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A PILOT SENTINEL SURVEILLANCE SYSTEM FOR DRUG USE BY DRIVERS IN CRASHES

Lessons Learned & Recommendations

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AUTHOR INFORMATION

Naomi Dunn, Ph.D.
Senior Research Associate
Impaired Driving Research, Evaluation and Analysis (IDREA), VTTI

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EXECUTIVE SUMMARY

There are many traffic databases that offer high quality data on traffic outcomes (e.g., arrests, crashes, and fatalities), as well as contributing or other associated factors (e.g., alcohol impairment, vehicle type, driver age, driving history, etc.). However, non-alcohol drug data is notoriously difficult to collect and interpret. As a result, many traditionally ideal traffic databases like the National Highway Traffic Safety Administration's (NHTSA's) Fatality Analysis Reporting System (FARS) are inadequate for usage with non-alcohol drug data. Common barriers to the collection of high-quality non-alcohol drug data includes the necessity of complex drug testing equipment (i.e., no breathalyzer equivalent for non-alcohol drugs), the cost of toxicology testing, inconsistent procedures regarding who is tested and what tests are performed, and the emergence of synthetic or designer drugs that can evade detection. Yet, these prevalence data on non-alcohol drugs are critical to understanding the scope of drug-involved driving, developing effective countermeasures, and monitoring changing trends in drug usage and driving.

The goal of this guidebook is to lay the framework for developing and creating a sentinel surveillance system for drug use by drivers in crashes, which would fill this critical public safety gap. This guide outlines the pilot implementation process for a sentinel surveillance system at two Level I trauma centers: one in Roanoke, VA, and the other in Winston-Salem, NC. The four phases of developing and implementing a sentinel surveillance system (i.e., preparation, data collection, data storage, and data analysis) are broken down into smaller steps and each chapter uses examples and lessons learned during the pilot implementation to illustrate the process from start to finish. Each chapter also includes a short highlights section of important considerations when developing a sentinel surveillance system.

This guidebook demonstrates the AAA Foundation of Traffic Safety's continuous efforts to prioritize research aimed at understanding and preventing impaired driving.

CHAPTER 1: OVERVIEW

DRUG-INVOLVED DRIVING

In 2018, approximately 36,500 people were killed in motor vehicle crashes on roadways in the United States (NHTSA, 2019). Of those fatalities, almost one-third involved alcohol-impaired driving (CDC, 2019). However, it is largely unknown what role drugs other than alcohol play in crashes, injuries, and deaths on the roads. The prevalence of drug-involved driving[1], both in general and in crashes, is difficult to estimate for a multitude of reasons typically stemming from the difficulty in collecting and interpreting information on drug use among drivers. For example, the National Highway Traffic Safety Administration (NHTSA) Fatality Analysis Reporting System (FARS) provides yearly data on fatal crashes in all 50 States, plus Washington, D.C., and Puerto Rico. Notably, the FARS dataset includes alcohol and other drug data. However, there are enough limitations to the non-alcohol drug data that NHTSA released a research note strongly discouraging the use of FARS drug data for research purposes (Berning & Smither, 2014).

The limitations of drug-involved driving data, including FARS, arise largely from inconsistencies and lack of standardization in drug testing protocols and procedures. This lack of standardization impacts virtually all aspects of the data collection process for drug-involved driving, from the testing procedures used by law enforcement to toxicology laboratory procedures and protocols. A summary of these limitations and the impact they have on the availability of high-quality, consistent, non-alcohol drug data is provided below:

- **Differences in who is drug tested.** There are many differences in law enforcement protocols that determine who is drug tested. When looking specifically at crash-involved drivers, some states only test fatally injured drivers, whereas others also test surviving drivers. In regard to general drug-involved driving (i.e., not involving a crash), law enforcement officers follow local procedures. This may involve requesting a drug recognition expert (DRE), who is trained to detect driver drug impairment. If a DRE is not involved, or not available, it is up to the discretion of the law enforcement officer whether a driver is drug tested. No consistent policy specifying the circumstances under which a driver should be drug tested currently exists.
- **Blood alcohol concentration (BAC) stop-test limits.** Many states do not have separate driving under the influence (DUI) statutes for drugs and do not distinguish between drug-impaired and alcohol-impaired driving. Thus, if alcohol is present, the driver is typically

[1] Throughout this Guidebook, use of the terms *drugs* and *drug-involved driving* refers specifically to drugs other than alcohol.

not tested for other drugs. Toxicology testing is expensive, so having sufficient evidence for a DUI charge based on a BAC above .08 g/dL renders additional testing unnecessary for the judicial process (Berning & Smither, 2014). This lack of drug data for drivers who are alcohol-impaired results in biased databases that do not accurately reflect the true representation of the impaired driver.

- **Time between driving and specimen collection for toxicology testing.** Drugs can metabolize quickly to low concentrations or even completely outside of detectable ranges within a person, particularly shortly after use. Expeditious collection of biological samples for toxicology testing is critical to obtaining accurate assessments of drug presence at the time of driving. Unfortunately, the time between driving and specimen collection is rarely (if ever) collected and reported in drug-involved driving databases. In addition, samples for drug testing may be taken hours or even days after driving.
- **Differences in what drugs are tested.** The types of drugs that are tested and how many drugs are included in a drug panel varies greatly between states and jurisdictions. Drug tests are complex and require costly equipment, meaning comprehensive drug testing may not be feasible for many small labs. Additionally, the growing directory of drugs that may cause driver impairment, including the emergence of new drugs, provides unique challenges to analyses of suspected drug use (Richard, Magee, Bacon-Abdelmoteleb, & Brown, 2018).
- **Differences in the testing matrix.** The specific matrix (e.g., blood, urine, or oral fluid) used for testing significantly impacts the compounds being tested, detection windows for drugs, and the ability to meaningfully assess concentrations of a drug in a person's system. Thus, information on the drug matrix significantly impacts the usability and interpretation of drug results.
- **Differences in the types of tests conducted.** Depending on the procedures and equipment available at a toxicology lab, drug test results may be reported from screening or from confirmation testing. Screening refers to initial testing for a drug and is generally reported as a positive (i.e., non-quantitative) indicator of a broad class of drug. Most often, confirmation testing is then used to validate the screening results and provide a concentration of a specific drug. Accordingly, confirmation results are more reliable and provide more detailed information on drug presence. Unfortunately, most databases (e.g., FARS) currently do not differentiate between these types of testing. Furthermore, testing *positive* for a drug does not necessarily imply that a driver was *impaired*. Drugs metabolize in the body at different rates and the resulting metabolites may be present days, weeks, or even months after use.

- **Inclusion of drugs administered by medical personnel as part of treatment.** When a driver is involved in a crash resulting in severe injuries and/or fatality, driver specimens for drug testing will occur after emergency medical services (EMS) or medical personnel have treated the driver, either at the scene of the crash or en route to the hospital. Thus, positive toxicology results may include drugs that were administered as a part of treatment rather than drugs present in the driver at the time of the crash. The most common are opioids (e.g., fentanyl), opiates (e.g., morphine), and benzodiazepines (e.g., Valium). The result of this issue is an increase in false positives for these drugs.

When interpreting drug test results, it is crucial to remember that testing *positive* for a drug does not necessarily imply a driver was *impaired.* Drugs metabolize in the body at different rates and the resulting metabolites may be present for days, weeks, or even months after use.

- **Differences in toxicology laboratory equipment and procedures.** A great amount of variation exists between toxicology labs in the type and quality of drug testing equipment, which impacts the sensitivity of tests and the cut-off levels indicating the presence of a drug. For example, some labs use a cut-off level of 5 ng/mL of delta-9-tetrahydracannabinol (THC), while others may use a cut-off level of 1 ng/mL. No national standard for drug testing currently exists; thus, it should be assumed that toxicology results from different labs are inconsistent.

- **Interpretation and entry of drug data into a database.** Database administrators and analysts who enter drug results into databases may have difficulty obtaining the actual toxicology results from the lab, meaning they have to rely on second-hand sources of information (e.g., police reports). Additionally, the database may not be set up in a way that is conducive to entering all the necessary drug data, such as the type of test performed (i.e., screening versus confirmation testing), the drug panel used, or the complete list of drugs detected in each driver (e.g., can only enter three drugs in the database).

The limitations of the currently available drug data make it very difficult to understand the scope of the drug-involved driving problem. Moreover, the lack of comprehensive and uniform drug testing poses difficulties in understanding the true prevalence and frequency of drug-involved driving. A small number of studies have been conducted that provide the best estimates currently available for prevalence of non-alcohol drug use by drivers and crash risk associated with drug-involved driving. The National Roadside Survey (NRS) of alcohol and drug use by drivers was a nationally representative study to assess the prevalence of drug and alcohol use among drivers (Kelley-Baker et al., 2017). The NRS has been conducted five times since the 1970s; however, only the last two instances have included drugs other than alcohol. Importantly, the results of the

NRS conducted in 2007 and again in 2013–2014, allow for comparisons across time to investigate changing trends in drug-involved driving. Overall, results from 2013–2014 NRS indicated that 22.3 percent of daytime drivers and 22.5 percent of nighttime drivers were drug-positive. THC was the drug component most frequently detected in drivers in both waves of the survey. Results also indicated an increase in nighttime drug prevalence between 2007 and 2013–2014 (Kelley-Baker et al., 2017).

The NHTSA "Crash Risk" study was the first large-scale U.S. study to include drugs other than alcohol (Lacey et al., 2016). Using a case-control design, data were collected from over 3,000 drivers involved in crashes (i.e., cases) and 6,000 drivers not involved in crashes (i.e., controls). This allowed for a between-subjects comparison of drug and alcohol use by drivers involved in crashes with drivers not involved in crashes, resulting in an estimation of the relative risk of crash involvement associated with drug or alcohol use. After adjusting odds ratios for demographic variables that are known to impact crash risk (i.e., age, gender, and alcohol use), none of the drugs included in the study significantly contributed to crash risk. However, it is important to note that most crashes in this study were property damage-only. This bias towards less severe crashes may account for the lack of significant results regarding the impact of drug use on crash risk. Thus, future work should be extended to include the more severe crash cases. Alcohol was the largest contributor to crash risk, and drivers with breath alcohol concentration (BrAC) ≥ 0.05 were twice as likely to be involved in a crash. At 0.08 BrAC, drivers were 4 times more likely to be involved in a crash, and at 0.1 BrAC the crash risk increased to 6 times that of drivers with zero BrAC (Compton & Berning, 2015).

While the NRS and the NHTSA crash risk studies provide invaluable data on the prevalence of non-alcohol drug use by drivers and the crash risk associated with drug- and alcohol-positive driving, both of these studies were enormous and costly undertakings involving large research teams and collaborations with state and local law enforcement agencies. The rapidly changing landscape of drug use in the U.S. due to the legalization of medicinal and recreational cannabis, as well as the current opioid epidemic, has heightened the need for improved data systems related to non-alcohol drug use by drivers on the road and in crashes. High-quality and timely drug data is critical to understanding the role drugs play in motor vehicle crashes and for developing effective countermeasures to prevent traffic-related injuries and deaths.

