Supporting Statement: Section A

Prevalence of Alcohol and Other Drug Use among Motor Vehicle Crash Victims Admitted to Select Trauma Centers

Background

The National Highway Traffic Safety Administration (NHTSA) is conducting this study to examine the prevalence of legal and illegal drugs in the systems of seriously- or fatally-injured drivers and other crash-involved road users (e.g., pedestrians, bicyclists, scooter riders) presenting directly to selected trauma centers or morgues. Little is currently known about the prevalence of drugs other than alcohol in drivers and other road users who are seriously- or fatally-injured in a motor vehicle crash (MVC). The proposed study approach will allow for an in-depth and accurate portrayal of drug prevalence among the populations of interest at the studied sites.

The prevalence of alcohol among trauma patients, including those injured in MVCs, is well-documented when a State requires blood alcohol concentration (BAC) testing.[1] NHTSA monitors drug toxicology results from impaired driving arrests and as part of its Fatality Analysis Reporting System (FARS), however, there are known limitations associated with the drug data being reported to FARS.[2] Some older studies in the United States have examined the prevalence of drugs in fatal and injury crashes, but these studies had small samples sizes, tested for a limited set of drugs,[3,4,5] and may be out of date. As such, little is known about current drug prevalence rate among seriously- and fatally-injured MVC victims in the United States.

Recent efforts in the European Union[6] and Canada[7] have sought to better understand drug prevalence among seriously injured drivers. The European Integrated Project, Driving Under the Influence of Drugs, Alcohol and Medicines (DRUID) study involved data collection across nine European countries to determine the prevalence of psychoactive substances in the general driving population and drivers who were seriously injured or killed in crashes. The data collection and

---

[1] Blomberg, R. D, Thomas, F. D., Long, W., Sifrit, K. J., & Korbelak, K. T. (2014, September). *BAC and crash responsibility of injured older drivers: An analysis of trauma center data.* (Report No. DOT HS 812 062). Washington, DC: National Highway Traffic Safety Administration.

[2] Berning, A. & Smither, D. (2014). *Understanding the Limitations of Drug Test Information, Reporting, and Testing Practices in Fatal Crashes.* (Report No. DOT HS 812 072). Washington, DC: National Highway Traffic Safety Administration.

[3] Terhune, K.W., Ippolito, C.A., Hendricks, D.L., Michalovic, J.G., Bogema, S.C., Santinga, P., Blomberg, R. and Preusser, D.F. (1992). The Incidence and Role of Drugs in Fatally Injured Drivers. Report No. 808 065. Washington, DC: National Highway Traffic Safety Administration.

[4] Soderstrom, C. A., Ballesteros, M. F., Dischinger, P. C., Kerns, T. J., Flint, R. D., & Smith, G. S. (2001). Alcohol/drug abuse, driving convictions, and risk-taking dispositions among Trauma Center patients. Accident Analysis & Prevention, 33(6), 771–782.

[5] Walsh, J. M., Flegel, R., Cangianelli, L. A., Atkins, R., Soderstrom, C.A., & Kerns, T. J. (2004). Epidemiology of alcohol and other drug use among motor vehicle crash victims admitted to a trauma center. *Traffic Injury Prevention*, *5*(3), 254-60.

[6] Hels, T., Bernhoft, I. M., Lyckegaard, A., Houwing, S., Hagenzieker, M., Legrand, S., Verstraete, A. (2011). Risk of injury by driving with alcohol and other drugs. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines).

[7] Brubacher, J., Chan, H., Martz, W., Schreiber, W., Abridge, M., Eppler, J., Lund, A., Macdonald, S., Drummer, O., Purssell, R., Andolfatto, G., Mann, R., & Brant, R. (2016) Prevalence of alcohol and drug use in injured British Columbia drivers. *BMJ Open*, *6*:e009278.

toxicology methods varied significantly across countries, however, which limits the usefulness of the information. The study in British Columbia, Canada utilized a methodology similar to that being executed for the current study. The Canadian study analyzed blood already collected during the clinical treatment of trauma patients to provide prevalence estimates for a variety of drugs in the systems of the injured drivers. The European and Canadian studies, however, likely have little generalizability to the United States given the different laws and populations of the countries.

