Impaired driving continues to be a significant source of injury, death, and financial burden on society. Alcohol-impaired driving alone accounts for one-third of traffic deaths. Unlike alcohol, however, the prevalence of non-alcohol drugs among drivers remains relatively unknown. With the legalization of marijuana, emergence of the opioid epidemic, and results from National Roadside Surveys, it has become increasingly clear that there is a strong societal need to quantify the scope of drugged driving and its associated negative consequences. Unfortunately, the numerous publicly available traffic databases are notoriously flawed at assessing drugged driving. In 2018, the AAA Foundation for Traffic Safety (AAA Foundation) commissioned a study to assess the feasibility of developing a sentinel surveillance system for drug use by drivers in crashes (Kelley-Baker et al., 2019). Optimal standards for a database that could form a nationwide sentinel surveillance system were identified and included. Trauma center–related data was ultimately deemed to be the most feasible and viable approach for the development and creation of a sentinel surveillance system. The second phase of this project entailed pilot testing the implementation of this sentinel surveillance system at two trauma centers. This Brief describes the pilot test and related lessons learned, as well as barriers encountered in the development and implementation of such a surveillance system. Additionally, the study was used to develop a guidebook on how to implement a sentinel surveillance system for drug use by drivers in crashes.

METHODS

For the pilot testing phase, two Level I trauma centers were recruited: Carilion Roanoke Memorial Hospital (CRMH) in Roanoke, VA, and Wake Forest Baptist Health Medical Center (WFMC) in Winston-Salem, NC. Before data collection commenced, each organization’s Institutional Review Board (IRB) approved the pilot study. A small number of designated personnel available to work on the pilot study at each trauma center underwent training. These designated sentinel personnel were responsible for acquiring the blood specimens and associated information prior to de-identifying and storing the specimen for future shipment to the testing facility.

The population of interest in this study were trauma patients identified as the driver involved in a motor vehicle crash (MVC) or a motorcycle crash. Upon arrival at the hospital, as a part of standard care, multiple vials of blood are collected from patients for diagnostics and testing. An additional vial of blood was collected at this time for inclusion in the sentinel surveillance system. Basic information about the patient was also collected at the time the blood specimen was taken after which the specimen was de-identified and stored until it was sent out for comprehensive drug testing. Data were collected from December 2019 through November 2020; however, data collection was put on hold for five months during the COVID-19 pandemic as hospital procedures did not allow research personnel in the trauma bay. An independent toxicology lab was selected to conduct comprehensive testing. This included confirmation testing on blood for alcohol and a broad range of over-the-counter (OTC), prescription, and illicit drugs. These data formed the basis of the sentinel surveillance system. A centralized data repository to store the de-identified data was created and standards were developed for data collection to ensure all trauma centers, both current and future, collect and record identical information.
An implementation guidebook was developed based on the pilot study. These materials articulate the benefits of participation in a sentinel surveillance system, as well as create an easy, streamlined pathway for trauma centers to participate. The guidebook provides tips and resources for obtaining IRB approval, training research team personnel, developing data collection and repository protocols, as well as data analysis techniques and lessons learned. The pilot study resulted in the successful implementation of a sentinel surveillance system at two sites and the guidebook is intended to reduce the necessary time and resources spent on the development and implementation process to help create a broad and consistent network of additional sentinel sites.

RESULTS

Human Subject Protection
Acquiring IRB approval is one of the most important steps in the process of becoming a sentinel site. Obtaining a waiver of consent, which waives the requirement for obtaining informed consent from patients, is a critical element of IRB approval. This proved to be a lengthy process during the pilot implementation. In the pilot study, both IRBs were especially concerned with any potential for the patient to be identified or the data to be linked back to the patient. As a result, the patient- and crash-related information collected during the pilot study was minimal. Ideally, patient records would be linked to crash reports and toxicology results. Although not feasible for the pilot study given the conservative nature of the IRBs, linking these data is possible as was demonstrated in the NHTSA Crash Risk study (Lacey et al., 2016).

Personnel Training
All trauma personnel involved in the pilot study were trained to collect the needed data. As the pilot study was conducted at two trauma centers, it was quickly surmised that training needs will vary depending on the standard patient care procedures in place. However, broadly, it must be based on the steps identified when creating the data collection protocol. While the two pilot sentinel sites differed in terms of the number and type of personnel involved, the data collection steps were essentially the same at both sites.

Data Collection Protocols
Central to demonstrating the feasibility of the approach was developing a data collection protocol. Figure 1 illustrates the necessary key steps of the data collection process.
Patient Enrollment
The data collection process starts with a motor vehicle or motorcycle crash. The severity of the crash and the resulting injuries determine if the crash victim becomes part of the sentinel study. The patient enrollment step of the data collection process is activated by an incoming trauma alert indicating that a patient is en route. Once the team has confirmed the patient meets the inclusion criteria for the study (i.e., a driver involved in a crash; not a passenger or pedestrian), the data collection step commences.

