials include a fact sheet about the mortality component (Attachment C.8) and recent DAWN publications on the mortality component. A business card for the primary recruiter is also included.

Step Four: Followup

If there is no response within 2 weeks, the recruiter researches prior communications with the ME/C office, its website, and needs of the community that may be addressed by the office's participation in DAWN. The recruitment staff, in consultation with the OAS DAWN staff, will also decide how to involve the community and public health advocates in the process.

Approximately one week after the mailing of the recruitment materials, the recruiter follows up by telephone to establish whether packet has been received. Protocols have been developed to guide the recruiter, depending on the result of the phone call. The recruiter will attempt to speak with the ME/C or Chief Administrator directly to discuss DAWN participation, operational issues, and the content of the agreement. If the recruiter is unable to reach the contact directly, s/he will leave an introductory voicemail using the following script:

Hello, my name is [name]. I am calling on behalf of the Substance Abuse Mental Health Services Administration, an agency of the U. S. Department of Health and Human Services (HHS). I would like to talk to you about gaining your office's participation in the Drug Abuse Warning Network (DAWN). DAWN's mission is to measure the impact of drug misuse and abuse by drug-related deaths. You should have received a Federal Express package containing background materials explaining more about DAWN and its benefits to your office. I will call again on [insert day/time] and look forward to talking more with you about DAWN. If you would like to return my call, you can reach me at [insert number].

If there is no response from the ME/C, the recruiter will conduct follow-up calls to the ME/C or to the Chief Administrator. Calls will be made at different times of the day, and on different days of the week, but they will leave no more than one message a week.

There is a great deal of variation among ME/C jurisdictions, ranging from offices in large cities with multiple pathologists and in-house toxicology, to rural areas with a part-time Coroner who is also a Funeral Director. Frequently, the ME/C is supportive of DAWN, and view DAWN participation as part of their public health mission, but staffing and other resource issues may influence their ability to participate. Therefore, the recruitment staff approach is tailored to address the particular needs and interests of each jurisdiction.

In 2008, the Operations contractor has embarked on a new project to visit all the participating ME/C jurisdictions in person. The trips fulfill dual needs. They are an opportunity to conduct data quality review and training at the participating jurisdictions and to affirm the relationship between DAWN and the jurisdiction, and the face-to-face meetings with non-participating jurisdictions can develop connections and relationships that may lead to enrollment. Improving local participation in DAWN benefits the local community, because DAWN may be the only source of local data on drug misuse/abuse.

Suppression of Data

Mortality data are suppressed if there are fewer than 4 deaths. The purpose of suppression is to protect the identities of the decedents.

Data Collection

Mortality data are collected in ME/C offices through a retrospective review of death investigation records for every case investigated by the ME/C. Families are never interviewed.

The review of source records is performed by a trained DAWN Reporter in each member facility. Most ME/C offices designate one of their own staff members to collect the data (a “Staff Reporter”). The Staff Reporter is trained by the Operations Contractor, which provides payments for data collection, either to the ME/C directly (if the staff collect data on work time) or to the staff member(s) directly if they collect the data on their own time.

Participating jurisdictions may also opt to use a reporter provided by the Operations contractor, which is responsible for hiring, supervising, and paying these Reporters.

Within each facility that participates in DAWN, the designated DAWN Reporter reviews all death investigation records to identify deaths related to drug use. The DAWN Reporter submits an electronic case report to the DAWN system for each decedent who meets specific case selection criteria. DAWN Reporters also track their progress in reviewing cases referred to the ME/C.

Mortality Component Cases

The criteria for a case in the mortality component of DAWN are:

- \$ The death was investigated by the medical examiner, coroner, or other official charged with the responsibility to investigate deaths in the jurisdiction, and
- \$ The death was related to recent drug use.

For decedents under age 21, alcohol-only deaths are reportable; for decedents 21 and older, alcohol is reportable only if it was consumed in conjunction with another reportable drug. The data elements that characterize decedent demographics match those of ED cases. Manner of death and cause of death are obtained from the death certificate. Proposed revisions to the case report form include increasing the number of drugs that can be entered and adding a field for the case description. A screenshot of the revised ME case report form is shown in Attachment A.4.

Activity Report

In addition to the data submitted on each case, DAWN Reporters are asked to maintain a running total of the total deaths handled by the ME and of the number of charts they were able to locate and review (associating charts with the date of the death). The information contained in the Activity Report is necessary for quality control, payment, and analysis:

- \$ Quality control. Direct chart review is the standard for identifying DAWN cases, but in some instances the number of death investigation records available for review is less than the total number of charts. Therefore, it is essential to know how many death investigation records were located and reviewed by the DAWN reporter and the relationship of that number to the total deaths reviewed by the ME/C for the same period.
- \$ Payment. The performance-based per-piece payment is calculated from the actual number of charts reviewed and the number of DAWN cases identified.

A monthly activity report is used to capture this information. An example of the electronic ME/C activity report is in Attachment A.6.