For the current study, NHTSA will employ research associates who will obtain already collected blood samples from participating trauma centers and medical examiner offices for patients involved in MVCs. Such samples are obtained by trauma centers and medical examiners during their routine clinical treatment for seriously- or fatally-injured patients involved in MVCs. Both trauma centers and medical examiners routinely collect more blood than is used during treatment or for autopsy purposes, and place such blood in storage tubes that are available for research purposes. The trauma centers regularly engage in research studies using such samples.

Neither trauma center nor medical examiner staff will be asked to do anything above and beyond their normal clinical or research activities. The study's research associates, paid for by the Government, will collect study blood tubes from the trauma bay or medical examiner refrigerator (after all treatment/autopsy activities are complete). The research associates will be responsible for packaging and shipping all study blood samples to the study's toxicology lab. The study will then conduct independent drug toxicology testing to determine the prevalence of alcohol and other drugs in the systems of the injured parties. The cost of the shipping materials, shipping, and the toxicology lab work will all be paid for by the study. The research associates will also be responsible for collecting all secondary source data (e.g. demographics, drugs administered prior to arrival, injury severity, and crash classification information) from hospital and medical examiner records. The trauma centers and medical examiners will provide the research associates with access to this already-collected and de-identified information for the study in accordance with all applicable Federal, State, local, and institutional regulations governing the sharing of such information and as approved by the study IRB.

Overall, this study seeks to fill a gap in the state of knowledge concerning drug prevalence among MVC victims who are seriously- or fatally-injured, and present directly to a trauma center or morgue. NHTSA will use the information to produce a technical report that will present results in aggregate (summary) statistics and tables of drug prevalence for the study groups; no individual's drug test results will be reported; nor will any personal information be reported. While the sample is not nationally representative and will not be used for national estimates, the results of this research will produce information on a large sample of MVC victims in multiple locations that will assist NHTSA in better understanding the prevalence of different drugs among the seriously- and-fatally-injured at the participating trauma centers and morgues. The technical report will be distributed to a variety of audiences interested in improving highway safety.

A. JUSTIFICATION

The National Highway Traffic Safety Administration (NHTSA) of the U.S. Department of Transportation (USDOT) is seeking approval from the Office of Management and Budget (OMB) to

conduct a data collection effort to determine the prevalence of drugs in motor vehicle crash victims transported to selected trauma centers and medical examiners. Undertaking this important research will support NHTSA's mission to save lives, prevent injuries and reduce economic costs due to road traffic crashes, through education, research, safety standards and enforcement activity.

A.1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection.

a. Circumstances making the collection necessary

NHTSA was established to reduce deaths, injuries, and economic losses that result from motor vehicle crashes on the Nation's highways. The agency develops, promotes and implements educational, engineering, and enforcement programs with the goal of ending preventable tragedies and reducing economic costs associated with vehicle use and highway travel. Current data on the problems faced is essential to develop future approaches to improve traffic safety. This is especially true for information on drug use and driving, where data is much more limited than regarding alcohol-impaired driving.

On March 15, 2018, NHTSA's Deputy Administrator Heidi King held a summit on drugged driving as a "Call to Action," to move forward in setting a course of action to address the nation's drugged-driving problem. A major first step in moving forward is understanding the prevalence of drugged driving in the costliest crashes where an individual is seriously- or fatally-injured. For the current study, NHTSA will collaborate with trauma centers and medical examiners to address the study objective of estimating drug prevalence among the seriously- and fatally-injured crash victims in their catchment areas. The study will only use blood samples and information already collected as part of the routine clinical and autopsy procedures at the trauma centers and morgues, respectively.