SENTINEL SURVEILLANCE SYSTEMS

One potential solution for collecting data from drivers on drugs other than alcohol is to develop a sentinel surveillance system. The World Health Organization (WHO) defines a sentinel surveillance system as involving only selected surveillance sites, which enables the collection of high-quality data in a timely way that is representative of a national population with regard to demographics and geography. Data collected in a well-designed, consistently functioning sentinel system can be used to signal trends and monitor the burden of disease in a community (WHO, 2015). Whereas a passive surveillance system, such as the National Notifiable Diseases Surveillance System, which includes all the diseases and conditions under national surveillance, places the onus on healthcare providers and facilities to regularly self-report specific data, sentinel surveillance involves collecting data from a limited number of sites that are recruited to report all cases of a specific health event (CDC, 2020). While passive surveillance is most commonly used to detect and monitor vaccine-preventable diseases, **a sentinel surveillance is an excellent system for detecting large public health problems**, such as HIV/AIDS or influenza. Examples of sentinel surveillance systems include the WHO and the Joint United Nations Programme on HIV/AIDS (UNAIDS), which tracks trends and monitors HIV infection levels around the globe; the Philippine National Epidemic Sentinel Surveillance System, which has aided the Philippine Department of Health to detect and investigate outbreaks of typhoid and cholera (White & McDonnell, 2000); and a recent effort by the Public Health Agency of Canada investigating suspected opioid-related overdoses (Do et al., 2018).

According to the WHO, sites selected for inclusion in a sentinel surveillance system should have the following characteristics:

- Be limited in number
- Have a high probability of seeing cases
- Have good laboratory facilities
- Have experienced and well-qualified staff

Regardless of the targeted public health issue, partnerships are crucial to the success of a sentinel surveillance system. Sentinel sites need to collect high-quality, complete data for all cases that match a set of predefined conditions. These data may then be generalized to indicate trends in the target population. A properly designed and implemented sentinel surveillance system can be used to assess and monitor trends, determine prevalence and measure the burden of a disease or other public health issue, prioritize the allocation of funds and resources, target prevention and intervention strategies, and evaluate the effectiveness of programs and policies (Birkhead and Maylahn, 2000).

DATA NECESSARY TO DEVELOP A SENTINEL SURVEILLANCE SYSTEM FOR DRUG USE BY DRIVERS IN CRASHES

In 2019, the AAA Foundation for Traffic Safety (AAAFTS) reviewed the existing landscape to determine the feasibility of developing a sentinel surveillance system to investigate and monitor the involvement of drugs in motor vehicle crashes (Kelley-Baker et al., 2019). The objective was to identify existing sources of data and assess the feasibility of accessing and using those data for research purposes. Data sources were assessed based on a number of criteria related to data usefulness, quality and completeness of data, and the potential for data linkage and integration. Eleven optimal standards were established to evaluate potential data sources for inclusion in a sentinel surveillance system, with availability of objective drug test results for crash-involved drivers considered to be the most important. Two viable approaches were identified for the creation of a sentinel surveillance system. One focused on leveraging information found in federal, state, or privately managed transportation-related databases, such as FARS or the Model Impaired Driving Access System (MIDAS), which link a variety of existing documents and databases, such as driver history records, arrest records, and/or crash reports. The second approach comprised trauma-related data sources, including general medical databases, such as real-time data collected by trauma centers, and existing surveillance systems of drug use, such as the Minnesota Department of Health Overdose and Substance Abuse pilot study. Further investigation revealed that each approach had strengths and weaknesses that would provide some, but not all, of the information necessary for a more complete picture of the prevalence of drug use by drivers. The transportation-related data sources, for example, typically included an abundance of driver and crash information; however, the lack of consistent drug testing protocols across the various data sources was a major limitation. Trauma-related data sources, on the other hand, provided less driver/crash information but far superior information on driver drug use. Additionally, a major benefit of working with trauma centers is they often have an inherent research mission, which drives the goal to collect high-quality data.

Kelley-Baker, T., Anorve, V., Smith, R., and Dunn, N. (2019). *Data Necessary to Develop a Sentinel Surveillance System for Drug Use by Drivers in Crashes: A Review of the Existing Landscape* (Research Brief). Washington, D.C. AAA Foundation for Traffic Safetv

Ultimately, the trauma center approach was deemed to be the most feasible and viable option for the development and creation of a sentinel surveillance system for drug use by drivers in crashes. Level I trauma centers in particular were identified as offering the ideal opportunity for data collection because of the consistency of drawing blood for testing, the mandated research

mission, standardization of procedures, and high-quality staff with research training. The conclusion of Phase I of the development of a sentinel surveillance system was to partner with individual trauma centers across the United States, which would form the foundation of a pilot program to collect surveillance data from multiple locations using the same data collection protocol and procedures across all sentinel sites.

The goal of Phase II was the pilot implementation of the sentinel surveillance system to demonstrate the efficacy of the trauma center approach. As noted in the AAAFTS report, an effective sentinel surveillance system of drug-involved driving must contain the following (at a minimum):

- A representative sample of drivers
- Use of a comprehensive drug panel that will provide results on a substantial number of drugs
- Confirmation testing to provide quantitative drug test results, not just drug presence
- Timely collection and analysis of samples to provide near real-time prevalence estimates
- Continuous data collection methodology for future monitoring
- Consistent toxicology protocol across all sites (e.g., drug panel, testing matrix, cut-off levels)

The Virginia Tech Transportation Institute (VTTI) acted as the coordinating agency during the pilot implementation of the sentinel surveillance system and was heavily involved in all aspects of the study, including the recruitment of study sites. Two Level I trauma centers agreed to participate in the sentinel pilot implementation: (1) Carilion Roanoke Memorial Hospital (CRMH) in Roanoke, Virginia; (2) Wake Forest Baptist Health Medical Center (WFMC) in Winston-Salem, North Carolina.

GUIDEBOOK LAYOUT

This guidebook summarizes all the necessary information required to develop and implement a sentinel surveillance system for drug use by drivers in crashes based on what was learned from working with CRMH and WFMC during the pilot implementation. It is designed to provide insight into all elements of the process, from the development of the data collection protocol and institutional review board (IRB) applications, to the selection of a toxicology testing laboratory and creation of a data repository. The guidebook also includes details of lessons learned and barriers encountered during the development and implementation of the pilot program in order to help new potential sentinel sites navigate the process more easily. The ultimate goal of the guidebook is to facilitate the growth of this sentinel surveillance network to other trauma centers across the United States.

There are four phases in the creation and execution of a successful sentinel surveillance system (Figure 1) and this guidebook will lead the reader progressively through each phase. Each phase may include more than one step, particularly the initial preparation phase, which is arguably the most crucial.

Figure 1. The four phases of implementing a sentinel surveillance system

Phase 1: Preparation

This covers the initial steps to creating a sentinel surveillance system and lays the groundwork for subsequent phases. The preparation phase includes information on identifying potential sentinel sites, forming research teams, submitting an institutional review board (IRB) application, developing a data collection protocol, creating training materials, and training research personnel. Time and effort expended in the preparation phase will lay a solid foundation on which to build the sentinel surveillance system.

Phase 2: Data Collection

Once all approvals are in place and personnel are trained, the data collection protocol developed in Phase 1 is implemented and data collection commences. The data collection phase covers liaising with trauma centers and the third-party toxicology laboratory to ensure the process is running smoothly and to keep track of progress.

Phase 3: Data Storage

Developing a data repository is necessary to store patient information and toxicology results. Consider project and data sharing needs when deciding on a software platform.

Phase 4: Data Analysis

Data analysis techniques will vary from project to project and will largely be dictated by sample size. Analyses may include frequencies of drug-positive results, prevalence calculations, and comparisons of mean drug concentrations.

CHAPTER 2: GETTING STARTED

The process of establishing a program such as a sentinel surveillance system is heavily reliant on identifying the right people within a hospital that are interested in getting involved. This can be more difficult than it sounds. Initial discussions are typically conducted via email or on the phone, which makes it easier for people to either ignore the initial contact (i.e., particularly if it is an email) or shut down the idea before it has been fully explored and explained. During Phase I, the coordinating agency quickly realized that it was important to contact people within the trauma department rather than the hospital in general. Since the trauma team is typically a smaller subset of emergency doctors and support personnel, the process of identifying the appropriate person with whom to open a dialogue should be easier. Level I trauma centers also have strong ties to universities, meaning they have a fundamental understanding of the value of research. **Initial talking points with trauma center contacts should focus on the need for quality drug-involved driving prevalence data and ways the proposed sentinel surveillance system could address the issue.** Doctors who work in emergency and trauma medicine have inevitably seen the devastating results of alcohol- and drug-impaired driving, so it should not be overly difficult to convince them of the value of this research. **Be prepared with responses to questions about patient confidentiality and privacy; these issues will likely be raised early in the conversation.**

> Introductory conversations should focus on the need for quality drug-involved driving data and ways a sentinel surveillance system can address the issue.

IDENTIFYING POTENTIAL SENTINEL STUDY SITES

Initial contact with potential study sites needs to focus on a number of issues that are critical to the implementation of a sentinel surveillance network. First and foremost, **the specimen collected from each patient for use in the study must be blood**. If hospital protocols, or available resources, only allow for the collection of urine, then the study site is not a viable option to include in the sentinel network.

Also of importance, especially given that sites may be spread over the entire country, is the **attitude of the potential research team**. Are they responsive to emails and phone calls? Are they helpful when a request is made? Do they see the importance of the project and want to work together? The project relies on extensive collaboration between multiple parties. Unresponsive, uninterested partners jeopardize its success.

Finally, a study site needs to be able to **identify if a patient was a driver (i.e., not a passenger) involved in a motor vehicle or motorcycle crash**. This depends on the level of information acquired from, or reported by, EMS personnel. Selecting potential sites based on these criteria will create a smoother path forward; however, depending on what is "missing" from a potential site and whether it can be improved, all Level I trauma centers should be considered for participation.

FORMING A RESEARCH TEAM

The coordinating agency is responsible for creating the research team and managing the project. The role of the coordinating agency will likely vary somewhat, depending on agreements between stakeholders in the project. Tasks may include recruiting new study sites, training research personnel at each site, liaising with the project sponsor(s) and toxicology laboratory, managing the data repository, and ensuring that each study site has the equipment and materials (e.g., shipping materials, blood vials, data collection forms) required to effectively participate in the sentinel surveillance system. During the pilot implementation, VTTI managed all aspects of the study and worked closely with the principal investigator (PI) at each pilot site when developing the data collection protocol and IRB application. VTTI also worked with the project sponsor (AAAFTS) to identify an independent toxicology laboratory and with data management experts to create the data repository.