Data Collection
Data collection involves obtaining a blood specimen from the patient, ideally as soon as the patient has an intravenous (IV) line inserted but before any additional medications are administered by the trauma team. Once the blood specimen is collected, the research team moves on to the next task, which involves obtaining and recording the pertinent patient information (e.g., age, sex). Additionally, EMS administered medications should be identified, including the name and dosage of each medication.

Data Storage
The data storage step involves storing the blood specimen until shipment to the toxicology lab and entering patient information into the data repository. Stored blood specimens need to be shipped to the toxicology lab on a regular basis (i.e., weekly or every two weeks) as storing the specimens for long periods of time may impact their quality. Patient information can be entered immediately or, if the trauma bay is busy, can be done as soon as time is available. In the pilot study, a secure web-based platform called REDCap was used for data storage. REDCap allows customizable data collection forms and data imports and exports to Excel or common statistical packages (e.g., SPSS, SAS) are straightforward. Both pilot sentinel sites had prior REDCap experience as it is commonly used for medical research.

Toxicology Testing
Many of the limitations of currently available drugged driving data arise from inconsistencies and lack of standardization in toxicology testing procedures and protocols. Toxicology laboratories differ in terms of equipment used, what drugs are tested, the types of tests conducted, the sensitivity of tests and the resulting cut-off levels. No national standard for drug testing currently exists; thus, it should be assumed that toxicology results from different labs are inconsistent. Ideally, to ensure consistent and comparable results across sentinel sites, a single toxicology laboratory should be chosen to mitigate these inconsistencies in equipment, protocols, and procedures.

Variability in drug test results largely stem from differences in the testing matrix (i.e., blood or urine), the drug panel, and the equipment and associated cut-off levels for testing. The importance of the testing matrix relates to the detection window for drug presence in drivers. Blood tests are considered the gold standard when it comes to drug testing as the results are more accurate and indicative of recent use. The chosen drug panel for the sentinel sites must be balanced between the desire to test for the presence of a large number of drugs against the cost of an extensive comprehensive drug panel.

As the pilot study was intended to test the data protocols and provide a foundation for expansion of the sentinel surveillance network, an extended drug panel was chosen in order to develop an understanding of the scope of drug use by drivers involved in crashes. The results of the pilot study can be used to narrow the list of drugs included in the drug panel, which may potentially reduce the overall cost of toxicology testing. The National Institute on Drugs (NIDA) emphasizes five substances important in testing: marijuana, opiates (including codeine, morphine, and heroin), amphetamines (including methamphetamine and ecstasy), phencyclidine (PCP), and cocaine (SAMHSA, 2017). This list should be considered the bare minimum drug panel for the sentinel surveillance system as it excludes an array of other potentially impairing drugs that may negatively impact driving.

Data Analysis
Data analysis techniques will vary depending on the data collected at each sentinel site and the sample size. Despite the potential differences in the detail of the data collected, the main focus of the analyses will be drug category prevalence stratified across other variables of interest, such as sex, age, and time and day of crash. The larger the sample size, the more specific the analyses. For instance, the pilot study collected blood specimens from 138 patients, which provided sufficient data to analyze by broad drug category (e.g., stimulants) but not by specific drug (e.g., methamphetamine).
Other issues to consider prior to data analysis is the exclusion of inactive metabolites and EMS-administered drugs detected in the toxicology results. The rationale for excluding cases that test positive for inactive metabolites only (e.g., Carboxy THC, Benzoylecgonine) is the highly variable time these metabolites can be detected in the blood, which may be weeks in some cases. Thus, a positive test result for an inactive metabolite provides no indication of when the driver consumed the parent drug or that they were impaired at the time of the crash. It merely indicates they used the drug at some point in the past. Excluding EMS-administered drugs from the toxicology results is critical to avoid artificially inflated prevalence rates of specific drugs. Fentanyl is an opioid commonly administered by EMS personnel, particularly to drivers seriously injured in a crash; not surprisingly, there were a large number of positive toxicology results for fentanyl. Approximately one-quarter of drivers tested positive for fentanyl; however, that dropped to under 7% when fentanyl administered by EMS was excluded. Thus, not excluding these data from the analysis would be extremely misleading.

**DISCUSSION**

The ultimate goal of this effort was to demonstrate the feasibility of the data collection protocol developed to support the implementation of a sentinel surveillance system. It is important to note that the results presented here are not generalizable but are included to serve as examples of data analyses and interpretation of results. Numerous caveats are associated with these data that illustrate the need to understand how the data collection process and related factors can impact the results. Critical to the interpretation and generalizability of these data is the occurrence of the COVID-19 pandemic, which not only shut down the data collection efforts for roughly five months but may also have fundamentally changed the drugged driving landscape and thus impacted the results of the pilot study. Indeed, an ongoing large-scale NHTSA study using a similar methodology found significant differences in drug and alcohol prevalence in drivers involved in crashes before and during the pandemic (Thomas et al., 2020).