The results of this project will assist NHTSA in understanding how prevalent different drug classes are in the most serious crashes at the participating sites, which will help the Agency provide guidance to the States and Federal Government on matters related to drug-involved driving.

b. Statute authorizing the collection of information

Title 23, United States Code, Chapter 4, Section 403 gives the Secretary authorization to use funds appropriated to carry out this section to conduct research and development activities, including demonstration projects and the collection and analysis of highway and motor vehicle safety data and related information needed to carry out this section, with respect to all aspects of highway and traffic safety systems and conditions relating to - vehicle, highway, driver, passenger, motorcyclist, bicyclist, and pedestrian characteristics; accident causation and investigations; and human behavioral factors and their effect on highway and traffic safety, including impaired driving. [See 23 U.S.C. 403(b)(1)(A)(i), 23 U.S.C. 403(b)(1)(A)(ii), 23 U.S.C. 403(b)(1)(B)(ii)].

A.2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

This is a new collection of information focusing on seriously- and fatally-injured patients involved in an MVC. No similar study in the United States has focused on this population using this methodology. This new collection will address the substantial gap in knowledge regarding the prevalence of drugs among seriously- and fatally- injured drivers and other road users. NHTSA will use the information gathered to produce a technical report that presents the results of the study. The technical report will provide aggregate (summary) statistics and tables of drug prevalence, but it will not include any personal information because none will ever be entered into the final analysis study database. The technical report will be shared with State Highway Safety Offices and other stakeholders interested in improving highway safety. Study results will be used by NHTSA to inform traffic safety stakeholders on drugs and driving.

A.3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical or other technological collection techniques or other information technology. Also describe any consideration of using information technology to reduce burden.

The research team will create a computer application that will be installed on Windows® tablets for use by study research associates who will operate at the trauma centers and medical examiners' offices. Running locally on a tablet, this data collection app will synchronize with a central database upon realizing a secure Wi-Fi connection. The research associates will manually transfer the already collected and de-identified study information from the local records to the separate study database. Only the study's paid research associates will enter data into the system for the study; there will be no burden on trauma center or medical examiner staff. This technology will improve the efficiency of collection and data management, help to preserve the integrity of data, never contain any personal identifiers, and reduce the likelihood of data loss.

A.4. Describe efforts to identify duplication. Show specifically why any similar information, already available cannot be used or modified for use for the purposes described in Item 2 above.

This is the only study to date of seriously- and fatally-injured drivers that has utilized this prevalence design to gather data on a large-scale in the United States. The DRUID study, conducted in several countries in Europe, sought similar information and included some similar data collection components. The DRUID study did not examine the full set of drugs that is important to NHTSA and included populations that are likely very different than those found in the United States. See Table 1 (below) for a list of drugs included in this study. The previously mentioned study conducted in British Columbia, Canada utilized a design similar to that to be employed here. The study utilized blood samples already collected as part of patient care and other classification information already collected during patient treatment. The study, however, was much smaller than the current effort and included a population outside of the United States.

Table 1. Drugs for screening and confirmation with cutoff levels

Drugs: Grouped by Class/Screening Package	Minimum Blood Concentration Detection Thresholds (ng/mL)	
	ELISA Screen	LC-MS/MS Confirm
Cocaine, benzoylecgonine, cocaethylene	25	10
6-AM, codeine, morphine, hydrocodone, hydromorphone	25	10
Amphetamine, methamphetamine, MDMA, MDA, ephedrine, pseudoephedrine, phenylpropanolamine	20	10
THC, THC-COOH, 11-OH-THC	5	1
Phencyclidine	10	10
Buprenorphine, norbuprenorphine	1	1
Alprazolam, chlordiazepoxide, oxazepam, nordiazepam, lorazepam, diazepam, clonazepam, 7-aminoclonazepam, temazepam	20	10
Phenobarbital, secobarbital, butalbital	100	100
Methadone, EDDP	50	10
Diphenhydramine, doxylamine, chlorpheniramine	25	10
Fentanyl, norfentanyl, furylfentanyl, acetylfentanyl, carfentanil, fluorofentanyl	1	0.5
Oxycodone; Oxymorphone	25	10
Tramadol	50	10
Carisoprodol; Meprobamate	500	500
Sertraline	50	10
Fluoxetine	50	10
Amitryptiline, nortriptyline, doxepin, imipramine, desipramine, citalopram, venlafaxine, trazadone, cyclobenzaprine	25	10
Zolpidem	10	10
Dextromethorphan	50	20
Ketamine	10	10
α-Pyrrolidinopentiophenone	5	1
Alcohol: Ethyl Alcohol	20 mg/dl	20 mg/dl