When recruiting new study sites, the value of **identifying a champion for the project within a study site** cannot be overstated. The two sites that were successfully secured for the pilot implementation were largely the result of the support of one person at each site. For example, at the CRMH, the PI for the pilot implementation was the Chair of Emergency Medicine. In addition to seeing the value of the project itself, he had extensive prior experience with the IRB process and understood the intricacies of what it would take to get a protocol requiring a waiver of consent approved by the IRB. He assisted and provided phone support for the WFMC IRB application as well, which would not have been approved if he had not been involved and had the knowledge to negotiate the path forward. Thus, it is critical for success in getting started to have a person who strongly supports the project and will do what it takes to get things approved and set up. The PI from WFMC was also instrumental in getting the second study site up and running as she pursued appeals related to the IRB's initial decision to deny a waiver of consent, as well as bringing residents and medical students on board to assist with 24/7 data collection.

Another critical member of the research team is the project manager. Given the scope of work, this was a paid position covered by the subcontracts in place at both pilot study sites. Although the project manager position can be filled by either a new hire or an existing employee, an existing employee will presumably have more in-depth knowledge about the workings of the hospital and patient procedures. Both pilot sites assigned an existing employee to the project manager position. Once the project has been approved and is ready to commence data collection, the project manager is the person who will run day-to-day operations at the site. Responsibilities of

the project manager may include data collection, data entry, packing and shipping specimens, supervising research staff or students who are working on the project, keeping track of missed patients (i.e., patients who fit the criteria for inclusion in the study but from whom a specimen was not collected), and generally ensuring that the project runs smoothly. The project manager at WFMC, for instance, came up with the idea to create individual packets containing all the supplies needed to collect data from each patient as they are admitted to the trauma bay (see Figure 4 in Chapter 6). Each packet contained a prelabeled blood vial and data collection sheet, both of which were assigned the same specimen number. These packets were kept in a specific location within the trauma bay so the person collecting the specimen could easily grab one and know they had everything they needed. Organization is key, particularly if many people are contributing to the data collection effort. Around-the-clock data collection at WFMC required the use of second- and third-year medical students, so the process needed to be as straightforward as possible to avoid any confusion or issues.

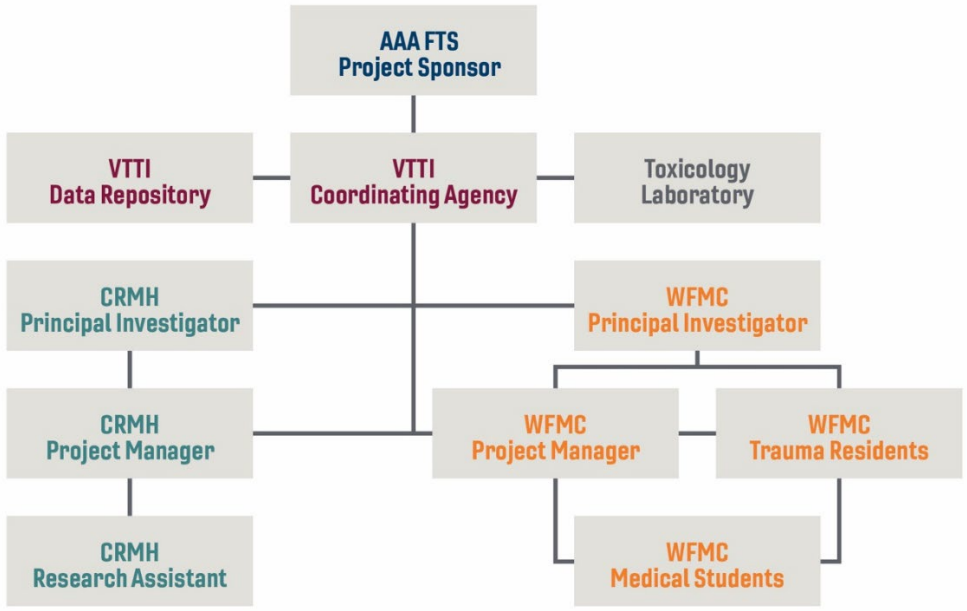


Figure 2. Organizational chart for the pilot implementation of a sentinel surveillance system

Figure 2 provides an overview of the organizational structure at the two pilot sites. VTTI acted as the coordinating agency and manager of the data repository. The PI from VTTI also liaised with the project sponsor (AAAFTS) and the toxicology laboratory. In the case of the two pilot sites, the organization of each independent research team differed depending on the availability of staff, residents, and medical students for data collection purposes. CRMH was not able to utilize residents or medical students, and thus relied solely on the project manager and a research assistant to collect data. As a result, unlike WFMC, CRMH did not have the capacity to collect data around-the-clock. The research team from WFMC comprised a larger number of people in order

to have around-the-clock coverage, with the trauma residents overseeing the medical students for data collection after hours and on weekends. The project manager was responsible for data collection during regular workdays (i.e., Monday to Friday, 8 a.m. to 5 p.m.) and also ensured all necessary materials were available in the trauma bay for the after-hours data collection team. The PI at each pilot site regularly communicated with the project manager, as well as with the PI from VTTI, to provide updates and figure out solutions to any problems that arose. The PI at WFMC also oversaw the trauma residents and medical students to make sure everyone involved in the data collection process was trained and followed the data collection protocol.

DEVELOPING A DATA COLLECTION PROTOCOL

Once members of the research team have been identified, discussions can begin regarding the data collection protocol. This is essentially the step-by-step breakdown of how the data collection process will work. **The PI and the project manager are crucial for this step of the project** as they have working knowledge of the patient admission process and ways to collect the necessary blood specimen and patient information without impacting the ability of the trauma team to care for the patient. For instance, the PI from CRMH indicated early on that the data collection needed to focus on the top two levels of trauma patients in order to ensure a blood specimen could be collected from every qualifying patient. The reason for this was that collecting blood is part of the "standard care" for level 1 and level 2 trauma patients; thus, acquiring a blood specimen was easy. Level 3 trauma patients, on the other hand, may not need to have blood drawn as part of their care. For example, a driver may only have broken bones and be sent from the trauma bay to orthopedics for x-rays. In this instance, blood does not need to be drawn and collecting a blood specimen for the sentinel study would require patient consent.

The PI and the project manager will also have valuable information on what is communicated by EMS personnel on arrival with the patient. The research team needs information regarding drugs that were administered by EMS personnel at the scene of the crash and/or en route to the hospital, as well as whether the patient was a driver involved in the crash. There appears to be substantial variation between hospitals as to how EMS personnel communicate this information to the research team. Some hospitals reported using an electronic system for EMS records; however, the turnaround time for record availability was weeks in some cases. Thus, verbal communication between EMS personnel and the research team was

The sentinel data collection protocol provides a step-by-step breakdown of the data collection process, including the following:

- Patient enrollment
- Blood specimen collection
- Collection of patient information
- Data storage
- Shipment of samples

agreed upon as the best way forward. Obviously, verbal communication relies on a member of the research team being present and ready in the trauma bay as soon as a qualifying patient is admitted to accurately collect and record the required information. Refer to the Step-by-Step Reference Guide in Chapter 4 for a complete list of the information obtained from EMS personnel at the pilot sites.

The final step in developing the data collection protocol involves tracking missed patients. In order for the resulting dataset to be useful for prevalence calculations, the total number of qualifying patients' needs to be known, not just the number of specimens collected. CRMH, for instance, had numerous days over the Christmas and New Year holiday period when no research staff were available; thus, a number of qualifying patients for the study were missed. The project manager tracked these via the trauma alerts that were being sent to his phone. Not knowing how many samples were missed will lead to unreliable and incorrect prevalence numbers.

ALTERNATIVE DATA COLLECTION PROCEDURE

The data collection protocol presented here is by no means the only method that should be considered when implementing a sentinel surveillance system for drug use by drivers in crashes. In fact, other studies carried out in the past or currently underway have collected the same types of information and data to address the lack of quality drug-involved driving data available. Indeed, some have collected more detailed data than the current study, including variables such as specific time of day and day of the week, as well as police crash reports and information from patient records. The NHTSA Crash Risk study (Lacey et al., 2016), for instance, matched crashes to control drivers (i.e., those who did not crash) based on the location of the crash, time of day, day of week, and direction of travel when the crash occurred.

A data collection procedure used by a Canadian research team (Brubacher et al., 2019; Masud et al., 2020) provides a valid alternative to the method presented here. This team worked with multiple hospitals to obtain samples of "leftover" blood taken from non-fatally injured drivers who were treated at the emergency department (ED) following a crash. Eligible drivers were identified via the ED logs, and the patient chart was then reviewed to confirm eligibility. Similar to the protocol used in the pilot study, a waiver of consent was obtained in order to reduce bias (e.g., drivers who had consumed drugs before the crash, or who were drug-impaired, would be less likely to consent to participate). Leftover blood that was obtained for clinical reasons (i.e., that would otherwise be discarded) was used; thus, no extra blood was taken using this methodology. This also meant that any instances where there was no leftover blood resulted in a missed sample. A temporary link was created between the patient record and the randomly assigned study ID number to allow

> Alternative methods exist to collect similar types of information and data to create a sentinel surveillance system.

for specific patient identifiers to be matched to the relevant blood specimen. Patient records provided a wealth of additional information, including crash time and date, crash and vehicle type, medical history (including prescription medications used and documented alcohol and drug use), and medications given as part of clinical care prior to the blood draw (e.g., EMS-administered drugs given at the scene of the crash). An additional analysis of the same data used patient identifiers from patient records, including name, age, sex, and date of crash to obtain police crash reports, where available, via probabilistic linkage. This analysis investigated crash responsibility of THC-positive drivers compared to those who tested negative (Brubacher et al., 2019).

Thus, **the information and variables obtained for the pilot implementation of the sentinel surveillance system covered in this guidebook should be considered the bare minimum**. During the development of the data collection protocol, in-depth discussions need to be had with the PI from each study site to determine the level of detail that they think their respective IRBs will approve. Often this will come down to how conservative the IRB is and whether similar studies have been approved in the past. For example, the CRMH IRB would not approve collection of either time or date of crash, even at a broad level of categorization, such as weekday versus weekend or daytime versus nighttime. The reason was that, during certain times of the year, CRMH may have very few high-level motor vehicle crash (MVC) trauma patients, so time and date of crash may be considered identifying information. The WFMC IRB, on the other hand, approved the collection of time and day information but only at the very broad level mentioned above. The PI from each study site should have sufficient experience with their IRB to provide guidance and input into what they think will be approved and what should be avoided or where to tread carefully. The ideal, if possible, is to obtain IRB approval to link patient records and police crash reports. The more information about the driver and the crash, the better.

CHAPTER HIGHLIGHTS

- ✓ Initial talking points with trauma center contacts should focus on the need for quality drug-involved driving prevalence data
- ✓ Issues about patient confidentiality and privacy will likely be raised early in the conversation so be prepared with responses.
- ✓ When identifying potential sites:
    - Ensure the specimen collected from each patient for use in the study will be blood.
    - Ensure the ability to determine if the patient was a driver (i.e., not a passenger).
    - The attitude of the potential site is critical. The less enthusiastic, responsive, and engaged they seem, the more difficult the process will be.
- ✓ When forming a research team:
    - Identifying a champion (PI) for the project within a study site cannot be overstated.
    - The project manager at each study site is also a crucial member of the research team.