Table 1 provides a summary of the data collected at each of the sentinel pilot sites, as well as the overall total across both sites combined. It may not always be advisable to combine data from multiple sites, particularly if there are too many differences between the data collection protocols used at each site. For example, in the pilot study, CRMH was only able to collect data on weekdays during the hours of 8am and 6pm, whilst WFMC collected data 24/7. The lack of nighttime and weekend data from CRMH could skew the conclusions if not factored into the interpretation of the analyses.

When including alcohol-positive results, between 50 and 60 percent of drivers tested positive for at least one drug and almost one-quarter tested positive for two or more drugs. Excluding alcohol and focusing specifically on non-alcohol drugs, roughly half of the drivers tested positive for at least one drug. A noticeable difference between the two pilot sites is in the prevalence of alcohol and cannabinoids. Alcohol prevalence, in particular, was surprisingly low at CRMH compared to WFMC (9% versus 27%). Critical to the interpretation of this finding is the understanding that a lack of specimen collection during late nights/early mornings and on weekends by CRMH would have impacted these results. Results of the NHTSA trauma center study (Thomas et al., 2020) indicate that prevalence of alcohol and cannabinoids is higher overnight and on weekends; thus, results from CRMH would likely be underestimations of drug prevalence. When looking at the two sites combined, the results indicate one in five drivers involved in a traumatic crash tested positive for alcohol or cannabinoids. Opioids were the next most prevalent drug category amongst seriously injured drivers, with almost 17% of drivers testing positive for an opioid. This was after EMS-administered opioids, such as fentanyl and morphine, had been excluded from the analysis.

**LESSONS LEARNED**

The development and implementation of the pilot sentinel surveillance system at two regional trauma centers highlighted a small number of elements that are crucial for success. Despite the differences between the two pilot sites, the lessons learned provide an invaluable resource for other agencies to build on in order to create a nationwide sentinel surveillance system. The factor that stood out above all others was the importance of effective communication. Establishing an open line of communication early on in the preparation phase, as well
as scheduling regular meetings with all stakeholders, is vital for success. The importance of communication also increases as the number of sentinel sites increases.

Streamlining the data collection and storage process is strongly advised. This reduces the chance of errors and mix-ups, especially at sentinel sites where a large number of personnel are involved in data collection. The pilot data collection protocol was developed in close collaboration with the principal investigator at each pilot site with some elements tailored specifically to each site to mitigate any sources of potential errors. Due to the de-identification process, most errors occurring during data collection cannot be rectified after the fact as the blood specimen and patient information cannot be linked back to the patient. Thus, early identification of errors is critical to avoid losing data.

The occurrence of the COVID-19 pandemic illustrated how important it is to be flexible and adapt as quickly as possible to changing situations. As the pandemic progressed, each trauma center faced increasing restrictions on staffing and limitations on the number of personnel allowed in the trauma bay. Eventually, all data collection activities were shut down by the IRB at each pilot sentinel site. Once research activities were allowed to recommence, it was at a reduced capacity at WFMC as non-vital research personnel were not permitted in the trauma bay. Thus, the pandemic had an undeniable impact on the pilot study as it interrupted data collection.
for approximately five months and the data that were collected were likely skewed due to changes in drugged driving behavior during the pandemic.

Despite the strict criteria to join a sentinel surveillance network, identifying barriers to participation and devising solutions and improvements to patient procedures allows more flexibility and creates a smoother path forward. One of the benefits of working with trauma centers is the inherent understanding of the value of research and the importance of collecting high-quality data. This makes it easier to argue the case for changing patient procedures or finding workarounds to current procedures in order to collect the required data. The staff and trauma surgeons at these facilities see first-hand the impact of drug-involved driving and have a strong desire to reduce its impact on the surrounding communities and society as a whole; thus, it will likely not be difficult to convince them of the benefits of participating in a sentinel surveillance system for drug use. Working with them to address any barriers to participation, using either new solutions or ones that have worked at other sentinel sites, will serve to increase and expand the sentinel network with the ultimate goal of creating a nationwide network of trauma centers collecting high-quality consistent drug data. Data from a nationwide sentinel surveillance system is critical to understanding the contribution of non-alcohol drugs and polydrug use to crashes and would allow effective drugged driving countermeasures to be developed and implemented. States often have very limited resources available to target drug-involved driving; thus, more useful, high-quality data would ensure these limited resources are put to good use.

REFERENCES


ABOUT THE AAA FOUNDATION FOR TRAFFIC SAFETY

The AAA Foundation for Traffic Safety is a 501(c)(3) nonprofit, publicly supported charitable research and education organization. It was founded in 1947 by the American Automobile Association to conduct research to address growing highway safety issues. The organization's mission is to identify traffic safety problems, foster research that seeks solutions and disseminate information and educational materials. AAA Foundation funding comes from voluntary, tax-deductible contributions from motor clubs associated with the American Automobile Association and the Canadian Automobile Association, individual AAA club members, insurance companies and other individuals or groups.

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