A key and unique feature of this study is that the crash-involved drivers and other crash-involved victims must be admitted to an emergency medical facility immediately after a crash and have a trauma team activated (i.e., are “seriously injured”), or have died before or during treatment (i.e., are “fatally injured”). Although others have investigated the prevalence of drugs in drivers, the methodological approaches of prior work have not obtained both motor vehicle crash-involved drivers and other motor vehicle crash victims from the same catchment area.

A.5. If the collection of information involves small businesses or other small entities, describe the methods used to minimize burden.

The collection of information does not involve small businesses or other small entities.

A.6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

The use of legal and illegal drugs by road system users potentially has major implications for highway safety. Little is known about the prevalence of drugs (with the exception of alcohol) in drivers and other road users who are seriously- or fatally-injured in MVCs. NHTSA has a responsibility to provide guidance to the public and traffic safety professionals about the potential dangers of drug-involved driving and drug use by other road users. Other Federal agencies, legislators, state highway safety offices, law enforcement agencies, and prosecution are looking to NHTSA for information on drug prevalence among road users. In the absence of this study, some will use incomplete data and public concern to guide decisions on traffic safety programs rather than sound scientific evidence.

A.7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the guidelines set forth in 5 CFR 1320.6.

No special circumstances require the collection to be conducted in a manner inconsistent with the guidelines in 5 CFR 1320.6.

A.8. Provide a citation for the FEDERAL REGISTER document soliciting comments on extending the collection of information, a summary of all public comments responding to the notice, and a description of the agency's actions in response to the comments. Describe efforts to consult with persons outside the agency to obtain their views.

NHTSA published a 60-day *Federal Register* Notice on April 24, 2019 (Volume 84, Number 79, pages 17233-17234), which notified the public of NHTSA's intent to conduct this information collection and provided a 60-day comment period. NHTSA received one comment, from the NTSB, that was supportive of the information collection. NTSB stated that it found the proposed collection of information to be necessary, proper, and useful; the methodology to be valid; the quality and clarity of the proposed collected information to be appropriate; and the collection techniques to be suitable. The comment expressed NTSB's support for NHTSA's research efforts to better understand the prevalence of alcohol and other drug use among crash victims admitted to selected trauma centers and morgues and stated that NHTSA's work on drugs and driving is crucial to NHTSA's proper performance of its agency functions, particularly addressing the safety hazards caused by driver impairment. In further support, NTSB referenced its own safety recommendation to NHTSA to develop and disseminate a common standard of practice for drug toxicology testing. NTSB also noted that because the blood specimens will be left over from those already drawn and used for medical care and that demographic data will be deidentified, there will be no evident burden placed on the public or the individuals involved in the research. NHTSA is not making any changes to the information collection based on the comment received.

NHTSA published a 30-day *Federal Register* Notice on July 16, 2019 (Volume 84, Number 136, Pages 34044-34045) with a 30-day public comment period to announce forwarding of the information collection request to OMB for approval.

A.9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

No payments or gifts will be made as part of this study.