CHAPTER 3: INSTITUTIONAL REVIEW BOARD (IRB) APPLICATION

Possibly the most important step in the entire data collection process is acquiring IRB approval. Although every institution will have different requirements and expectations of researchers when submitting IRB applications, there are some fundamental points that need to be well articulated and emphasized for this project to have a better chance of being approved by the trauma site's IRB.

REQUESTING A WAIVER OF CONSENT

A waiver of consent waives the requirement for obtaining informed consent from participants in a research study.

The waiver of consent was a sticking point for both of the pilot sites. Neither IRB had ever approved a project requesting a waiver of consent in the past. The PI from CRMH was the main reason both sites received IRB approval as his knowledge of the process and how to present the information to the Board helped secure their confidence in the proposed protocol.

The waiver of consent is often vital to the data collection procedure for a number of reasons. Firstly, accompanying the waiver of consent is a very strict de-identification process, which protects the patient from legal, insurance, or personal ramifications or repercussions from the results of the toxicology testing on the blood specimen. If a patient has to sign a consent form, strict safeguards have to be in place so that results are not traced back to the individual. This is often very difficult, and convincing an IRB of the protections is challenging. In addition, if a patient is traumatically injured, they may be unconscious or unfit to give informed consent; if this happens, a family member would need to be involved to provide consent on behalf of the patient. This could add to the trauma of the situation for family members who are already involved in a highly stressful situation which, again, concerns an IRB.

A waiver of consent is crucial for the sentinel surveillance system:

- Strict de-identification process protects the patient
- Incapacitated patients cannot give consent
- Reduces potential bias
- Ensures a representative sample

A waiver of consent is beneficial because the act of requesting consent can bias the sample. Someone who is impaired by alcohol and/or drugs and admitted to a hospital following a crash may be very unlikely to agree to have a blood specimen taken for toxicology testing, given fears that it can be used against them as evidence of a DUI/driving under the influence of drugs (DUID) charge. Thus, the patients who are most likely to consent to participate might be ones who would not have tested positive anyway. This is not always the case, but it is important to consider.

Finally, the waiver of consent is necessary to ensure a representative sample; i.e., that all traumatically injured drivers involved in a motor vehicle or motorcycle crash are included in the study. If the sample only includes a selection of drivers who consent to participate, the sample is no longer representative of all traumatically injured drivers as it does not include those who refused to give consent.

For the sentinel pilot study, the CRMH IRB deemed the waiver of consent justified with a stipulation that the research team also obtain a Certificate of Confidentiality (CoC) from the National Institutes of Health (NIH) in order to further protect the participants.

From the NIH website, **"Certificates of Confidentiality (CoCs) protect the privacy of research subjects** by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations." Given the de-identification process that was used in the sentinel pilot study, the associated data was not identifiable anyway; however, the IRB requested the CoC. The CRMH PI submitted the appropriate paperwork to the NIH and obtained one. **Acquiring a CoC may make an IRB feel more secure in their decision to approve a study with a waiver of consent, making it a good suggestion to keep in reserve to propose as a way forward if the IRB seems unsure of approving the protocol**. Once the CRMH IRB had officially approved the project, the documentation was sent immediately to the WFMC IRB as a reassurance that the protocol met the conditions for a waiver of consent to be granted. The research team managed to provide the

According to IRB regulations, five conditions need to be met for a waiver of consent to be granted:

1. The research involves no more than minimal risk to the subjects
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects
3. The research could not practicably be carried out without the waiver or alteration
4. Whenever appropriate, the subjects will be provided with additional pertinent information for participation
5. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format

WFMC IRB with enough evidence and assurances that the study met the "minimal risk" criteria, and they approved the application without requiring an additional CoC. A multi-site CoC is also available, which would cover all sites and is managed by a designated lead site. **Thus, while the sentinel sites function independently from each other and are overseen by a coordinating agency to ensure that each site runs effectively, it is critical that the sentinel sites also understand they are part of a network that can support each other in order to grow the sentinel network.**

IMPORTANCE OF LANGUAGE AND JUSTIFICATION IN THE IRB APPLICATION

The concept of "minimal risk" is crucial for any IRB application. Minimal risk is defined in IRB regulations as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." Thus, the de-identification process during the data collection phase is the most significant piece of an IRB application in order to ensure that patients are not subjected to greater than minimal risk. In the pilot study, both IRBs were particularly concerned with the possibility that various pieces of information, if collected, could be used to trace the sample and test results back to the patient. **When writing the IRB application, take every opportunity to emphasize that no identifying information will be recorded at any point in time and the blood specimen will be immediately de-identified upon collection.** The data collection protocol used in the pilot implementation hinged on the blood specimen being collected from the patient and immediately being assigned a random sample ID number.

As an example of the language used to address the IRB criteria for a waiver of consent, the CRMH PI highlighted some critical pieces of information in the IRB application:

1. **The research involves no more than minimal risk.** Minimal patient information will be collected from an eligible patient's chart: age, sex, and EMS report detailing medications administered while in transit to CRMH. All information collected will be completely de-identified. Additionally, all de-identified information will be stored in a secure, online database. The study population will be patients presenting to CRMH after a motor vehicle or motorcycle crash. In addition, the eligible patient must be the driver of the vehicle and presenting to CRMH as a level 1 acuity patient (i.e., trauma alert or gold alert). The workup for a patient of this acuity includes starting IV access and a plethora of blood samples. Drawing an additional ~2 cc blood sample for a serum drug test is negligible. The blood specimen will not be used for genetic testing and will be destroyed after the serum drug test is completed and entered into the database. The blood specimen will be de-identified and labelled with a study number. The study blood specimen will not be entered into the patient's chart; thus, the patient will not be charged for the blood collection. The study blood specimen will be stored in the CRMH lab until transfer to the toxicology lab.

All possible risks to the subjects can only be minimized if a waiver of consent is granted. The waiver of consent will allow the CRMH research team to collect the blood specimen and patient demographics then immediately de-identify this information prior to storing the specimen for later shipment and toxicology testing. If informed consent were required from the patient, this would likely need to occur at a later date due to the condition of the patient on admission to the trauma center (i.e., the patient may be unconscious or severely injured; thus, would be unable to provide consent at the time of admission). If the patient were to die during treatment, consent would need to be acquired from next of kin, which would be highly stressful and inappropriate at any point after data collection has occurred. Following up with a patient at a later date to acquire informed consent means the blood specimen would need to be linked to the patient, which would introduce a whole host of potential issues, including psychosocial harm, economic harm, and legal jeopardy if the patient's blood specimen tested positive for drugs. The waiver of consent and immediate de-identification of the data is the ideal way to minimize all future risks to the patient as no information will be linked to them at any point, which means the results of the toxicology testing cannot be linked back to them in any way either. Breach of privacy or confidentiality will not be an issue as all samples and information will be immediately de-identified and blood specimens will be destroyed by the toxicology laboratory once testing is complete.

2. **The waiver will not adversely affect the rights and welfare of the subjects and the research could not practicably be carried out without the requested waiver.** Patients meeting eligibility for this research study will require a treatment plan for a critically ill individual and in most cases, the study patient will be critically ill/severely injured. There are three reasons for the request to waive informed consent. First, this is a minimal risk research study. There will be no additional procedures performed. Only ~2 cc blood collection and minimal information pulled from the patient's chart. Second, the majority of eligible patients will have some form of altered level of consciousness (ALOC) or altered mental status (AMS); the mechanism of this either from the severity of their sustained injuries or medications administered by EMS or medical personnel. Third, attempting to obtain written or verbal consent would interfere with the patient's workup/treatment in the trauma bay and ED in general.

It is important to consider what information can be potentially identifiable. Obvious identifiable information includes name, address, social security number, driver license number, and crash report number, among others. For the pilot study, only basic patient demographics, such as sex and age category, were collected. Age can be categorized in a variety of ways depending on how specific the information needs to be. Given the conservative nature of the IRBs from the pilot sites,

the age categories needed to be relatively broad to avoid the collection of data deemed identifying. The two IRBs from the pilot sites approved the following sex and age categories:

- Sex
  - Male
  - Female
- Age Category
  - 18–21 years
  - 22–29 years
  - 30–39 years
  - 40–49 years
  - 50–59 years
  - 60–69 years
  - 70–79 years
  - 80+ years

Other studies, such as the NHTSA Crash Risk study (Lacey et al., 2016), received IRB approval to collect far more detailed patient information; thus, working closely with the PI from the study site is highly recommended to determine the level of information that they think will be attainable from their IRB. **The ideal, if possible, is to obtain IRB approval to link patient records and police crash reports. The more information about the driver and the crash, the better.**

One not so obvious piece of information is "time and day of crash." Unfortunately, given the conservative nature of the two IRBs from the pilot sites, time and day of crash and/or time and day of specimen collection were deemed "identifying" and were removed from the data collection protocol. Understandably, in hospitals that have a low volume of high-level trauma patients, these variables could be considered identifying. If the trauma bay only had one patient admitted on a Tuesday at 2 a.m., then linking those pieces of information to patient and crash records is a possibility. The WFMC PI successfully appealed to the IRB to allow for the collection of broadly categorized time and day of specimen collection. As a result, the IRB allowed the following time and day variables to be collected:

- Day of specimen collection
  - Weekday (Monday 6:01 a.m. to Friday 6 p.m.)
  - Weekend (Friday 6:01 p.m. to Monday 6 a.m.)
- Time of specimen collection
  - Day (6:01 a.m. to 6 p.m.)
  - Night (6:01 p.m. to 6 a.m.)

Although these categories are very broad, they allow for analysis based on weekend versus weekday and daytime versus nighttime, which are crucial in terms of prevalence estimates. Depending on the IRB, more detailed information may be achievable; however, for the pilot study, this was all that could be done for one site only. The CRMH IRB refused to approve even these broad categories.

Additional elements on which to focus in the IRB application include the lack of prevalence data available for non-alcohol drugs and how the results of this study will help researchers better understand the drug-involved driving landscape and develop more-effective targeted interventions. It is also important to highlight that the blood specimen is collected as part of the blood drawn for standard care and treatment. Treatment for high-level trauma patients includes starting IV access immediately upon admission for a plethora of blood samples; thus, one extra blood vial (i.e., approximately 2 cc) is negligible. No additional procedures will be performed on the patient and the blood specimens collected for research purposes will ideally be analyzed through a third-party toxicology laboratory; thus, the research will not interfere with the patient care or treatment procedures.

CHALLENGES AND LESSONS LEARNED

The most difficult and surprising element of the sentinel pilot implementation was the lengthy IRB approval process; therefore, it is important to prepare an application as soon as possible. As mentioned earlier, this may have been unusual given that neither IRB had previously approved a waiver of consent, so the conservative nature of these IRB panels caused extensive delays. Unfortunately, once the process is underway, nothing can be done to speed it up. Prompt responses to requests for documentation from the IRB is the only way forward until a decision is made. The CRMH IRB also only met once each month. For each time additional documentation or follow up was requested, there was another month to wait until the Board would meet to discuss the protocol again. This may not be the case for all IRBs, particularly those associated with larger hospitals that meet more frequently or those that are more comfortable and experienced with requests for a waiver of consent.