Quality Control for Mortality Component Data Collection

New quality control procedures have been incorporated into DAWN systems at multiple levels and locations to ensure that DAWN data are accurate. These include

- \$ Data collection
 - Direct review of each death record by DAWN Reporters.
 - Electronic reporting with built-in edits and alerts to improve accuracy and timeliness of data.
 - Recruitment of Reporters familiar with the ME/C environment and records, skillful in computer and Internet use, dependable, and able to meet DAWN objectives for timeliness.
 - Ongoing training of Reporters in person and through a computer-based training tutorial.
 - Monitoring of data collection performance measures with feedback to DAWN Reporters.
 - Site visits by contractor=s facility liaisons for problem resolution and quality control.

- Routine contact between Reporters and regional monitors at the DAWN operations office.
- Help Desk hot line where Reporters can seek technical assistance.

\$ Data management and processing

- Generation of standard periodic reports on preparation, process, and quality assurance by the decision support system/management information system.
- Incorporation of quality assurance tools in data processing (e.g., procedures to identify duplicate records and nonspecific drug codes).
- Statistical Process Control methods to monitor Reporter performance and data quality (by identifying unusual events).
- Data verification with ME/C before production of annual publications.

\$ Maintenance and updating of the Drug Reference Vocabulary (DRV) and analysis file. The DRV is the *Alanguage@* of DAWN, providing names and categories of illicit, prescription and over-the-counter drugs. Like the ED component, it is based on the *Multum Lexicon*.¹⁰ Maintenance of the DRV includes:

- Bimonthly updates from the Multum website,
- Verification and incorporation of new drugs reported in DAWN cases, and
- Quality assurance checks for errors and data corruption.

3. Methods to Maximize Response Rates

Emergency Department Component

Non-response is common in all voluntary, sample-based surveys. In DAWN, non-response may occur at the hospital level, when sampled hospitals do not participate or drop out, and within the hospital, because of incomplete data reporting. Inadequate response rates can result in estimates too imprecise for publication or in biased estimates, if the distribution of hospitals by geography, ownership, and/or size is uneven. Therefore, efforts to maximize response rates and address issues of non-response are targeted at decreasing hospital nonresponse, increasing the response rate within facilities, and minimizing bias.

To encourage hospital participation, DAWN has adopted recruitment strategies that reflect the different audiences that must be reached to achieve a successful expansion of the system. Facilities are first contacted with a letter from the Division Director of Facility Surveys at OAS, which is followed up by the Operations contractor recruitment team. The OAS staff develops networks of supporters in the local and State public health agencies to increase awareness of DAWN and its data, and gain local support for hospital recruitment efforts. Resources for local DAWN advocates include access to local data and DAWN *Live!* user accounts (where appropriate) and helps generate enthusiasm for the system among local public health agency staff, who may assist with outreach and recruitment efforts.

Once the foundation had been laid, the Operations contractor's recruitment staff contact each facility individually, arrange informational meetings with various administrative officers (e.g., medical directors of EDs and HIPAA privacy officers, as well as hospital administrators), and discuss the details of the terms of participation, the payment protocol, and the option to have a Field Reporter or Remote Reporter conduct the data abstraction if required for hospital participation. When needed, the recruiter and field operations staff travels to the facilities to conduct in-person interviews and presentations.

As discussed in Section A.9, Payments to Respondents, the DAWN hospitals receive an access fee. Hospitals that use their own staff to collect data also receive a per-piece payment based on the volume of work they perform. These payments are part of a comprehensive incentive strategy to encourage and recognize the importance of participation. As part of the incentives package, authorized hospital staff have access to DAWN *Live!*, the online system that enables them to access to their facility's own de-identified raw data and customized reports on an ongoing basis. This online system was designed based on feedback from ED physicians, MEs, and public health officials received during the redesign phase, and since deployment, based on feedback received from users.

In addition, DAWN provides ongoing training and materials, technical assistance, and, as needed, hardware, software, and Internet access to support data collection in participating facilities.

\$ DAWN field operations divided the country into five administrative regions. Each region has a designated Facility Liaison to provide technical support through regularly

scheduled site visits to troubleshoot and resolve problems and monitor the application of case selection criteria by Reporters.

- \$ Ongoing assistance is available to Reporters through a toll-free telephone number and a help desk staffed by the DAWN Operations contractor central office.
- \$ Reporting Specialists, who are members of the DAWN field staff, are available to cover for Facility Reporters if they are sick or if they resign.
- \$ Field Reporters are recruited and trained to collect data on behalf of facilities that require this option. Remote Reporters are recruited and trained to collect data for facilities that have electronic ED records and choose this option.

Mortality Component

Most ME/C jurisdictions are recruited in the same metropolitan areas where hospitals are oversampled for the ED component. The goal is to have full participation in each of the DAWN OS areas, so the mortality data will complement the emergency department data. DAWN also recruits centralized State medical examiner systems, which then provide data on urban and non-urban areas of those states.

The ME/C offices that participate receive an annual access fee as an incentive. They also receive access to *DAWN Live!*, so they can use their own de-identified DAWN data on an ongoing basis. In addition, DAWN provides ongoing training and materials, technical assistance, and, as needed, hardware, software, and Internet access to support data collection in participating facilities. The field operations for the ME component are organized in the same way as the field operations for the ED component. Field Liaisons are assigned for each of the five regions to monitor and provide in-person technical assistance to DAWN Reporters. A help desk is also available at a toll-free telephone number, and Reporting Specialists are available to step in when necessary.