A.10. Describe any assurance of confidentiality provided to respondents

The study is not making contact with any patients. The participating trauma centers and medical examiners are allowing our research associates access to de-identified blood samples, when available, and other de-identified classification information that was already collected during the clinical treatment procedures. Only study research associates will have access to the data collection system.

The study ensures privacy through several tiers of protection: 1) blood samples and classification information provided by the trauma centers and medical examiners will only have a randomly generated study ID attached; 2) no personally-identifiable information is being provided by the trauma centers or medical examiners; 3) toxicology results are not being reported back to the trauma centers or medical examiners, 4) all data are only being stored by the randomly assigned study ID numbers; and 4) only aggregate-level data will be reported.

Approximately twice a week, the research associates will obtain and ship blood samples to the toxicology laboratory. All shipping materials and shipping costs will be paid for directly by the study. A toxicologist will then conduct a series of tests to determine whether each of the drugs of interest is present in the sample. The toxicologist will record the results for these tests, again only using the study ID number as an identifier. The toxicologist will not have any identifying information about the blood sample other than the study ID nor any information that could link any individual sample to the respective participant. The drug test results will be kept in the password-protected database, on a secure server.

As study results are prepared and disseminated, only aggregate categories will be used, such as “males had a higher prevalence of ….” or “drivers under 21 had a lower prevalence of…”

A.11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private.

There are no questionnaires or surveys of respondents that will include any questions of a sensitive nature. The trauma centers and medical examiners will allow the study research associates access to de-identified blood samples and de-identified information on severely- and fatally-injured MVC patients that they already collected as part of their normal clinical treatment or autopsy activities and for their own research activities. This information will include patient demographics, cause of injury, and injury severity.

A.12. Provide estimates of the hour burden of the collection of information on the respondents.

There is no burden to respondents (0.00 hours). The trauma centers and medical examiners will allow the study access to de-identified blood samples and de-identified information on severely- and fatally-injured patients that was already collected during their normal clinical treatment activities. Study research associates will be responsible for collecting the tubes of blood and accessing data from the trauma center and medical examiner records. Only the study research associates will ever collect, package, and ship the specimens and collect and enter information from existing de-identified records for this study.

A.13. Provide an estimate of the total annual cost to the respondents or record keepers resulting from the collection of information.

There are no costs to respondents resulting from the collection of information because all information was already being collected during normal clinical procedures. The trauma centers and medical examiners are simply providing access to the blood samples and other information that was collected during their normal activities. There is no preparation of data required or expected of respondents, thus there are no record keeping costs to the respondents. Participants do not incur: (a) capital and start-up costs, or (b) operation, maintenance, and purchase costs as a result of participating in the study.

A.14. Provide estimates of the annualized cost to the Federal Government.

The actual data collection portion of this study is slated to take place over a two-year period with a total of 7,500 fully completed cases (3,750 per each of two years). All costs for this study are paid for by the Government. Total annual estimated cost to the Government for data collection for this study is shown in Table 2 (note that this does not include costs for project administration, study design, data analyses or report writing):

Table 2 Annual Cost to the Government

Item	Cost Per Year
Research Assistants ($45.33 loaded rate x 8,000 hours)	$362,640
Lab Fees ($110 x 3,750 participants)	$412,500
Shipping costs ($40 per shipment)	$12,480
TOTAL ESTIMATED COST TO GOVERNMENT PER YEAR OF DATA COLLECTION	**$787,620**

A.15. Explain the reasons for any program changes or adjustments in Items 13 or 14 of the OMB 83-I.

This is a new information collection. As such, it requires a program change to add the estimated hours for the new information collection to existing burden.

A.16. For collection of information whose results will be published, outline plans for tabulation and publication.

NHTSA plans to issue a final technical report on the study, and one or more journal articles may be submitted to refereed journals depending on the nature of the findings.

A.17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

NHTSA will display the expiration date for OMB approval.

A.18. Explain each exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions" of the OMB Form 83-I.

No exceptions to the certification are made.