Both IRBs were especially concerned with any potential for the patient to be identified or the data to be linked back to the patient. It is critical to highlight and emphasize the immediate de-identification of blood specimens in the IRB application whenever appropriate. Without this, the waiver of consent will likely be denied, and the protocol will no longer be viable. Offering to obtain a CoC can provide an additional assurance of patient confidentiality. **Above all, have the PI promote and champion the project with the IRB to help convince them of the worthiness of the study.**

CHAPTER HIGHLIGHTS

- ✓ The waiver of consent is vital to the data collection procedure in this project.
- ✓ A CoC protects the privacy of research subjects. Acquiring a CoC may make an IRB feel more secure in their decision to approve a study with a waiver of consent.
- ✓ While the sentinel sites function independently from each other, it is critical that the sites also understand they are part of a network that can support each other.
- ✓ Note the following when writing the IRB application:
    - Take every opportunity to emphasize that no identifying information will be recorded at any point in time and the blood specimen will be immediately de-identified upon collection.
    - It is important to consider what information can be potentially identifiable. Extra measures need to be put into place when dealing with personally identifying information.
- ✓ Ideally, try to obtain IRB approval to link patient records and police crash reports. The more information about the driver and the crash, the better.
- ✓ The IRB approval process was surprisingly lengthy. Prepare an application as soon as possible and quickly address any issues or requests for further documentation in order to keep the process moving.
- ✓ Above all, have the PI promote and champion the project with the IRB to help convince them of the worthiness of the study.

CHAPTER 4: TRAINING RESEARCH PERSONNEL

One of the benefits of working with Level I trauma centers is that the trauma team is typically a small, designated group of doctors and nurses who are extremely well-trained and have very specific roles to fill when dealing with a traumatically injured patient. **Training research personnel to efficiently collect the data needed for the sentinel study is vital to ensure that no disruption or interference is created with any other trauma team members**. Training will be based on the steps identified during the creation of the data collection protocol, and each sentinel site will likely vary slightly depending on the standard patient care procedures that are currently in place.

Benefits of working with Level I trauma centers:

- Small team of highly skilled, well-trained doctors and nurses
- Capable of providing care to patients regardless of injury severity
- Understand the value of research and the importance of collecting high-quality data

The two sentinel sites included in the pilot study differed largely in terms of the number of personnel who would be involved in the data collection process, but the steps to obtain the data were largely the same. The research team at CRMH, for example, comprised three people: the PI, who was also the head of Emergency Medicine; the project manager, who was responsible for the day-to-day running of the project; and an additional research team member, who provided back-up coverage when the project manager was unavailable. The WFMC team, on the other hand, included the PI and the project manager, as well as at least a dozen other research staff, residents, and medical students. The availability of the medical students and residents was the difference between the two pilot sites in terms of the capacity to collect data around-the-clock every day of the week. Lack of available staff at CRMH limited their capacity to collect data 24/7.

Training at each sentinel site covered all the steps involved in sample collection and de-identification, gathering associated patient information, storing blood samples, entering patient information into the data repository, and packing samples appropriately for shipment to the toxicology laboratory. Additionally, it is vital for the research team to understand the background of the study and the reasons this data collection effort is needed. **Highlighting the major limitations of the currently available drug-involved driving data and the ways a sentinel surveillance system would address those limitations helps the research team recognize that they are contributing to an important and unique data collection effort.**

Training at each site took approximately two hours and comprised a PowerPoint presentation, a short step-by-step version of the data collection protocol (included below), a demonstration of

data entry into REDCap (the data repository used by the pilot sites), and a demonstration of the packing and shipping procedure. The training wrapped up with question and discussion time. During the pilot implementation of the sentinel surveillance system, the PI from the coordinating agency, in this case VTTI, led the training at the two pilot site locations. The PI and project manager from each site were required to attend the training. Additional personnel who played a role in the data collection process, such as trauma residents who were supervising the data collection process at WFMC, were also strongly encouraged to attend the training; however, given the 24/7 nature of a doctor's schedule, the trauma residents were not all able to attend the training session. In these instances, it was the job of the PI from the sentinel site to ensure that the residents knew and understood the data collection protocol and study requirements.

EXAMPLE STEP-BY-STEP REFERENCE GUIDE

During training at the pilot sentinel sites, research personnel were provided with an easy-to-use, step-by-step reference guide that summarized the steps of the data collection process and provided the link to the REDCap data repository. This reference guide is especially important for sentinel sites with larger research teams, such as WFMC, to ensure that all research personnel participating in the data collection process have a resource on-hand to guide them, if necessary. The project manager from the WFMC research team always kept copies of this reference guide in a designated space in the trauma bay where other project supplies, including data collection packets, were stored. If a member of the research team was unsure of the process and the PI was unavailable to answer questions, they could consult this reference guide and move through the data collection steps easily.

The reference guide needs to be tailored to each individual sentinel site and cover all the steps in the data collection process in enough detail to guide someone through, but without so much detail that the guide becomes burdensome. The following is a generic version of the reference guide that can be modified as necessary for use at different sentinel sites.

A generic version of the PowerPoint presentation given at both pilot sentinel sites is included in Appendix A. Site-specific details have been removed, but the basic structure and flow of information remains unchanged. The most important points to highlight include the immediate de-identification of the blood specimen and ensuring the same Sample ID number is assigned to the blood specimen and the patient information recorded for the study. This presentation can easily be adapted to incorporate site-specific details of the research study and any additional information that may be important at each location.

Step-by-Step Guide to Developing a Sentinel Surveillance System for Drug Use by Drivers in Crashes

Specimen Collection Protocol

The population of interest for this study is trauma patients who have been identified as a 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 testing. An additional vial of blood will be collected at this time for inclusion in the sentinel surveillance system.

Patient Inclusion Criteria:

- Driver involved in a MVC or motorcycle crash.
- Patient is identified at a trauma level requiring blood drawn as a part of standard care.
- Patient is 18 years of age or over.

Specimen Collection:

1. Once a qualifying patient enters the trauma bay, collect an additional vial of blood for testing using a special color cap (i.e., gray) research blood vial.
2. Add a sample number label (e.g., C7337 or W1543) to the blood vial from the label sheet on the clipboard.
3. On the Sentinel data collection sheet, record the sample number from the label on the side of the research blood vial (e.g., C7337 or W1543) in the designated Sample Number space (see image below).
4. Choose the appropriate box to indicate the patient's sex and age (see image below).

Sample number:
Enter the letter and the number for the sample
(e.g. C1234 or W1234) _____

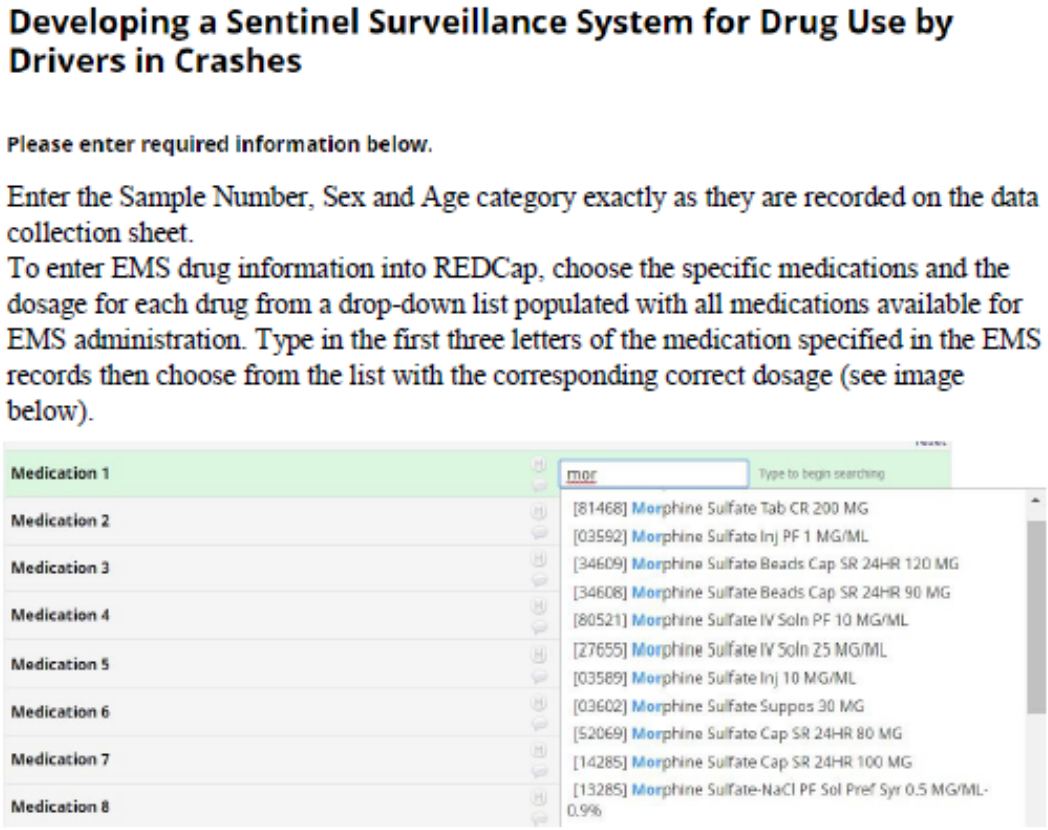
Sex:
□ Male
□ Female

Age:
□ 18-21
□ 22-29
□ 30-39
□ 40-49
□ 50-59
□ 60-69
□ 70-79
□ 80+

5. Record information provided by EMS regarding specific medications and dosage for each drug administered to the patient at the scene of the crash or en route to the hospital. Each medication should be listed separately on a new line with multiple doses recorded individually (e.g., dose 1, dose 2, etc.). Accurate dosage information is **crucial**. Use the comment section at the bottom of the page to add any other drug-related information that may be important.

_____ Dose 1:____mg Dose 2:____mg Dose 3:____mg
_____ Dose 1:____mg Dose 2:____mg Dose 3:____mg
_____ Dose 1:____mg Dose 2:____mg Dose 3:____mg

6. Once the data collection sheet is complete, transfer this information into REDCap using the designated link to the Sentinel study (*insert REDCap link here*). This will take you directly to the data entry page (see image below).



7. Enter the Sample Number, Sex and Age category exactly as they are recorded on the data collection sheet.
8. To enter EMS drug information into REDCap, choose the specific medications and the dosage for each drug from a drop-down list populated with all medications available for EMS administration. Type in the first three letters of the medication specified in the EMS records then choose from the list with the corresponding correct dosage (see image below).
9. Once the patient information is complete and entered correctly, press the "Submit" button at the bottom of the page.
10. Do not record any personally identifying information on the sheet. No other information is to be recorded other than what is specified.
11. Once the de-identified blood specimen is collected and the data collection process is complete, the blood specimen can be immediately taken to the storage facility and stored in the fridge in the designated area for the Sentinel study.
12. At weekly intervals, these blood samples will be packaged by a designated research team member using the packaging materials provided and shipped via FedEx to an independent toxicology laboratory.