Recruitment of ME/C jurisdictions for participation in DAWN focuses first on adding jurisdictions in the OS areas. Absent a sample, the objective is to capture a census of drug-related deaths investigated by the ME/Cs for each of these OS areas so that reliable mortality data can be analyzed in conjunction with ED estimates of drug-related morbidity for the same areas. In the OS areas that do not represent themselves in the ED estimates and in the remainder areas of the Nation, the DAWN mortality data may be the only source of data on drug abuse problems for a community and therefore has considerable value for local public health authorities. To achieve full participation by ME/Cs in the areas oversampled for the ED component, DAWN plans to recruit approximately 20 more ME/C offices from 2009 to 2011, and approximately 20 ME/Cs from metropolitan areas in the rest of the country.

Efforts to gain participation from additional States with centralized death reporting systems will also continue. State-wide systems provide an efficient means of achieving 100% coverage of OS and other metropolitan areas in the State, have a clear population base, and enable DAWN to include data from rural areas. Presently, 11 States are submitting mortality data to DAWN (**Table 5**). From 2009 to 2011, DAWN plans to recruit 2 to 3 additional States with centralized ME systems.

4. Tests of Procedures

All of the data forms and data collection procedures that DAWN follows were extensively tested before the implementation of new DAWN in 2003. There are no further plans for changes in procedures. Current efforts focus on improving the procedures and approaches that were set in place earlier to maximize response rates and ensure data quality, as described in Sections B.2 and B.3.

Statistical Consultants

The following statistical consultants are involved in the maintenance of the DAWN sample. Peter Frechtel is the statistician responsible for ongoing statistical aspects of DAWN.

Non-Federal Statisticians and Researchers	
James Chromy 919-541-7019	Senior Fellow in Statistics RTI International
David Morganstein 301 251-8215	Vice President/Senior Statistician Westat
Karol Krotki (202) 728-2485	Senior Statistical Advisor RTI International
James Green (301) 251-4295	Senior Statistician Westat
Larry Campbell (919) 541-6809	Sample Maintenance Task Leader RTI International
Peter Frechtel (202) 974-7833	Research Statistician RTI International

The following key individuals are responsible for DAWN data collection and analysis under two existing contracts:

Data Collection/Analysis Contractors	
David Maklan (301) 294-2805	Corporate Officer Operations Contract, Westat
Josefina Moran (301) 610-5560	Corporate Officer Operations Contract, Westat
Kathy Chimes (301) 251-4302	Project Director Operations Contract, Westat
Michael Rhoads (301) 251-4308	Director of Computer Systems and Applications Operations Contract, Westat
Katie Gasque (301) 294-3915	Field Director, ED component Operations Contract, Westat
Michelle Kiser Scheele (301) 610-5572	Deputy Project Director, Mortality component Operations Contract, Westat

Data Collection/Analysis Contractors	
Rob Pillmeier (301) 610-4926	Data Management Operations Contract, Westat
Tim Gabel (919) 541 7415	Vice President, Survey and Computing Sciences Analysis Contract, RTI International
John Loft (312) 456-5241	Senior Corporate Manager Analysis Contract, RTI International
Victoria Albright (919) 541-6805	Project Director Analysis Contract, RTI International
Susan Myers (919) 541-7441	Database Manager Analysis Contract, RTI International
Erin Mallonee (301) 816-4613	Task Leader, Publications Analysis Contract, RTI International

The SAMHSA Project Officer responsible for both the current DAWN Operations and Analysis contracts is Judy K. Ball, Ph.D., M.P.A. Dr. Ball is the Director, Division of Facility Surveys, Office of Applied Studies (OAS), SAMHSA, (240) 276-1256. The Alternate Project Officer for both contracts is CAPT Kathy Poneleit, DAWN Team Leader, OAS, SAMHSA, (240) 276-1254.

LIST OF ATTACHMENTS

Attachment A: New DAWN forms

- A.1 eHERS Case Report Form
- A.2 eHERS Public Burden Statement
- A.3 eHERS Activity Report
- A.4 eMERS Case Report Form
- A.5 eMERS Public Burden Statement
- A.6 eMERS Activity Report

Attachment B: Instructions to Reporters

- B.1 Emergency Department Component Decision Tree
- B.2 Emergency Department Component Manual
- B.3 Mortality Component Manual

Attachment C: Facility Recruitment Materials

- C.1 DAWN ED Recruitment Letter 2008
- C.2 DAWN Brochure 2008
- C.3 “Trying to Reach You” Letter
- C.4 *How Hospitals Join DAWN*
- C.5 *DAWN Measures All Drug-Related Emergencies: It’s Not Just Drug Abuse*
- C.6 DAWN ME Recruitment letter
- C.7 DAWN State ME Recruitment letter
- C.8 *How Medical Examiners and Coroners Join the Drug Abuse Warning Network*