CHAPTER HIGHLIGHTS

- ✓ Training research personnel to efficiently collect the data needed for the sentinel study is vital to ensure that no disruption or interference is created with any other trauma team members.
- ✓ Highlighting the major limitations of the currently available drug-involved driving data and the ways a sentinel surveillance system would address those limitations helps the research team recognize that they are contributing to an important and unique data collection effort.
- ✓ Note the following when creating the reference guide:
    - Ensure it is tailored to each individual sentinel site.
    - It should cover all the steps in the data collection process in enough detail to guide someone through, but without so much detail that it becomes burdensome.

CHAPTER 5: TOXICOLOGY TESTING

There are numerous elements that need to be taken into consideration when planning the toxicology testing portion of the study. **Many of the limitations of currently available drug-involved driving data arise from inconsistencies and lack of standardization in toxicology testing procedures and protocols**. Toxicology laboratories differ in terms of equipment, what drugs are tested, the types of tests conducted, the sensitivity of the tests, and the resulting cutoff levels (i.e., the minimum detectable amount of a drug). Although recommendations have been published (Logan, 2017), No national standard for toxicology testing currently exists; thus, it should be assumed that different toxicology laboratories will produce different test results. Ideally, in order 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.

> Using a single toxicology lab for drug testing will eliminate equipment, protocol, or procedural inconsistencies in the results

SELECTING A TOXICOLOGY LABORATORY

When setting up the two sentinel pilot study sites, there was initial debate about the pros and cons of using the in-house toxicology laboratories at each hospital location. Using the in-house labs was the less expensive and more convenient option and would have saved costs in terms of the tests themselves (i.e., cost per sample to be tested) as well as shipping costs. However, discussions with the lab managers revealed the differences in the equipment and testing protocols at each location, which would have produced largely inconsistent testing results. For example, one of the in-house laboratories used urine as the testing matrix, not blood. Drug test results using urine specimens are not comparable to blood test results, meaning each site would have essentially been a stand-alone site rather than part of a sentinel surveillance network. Thus, it was decided to use an external independent toxicology laboratory to test all samples for the pilot study. **If multiple toxicology laboratories are selected, for cost, convenience, or any other reason, detailed in-depth discussions need to be held with lab managers and resident toxicologists prior to commencing data collection to determine screening procedures and cutoff levels for testing.** Similar, if not identical, levels must be used across sites for test results to be comparable.

TESTING MATRIX AND DRUG PANEL

Variability in drug test results largely stems from differences in the testing matrix, the drug panel, and the equipment and associated cutoff levels for testing. The importance of the testing matrix relates to the detection window for drug presence in drivers. Drugs can remain present in urine for weeks, which greatly impacts the potential to link urine drug-test results to drug use or driver impairment near the time of the crash, arrest, or other event. Using urine as a testing matrix for drugs requires a different interpretation of test results due to the different compounds being tested (i.e., what is left of the drug after it has been metabolized by the body) and the longer detection window. **Blood tests are considered the gold standard when it comes to drug testing as the results are a better indicator of recent use**. Blood tests also detect the parent drug as well as metabolites, which allows for a more meaningful assessment of drug concentrations in a driver's system at that specific point in time (e.g., is the driver actively under the influence of drugs?) compared to urine tests, which only detect metabolites. Oral fluid is another option that provides a reliable indication of recent drug use, with oral fluid test results being well-correlated with blood test results for some drugs in a controlled setting. While law enforcement is focused on developing roadside oral fluid testing devices for rapid detection, oral fluid may be difficult to obtain from an unconscious patient in a trauma setting and/or be tainted by blood from facial injuries. Thus, for the purposes of the sentinel surveillance network, blood remains the strongly recommended testing matrix.

The NIDA Five should be considered the bare minimum drug panel for a sentinel surveillance system, which includes:

- Marijuana
- Opiates/opioids
- Amphetamines (including methamphetamine and ecstasy)
- Cocaine
- PCP

Note: This list excludes an array of other potentially impairing drugs that may negatively impact driving

Regarding the drug panel chosen for the sentinel sites, the desire to test for the presence of a large number of drugs needs to be balanced against the cost of an extensive comprehensive drug panel. The more drugs included in a drug panel, the more costly testing will be. In terms of variability in available drug panels, standard drug tests typically include The National Institute on Drug Abuse (NIDA) Five (Substance Abuse and Mental Health Services Administration, 2017), which comprises marijuana, opiates (including codeine, morphine, and heroin), amphetamines (including methamphetamine and ecstasy), phencyclidine (PCP), and cocaine. However, testing for these drugs alone omits a number of others that may impair drivers, particularly when multiple drugs are taken at the same time or are combined with alcohol. For example, antidepressants, barbiturates, benzodiazepines, additional opioids, and many other compounds,

such as over-the-counter (OTC) drugs, are not included in these panels. If possible, a more comprehensive drug panel should be chosen that includes additional drugs that are important to the goal of the sentinel surveillance system, such as those that may impair driving performance and ability. The toxicology laboratory chosen for the sentinel pilot study created an extended drug panel based on the results of the National Roadside Study (Kelley-Baker et al., 2017), which comprised the drugs and their respective metabolites shown in Table 1.

Since the pilot study was intended to test the protocols at each site and provide a foundation for expansion of the sentinel surveillance system network, the 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 for future sentinel surveillance sites.

CUT-OFF LEVELS FOR SCREENING AND CONFIRMATION TESTING

In addition to the drug panel, it is vital to consider and understand the importance of screening and confirmation testing and associated cut-off levels. One key difference between screening and confirmation testing is the purpose of the drug test. **Screening tests are completed to determine if a drug is present in a driver's system, whereas confirmation testing is completed to determine the amount of drug present in a driver's system.** The results of a screening test are presented as positive (i.e., yes, the drug was present) or negative (i.e., no, the drug was not present). The confirmation test results are quantifiable amounts or concentrations, typically presented in ng/mL for drugs and mg/dL for alcohol. The associated cut-off levels refer to the amount of drug that needs to be present for reliable detection to occur. In other words, the lowest drug concentration the laboratory equipment can reliably detect. Cut-off levels are strongly linked to the quality and type of laboratory equipment in use, with older outdated technologies requiring the presence of higher concentrations of drugs for reliable test results. Assays used for screening tests are cross-reactive to additional related compounds and metabolites; thus, cut-off levels for screening tests are often higher than those for confirmation testing. Table 1 shows the screening and confirmation testing cut-off levels used by the toxicology laboratory for the sentinel pilot sites.

Table 1. Screening & confirmation testing cut-off levels for sentinel surveillance pilot sites

Drug/Drug Class & Metabolites	Screening (ng/mL)	Confirmation (ng/mL)
Alcohol Ethyl alcohol	20 mg/dL	20 mg/dL
Cannabinoids THC, THC-COOH, 11-OH-THC	10	1
Cocaine, BZE, Cocaethylene	25	10
Amphetamine Amphetamine, Methamphetamine, MDMA, MDA, Phentermine, Methylphenidate	20	10
Benzodiazepines Diazepam, Nordiazepam, Oxazepam, Temazepam, Clonazepam, Alprazolam, Lorazepam, Chlordiazepoxide, 7-aminoclonazepam, Bromazepam, Midazolam	20	10
Barbiturates Butalbital, Secobarbital, Phenobarbital	100	100
Zolpidem	10	10
Opiates Morphine, Codeine, 6-AM, Hydrocodone, Hydromorphone	25	10
Opioids Oxycodone, Oxymorphone	25	10
Methadone, EDDP	50	10
Buprenorphine, Norbuprenorphine	1	1
Fentanyl, Norfentanyl, Furanylfentanyl, Acetylfentanyl, Carfentanil, Fluorofentanyl	1	0.5
Carisoprodol, Meprobamate	500	500
Tramadol	50	10
Antidepressants Sertraline, Fluoxetine, Amitriptyline, Nortriptyline, Imipramine, Desipramine, Citalopram, (Cyclobenzaprine), Doxepin, Venlafaxine, Trazodone	50	10
Dextromethorphan	50	20
Antihistamines Diphenhydramine, Chlorpheniramine, Doxylamine	25	10
PCP	10	10
Ketamine	10	10
Alpha-PVP	5	1

DRUGS ADMINISTERED BY EMS PERSONNEL

One major challenge with focusing on traumatically injured patients is the increased likelihood that these patients have been given drugs either at the scene of the crash or en route to the hospital (e.g., from the crash or being transferred from a different hospital). Some of the drugs that are the focus of this study, opiates for example, are frequently administered by EMS personnel for pain management. Thus, a positive drug test result showing morphine or fentanyl, for example, in a patient's system should not necessarily be counted in the drugged driving prevalence estimates as it may have been administered therapeutically by EMS. The blood specimen for the sentinel study is acquired once the patient is admitted to the trauma bay so the patient may have been given multiple doses of numerous different drugs in the time between the crash and arrival at the trauma bay. **In order to account for this in the toxicology test results, it is critical to obtain accurate drug information from EMS personnel regarding what drugs were given, how much of each drug was given, and how many times each drug was given.** This information can then be factored into the analysis of the toxicology test results to differentiate between therapeutic administration and recreational consumption of these drugs. If confirmation testing reveals a higher concentration of a certain drug than what was administered by EMS, that may lead to the conclusion that the drug was taken recreationally before the crash then administered again post-crash. It is strongly recommended to obtain advice from a reputable toxicologist to assist with the interpretation and analysis of toxicology test results, especially when attempting to differentiate between therapeutic and recreational drug use, as it is a very complicated topic.

CHAPTER HIGHLIGHTS

- ✓ Using one toxicology laboratory for all sentinel drug testing mitigates the inconsistencies and lack of standardization in toxicology testing procedures and protocols.
- ✓ If multiple toxicology laboratories are selected, detailed in-depth discussions need to be held with lab managers and resident toxicologists to ensure consistency in screening procedures and cutoff levels for testing.
- ✓ Blood tests are considered the gold standard when it comes to drug testing.
- ✓ The drug panel chosen for the sentinel sites and the desire to test for the presence of a large number of drugs needs to be balanced against the cost of an extensive comprehensive drug panel.
- ✓ Screening tests are completed to determine if a drug is present in a driver's system, whereas confirmation testing is completed to determine the amount of drug present in a driver's system.
- ✓ It is critical to obtain accurate drug information from EMS personnel regarding what drugs were given, and what dosage, in order to account for those drugs in the toxicology results.

CHAPTER 6: THE DATA COLLECTION PROCESS

Details of the data collection process may vary slightly between different sentinel sites, as the main goal is to not disrupt or interfere with the patient care process. However, the basic flow of tasks will be largely the same. As shown in Figure 3, the steps involved in the data collection process can be grouped into patient enrollment (orange), data collection (maroon), and data storage (blue).

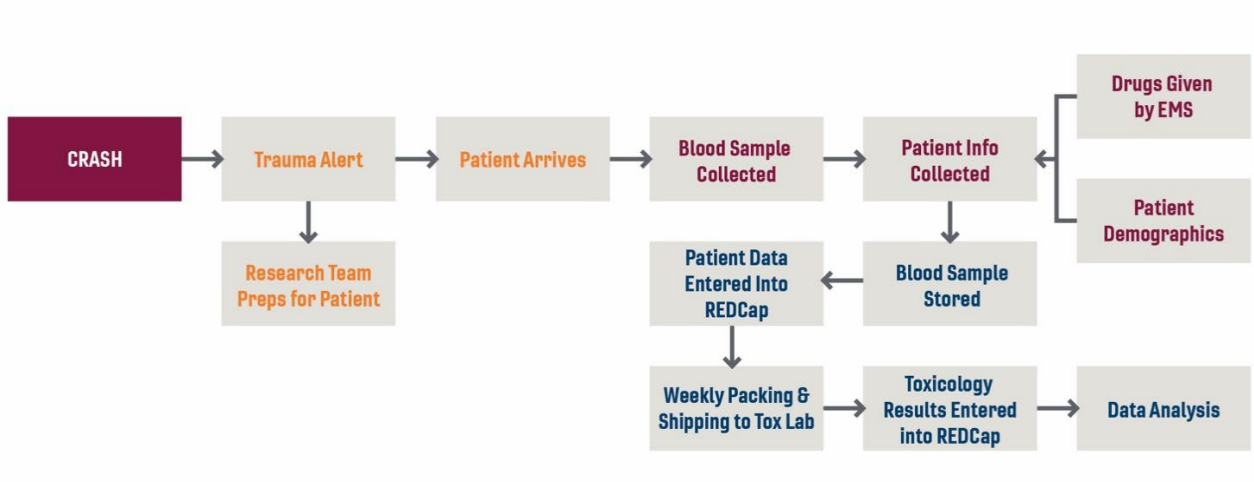


Figure 3. Flow chart of the data collection process

The process starts with a motor vehicle or motorcycle crash. The severity of the crash and the resulting injuries will determine if the crash victim ends up being part of the sentinel study. As outlined in Chapter 2: Getting Started, only level I and level II trauma patients are included in the study as these patients have the most severe injuries and are required to have blood drawn as part of their standard care. If a patient died at the scene or en route to the hospital, this patient would not encounter the trauma team and thus would not be included in the study. To include fatalities such as these, discussions and agreements would need to be in place with the coroner or medical examiner's office in order obtain blood samples from the deceased victims. While this is an option to pursue for other potential sentinel sites, the two pilot sites did not include fatalities.

PATIENT ENROLLMENT

The patient enrollment step of the data collection process (represented by the orange boxes in Figure 3) is activated by an incoming trauma alert, which indicates that a patient is en route to the hospital. Trauma alerts vary between hospitals depending on the method of communication. For instance, CRMH recently switched from pagers to an integrated online system that sends trauma alerts to mobile devices and smart phones. As a result, CRMH trauma alerts include more detail than those from WFMC, which still uses a traditional pager communication system. Of particular relevance to this project, alerts for CRMH indicated whether the patient was involved

in an MVC and provided the age and sex of the patient so the project manager could immediately determine if the incoming patient met the criteria for inclusion in the study. Potentially relevant pager alerts from WFMC, however, listed the mechanism of injury as blunt force trauma. Blunt force trauma occurs when force applied to the body is not sharp (e.g., stab wound) or penetrating (e.g., gunshot wound) in nature, which means the injuries may also be the result of falling from height, for instance. Thus, the incoming patient may or may not have been involved in an MVC. Regardless, **the research team preps for patient arrival by ensuring that an appropriately labeled blood vial is ready for specimen collection** (refer to Chapter 2: Getting Started). The team then reevaluates once additional information is received from EMS about the cause of the blunt force trauma, which allows them to establish whether the patient was involved in an MVC. After the research team has confirmed that the patient was involved in an MVC or motorcycle crash and was the driver (i.e., not a passenger or pedestrian), the data collection phase commences. **It is important to work with the research team at each site to identify a method to determine if the incoming patient was a driver as this may vary between sites.**

DATA COLLECTION

Data collection (represented by the maroon boxes in Figure 3) involves obtaining a blood specimen from the patient, ideally as soon as the patient has an 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 associated patient information (e.g., sex, age, EMS drugs). The details of this process should ideally be decided when developing the data collection protocol (see Chapter 2: Getting Started), as it is largely dependent on the capacity of the research team as well as how this information is conveyed by EMS personnel. For instance, in order for WFMC to have 24/7 coverage of research personnel available to collect blood specimens, the research team comprised a large number of medical students, residents, and a number of other research personnel (depending on the day of the week or time of day). **Thus, every effort was made to reduce the burden and to make the data collection process as straightforward as possible to avoid confusion.** The PI and project manager created individual patient packets that were kept in a designated location in the trauma bay (Figure 4). These packets contained a prelabeled blood vial and a printed data collection form with the same patient ID number as the blood vial. As

It is vital to keep the data collection process as straightforward and simple as possible.

- Pre-label the blood vial and data collection form with Sample ID # prior to patient arrival
- Design a simple check box data collection form
- Ensure all staff are well-trained and understand the protocol before starting data collection

shown in Figure 5, the data collection form listed each of the patient variables with check boxes next to the sex and age options. The time and day of crash variables were also presented as categorized check box options on the WFMC form (CRMH was not permitted to collect this information).

Figure 4. Individual packet for specimen collection at WFMC

During discussions with the research team at each pilot site, a list of the most common EMS-administered medications was developed and added to the data collection form along with multiple spaces to record doses. This list was applicable to the two pilot sentinel sites; the EMS medications to be included at each future sentinel surveillance site should be discussed with the PI to determine if any other medications should be added. In addition to the preselected list of EMS medications, there was a blank section for research personnel to record the name and dose of any drug not provided in the list. Research personnel were directed to include information about any medication they were uncertain about in this blank section.

Information on EMS-administered medications is not reported or shared with the trauma team in any standardized fashion when the patient is admitted to the trauma bay (i.e., there is no universal formalized method of communication between EMS and trauma personnel). The information may be communicated verbally by EMS personnel to the trauma team when the patient arrives in the trauma bay; thus, a member of the research team needs to be available and ready to collect and record this information immediately. **Due to the de-identification process, it is not possible to add EMS medications at a later date once paperwork and patient records have been amended to include these details.** This information is collected and recorded on the spot; accuracy and completeness are key. Once the blood specimen is obtained and all the patient information is recorded, the data collection phase for that patient is complete. No personally identifiable information is recorded at any point during this process and no additional information is recorded on the data collection form.

Pilot Implementation of a Sentinel Surveillance System
Data Collection Form

1. Sample number:
   Enter the letter and the number for the sample (e.g. C1234 or W1234) _____

2. Sex: ◻ Male ◻ Female

3. Age: ◻ 18-21 ◻ 22-29 ◻ 30-39 ◻ 40-49
   ◻ 50-59 ◻ 60-69 ◻ 70-79 ◻ 80+

4. Day of crash:
   ◻ Weekday (Monday 6:01am to Friday 6pm)
   ◻ Weekend (Friday 6:01pm to Monday 6am)

5. Time of crash:
   ◻ Day (6:01am to 6pm)
   ◻ Night (6:01pm to 6am)

6. Medications:
   Circle the medications below and write the dose to the right. Record multiple doses. Do not record the time of administration.

Opiates			
Fentanyl	Dose 1:____µg	Dose 2:____µg	Dose 3:____µg
Hydromorphone (Dilaudid)	Dose 1:____mg	Dose 2:____mg	Dose 3:____mg
Morphine	Dose 1:____mg	Dose 2:____mg	Dose 3:____mg
Benzodiazepines			
Midazolam (Versed)	Dose 1:____mg	Dose 2:____mg	Dose 3:____mg
Lorazepam (Ativan)	Dose 1:____mg	Dose 2:____mg	Dose 3:____mg
Ketamine (Ketalar)	Dose 1:____mg	Dose 2:____mg	Dose 3:____mg
Other drugs			
Write the name and dose of any drug(s) given that are not on the above list.			
_____	Dose 1:____mg	Dose 2:____mg	Dose 3:____mg
_____	Dose 1:____mg	Dose 2:____mg	Dose 3:____mg
_____	Dose 1:____mg	Dose 2:____mg	Dose 3:____mg

Do not record the following drugs:
Propofol
Etomidate
Succinylcholine (aka Sux)
Rocuronium (aka Roc)

Comments: _____
DO NOT INCLUDE ANY PERSONALLY IDENTIFYING INFORMATION IN THE COMMENTS SECTION _____

Figure 5. Example data collection form used at the sentinel pilot sites

DATA STORAGE

The data storage step (represented by the blue boxes in Figure 3) involves storing the blood specimen until shipment to the toxicology lab and entering patient information into the data repository. **Discussions should be held with the chosen toxicology lab to determine the ideal storage conditions for blood specimens**. Blood vials can be frozen for storage if necessary; however, this raises the possibility of losing specimens as the vials may crack when frozen. Ideally, blood specimens should be refrigerated between 2° and 8° Celsius (i.e., 35° to 46° Fahrenheit) and shipped for toxicology testing on a regular basis (e.g., weekly or every two weeks at the most). **During the development of the data collection protocol, the research team needs to identify and secure a location for storage of the sentinel blood specimens.** In the pilot, each of the sites had a refrigerator for temporary storage located in the trauma bay to immediately store specimens as they were collected (Figure 6). Following this procedure also allows for storage of multiple specimens in the event that more than one patient arrives at the same time or numerous patients arrive consecutively. The secondary storage location for blood specimens will depend on the hospital facilities. CRMH, for instance, had a Quest laboratory on site with an abundance of spare refrigerator space to store the specimens at the required temperature. The research team worked with the on-site lab to secure access to a space designated for sentinel specimens. The PI and project manager from WFMC, on the other hand, worked with hospital facilities personnel to locate an empty refrigerator in a secure location, which they then designated as reserved space for the sentinel surveillance study. Each day, the project manager retrieved the blood specimens from the storage space in the trauma bay and transferred them to the secondary designated storage space, then once a week packed and shipped all specimens to the toxicology laboratory for testing.

Figure 6. Temporary storage refrigerator located in the trauma bay

Entering patient information into the data repository can be done immediately or, if the trauma bay is busy, can be done as soon as time is available. One of the advantages of using REDCap for data storage is that the data repository can be accessed anywhere at any time from a laptop or mobile device using a system-generated survey link. Depending on the IRB agreement, the data collection sheets containing the patient information may need to be kept in a secure location (e.g., locked file cabinet in the PI's office) or destroyed as soon as the information is entered into REDCap (see Chapter 7: Data Repository).

PACKING AND SHIPPING SAMPLES TO THE TOXICOLOGY LABORATORY

Blood specimens need to be shipped to the toxicology laboratory on a regular basis as the quality of the specimens may be negatively impacted if they are stored for long periods of time. **It is recommended that research teams ship specimens either weekly or every two weeks**. Shipment requires appropriate packaging materials in order to keep the specimens cold and protected from breakage. FedEx offers temperature-controlled packaging specifically designed for this purpose (Figure 7). Packages are available in three box sizes (small, medium, and large) and each FedEx Temp-Assure box is equipped with a lightweight cooling unit that is activated with a button press once packing is complete. The cooling units are available for a standard duration of up to 48 hours, which was sufficient for the purposes of the pilot study, or an extended duration of up to 96 hours, which may be necessary if shipping times are longer. Overnight shipping was selected for the pilot study; however, other options are available depending on budget. Cost of shipping varies based on the location of each sentinel site and the distance to the toxicology laboratory, as well as the shipping speed selected. If less expensive, longer shipping times are chosen due to budget constraints, the additional cost of the extended duration cooling unit needs to be considered as it is vital that samples be kept at the recommended temperatures. Additional information regarding cost of packaging and shipping rates can be found on the FedEx website (https://www.fedex.com/en-ca/shipping-services/healthcare/cold-shipping.html).

Figure 7. FedEx Temp-Assure boxes were used at the sentinel pilot sites

Shipping and packing supplies were pre-purchased and distributed to the sentinel pilot sites where they could be easily accessed by the research teams. Boxes were pre-labeled with all necessary shipment information (i.e., addresses of recipient and sender plus contact information for the PI in case there was an issue with the shipment) and filled with appropriate absorbent material in case of accidental spillage or breakage (e.g., paper towels). FedEx also required specific labels to be displayed on each box designating that it contained a biological substance (Figure 8). Once each week (or once every two weeks), the project manager from each pilot site used one of these temperature-controlled FedEx boxes to pack all blood specimens obtained during the week prior. After being securely packed and the cooling unit was activated, the box was sealed for shipment (Figure 8). FedEx provides package pickup as part of the cold shipping service or the packed and sealed box can be dropped at a designated FedEx pickup location. Each box contains step-by-step instructions on packing and activating the cooling unit (Figure 8), as well as a phone number to arrange package pickup.

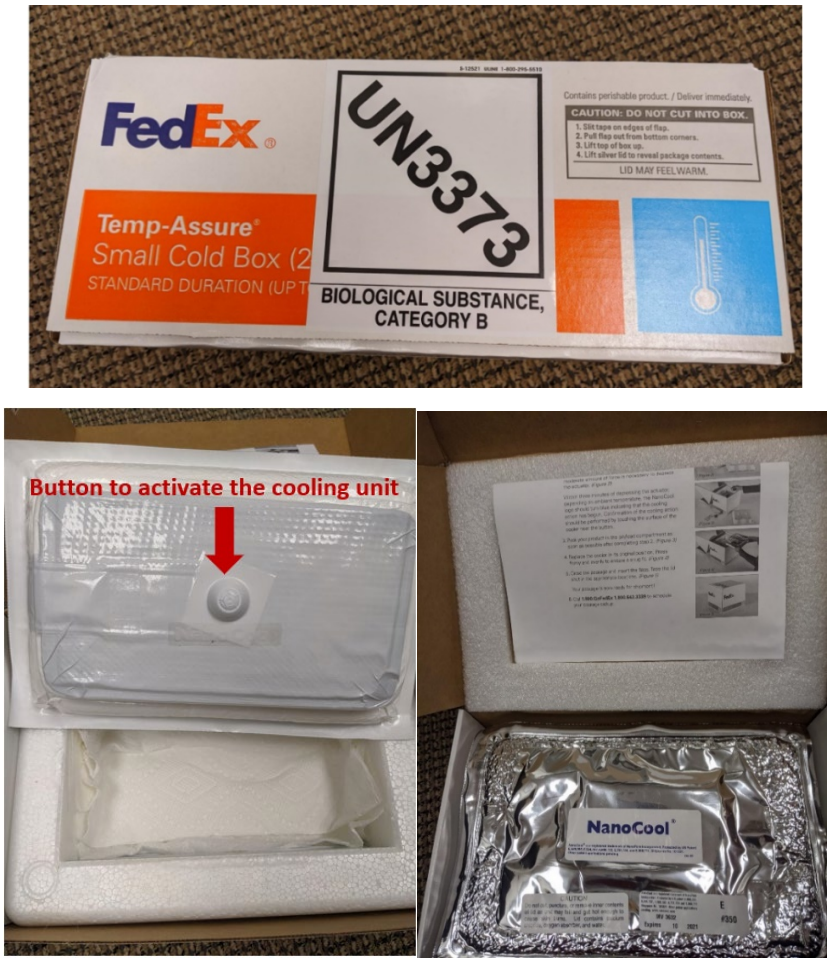


Figure 8. FedEx labeling and packing materials for sample shipment

The final factor to consider when shipping samples to the toxicology laboratory is to take into account weekends and holidays. Shipping a temperature-controlled package on a Thursday or Friday may result in the package arriving on the weekend, meaning samples may be lost if the cooling unit expires before lab personnel can unpack and refrigerate the samples. Choose a shipping day earlier in the week to ensure that the package arrives at the lab before the weekend. Also be prepared to adjust the shipping schedule to accommodate holidays.

CHAPTER HIGHLIGHTS

- ✓ Once notified of an incoming patient, the research team preps for patient arrival by ensuring that an appropriately labeled blood vial is ready for specimen collection.
- ✓ Identify a method to determine if the patient was a driver (i.e., not a passenger) involved in a motor vehicle or motorcycle crash.
- ✓ Remember, information on EMS-administered medications needs to be obtained on-the-spot. Due to the de-identification process, it is not possible to add EMS medications at a later date once paperwork and patient records have been amended to include these details.
- ✓ Note the following for storage of blood specimens:
    - Discussions should be held with the chosen toxicology lab to determine the ideal storage conditions.
    - The research team needs to identify and secure a suitable location for storage of the blood specimens.
- ✓ The following is of note when packing and shipping specimens:
    - It is recommended that blood specimens be shipped either weekly or every two weeks by the research team.
    - Be sure to factor in upcoming weekends and holidays. If the shipment arrives when no one is there to collect and store it, the specimens may be compromised.

CHAPTER 7: DATA REPOSITORY

The data storage phase incorporates the creation of a data repository to store and manage the patient information and the associated toxicology test results. Although patient information (e.g., demographics, EMS drugs) and toxicology test results are associated with the same patient, these become two separate data sources linked only by the sample ID number (assigned during the data collection phase) after the blood specimen is shipped to the toxicology laboratory, which ensures patient anonymity. Thus, a key capability of the data repository should be the ability to import, store, and link information from multiple sources. The larger the study, the more important this becomes, as entering or linking data manually would become too time-consuming and burdensome. In this context, *larger* may relate to the number of sentinel sites involved (i.e., more sites would typically mean a higher volume of patients) or more data sources included in the sentinel surveillance system (e.g., patient information, toxicology results, crash reports, coroner's reports). In addition to importing and linking data, **a sentinel surveillance system data repository should, at a minimum, have a user-friendly interface, store data in an easily exportable and readable format, and offer sufficient data protection.** Data protection may include password-protected servers, restricted access to approved research personnel only, and/or individual secure login access to the data repository.

Ideally, a data repository should be able to import, store, and link information from a variety of sources. At a minimum, a sentinel surveillance system data repository needs the following:

- A user-friendly interface
- Easily exportable data in a readable format
- Sufficient data protection to satisfy any IRB requirements

The choice of software or web-based platform to create the data repository should be based on the needs of the sentinel surveillance system being created. There may be specific requirements related to acquiring IRB approval that will impact the decision. For instance, depending on the specificity of the patient information acquired during data collection, the IRB panel may request that the data repository be compliant with the Health Insurance Portability and Accountability Act (HIPAA) guidelines and formatted to encrypt medical information. **Advice from an Information Technology (IT) expert is strongly recommended to determine the most feasible data repository options that fit the needs of the study.**

OVERVIEW OF REDCAP

The following section describes the setup and use of the secure web-based platform that was selected for the pilot study. **The Research Electronic Data Capture (REDCap) system is not the only solution available; if another system is chosen, please bypass this section of the Guidebook.**

In the pilot study, it became clear after consultation with the PI and project manager that both sites were already using the same system to collect, store, and manage data associated with other current research projects. The REDCap system is a secure web-based platform for building and managing online databases and is widely used in medical research; many hospitals may already have access to and experience using the platform. REDCap provides a streamlined process for designing and creating data repositories that can be tailored to suit almost any data collection strategy (Harris et al., 2009). It is easy to set up and use, has customizable data collection forms, and imports and exports of data to Excel or common statistical packages (e.g., SPSS, SAS) are straightforward.

REDCap is free for non-profit organizations who join the global REDCap consortium (Harris et al., 2019), which as of 2020 incorporates approximately 4,100 institutions in 137 countries. Many organizations interested in implementing a sentinel surveillance system are likely already affiliated with an existing REDCap partner site. The coordinating agency for the pilot study, VTTI, had an existing affiliation and license agreement with REDCap; thus, the Virginia Tech (VT) REDCap infrastructure was chosen to host the data collection effort in order to maintain easy access to institution-wide technical support. The VTTI team worked closely with VT IT specialists to get the appropriate institutional license agreements and approvals in place, after which the VT REDCap site was available and ready for use. This procedure will vary depending on the REDCap partner site used. **More-detailed information on licensing and technical support requirements can be found on the Project REDCap website (https://projectredcap.org/partners/join/).**

SETTING UP REDCAP

Online guides and videos are available on the REDCap website to help users get started and gain a better understanding of REDCap functionality (https://projectredcap.org/resources/videos/). Due to the highly customizable nature of the REDCap platform, it is strongly recommended to review the online resources prior to setting up and commencing data collection. All help features and video tutorials are accessible from the menu on the REDCap Project Home page (Figure 9).

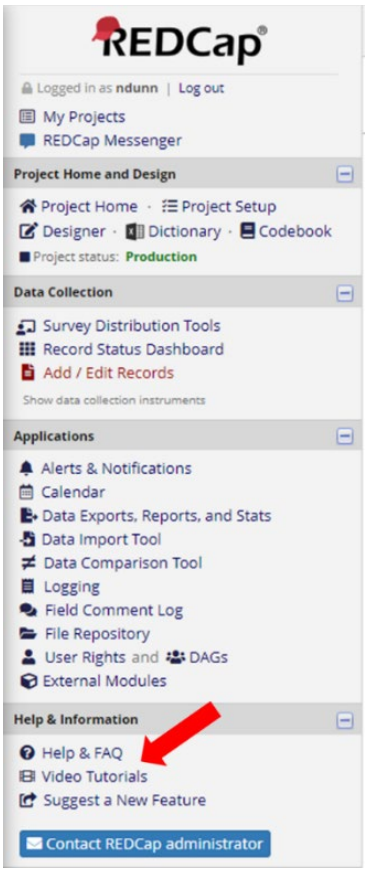


Figure 9. Help features available on the REDCap Project Home page

The following procedure explains how to create a REDCap data repository using the sentinel surveillance system pilot study as an example. As described above, the pilot study involved two individual survey instruments, patient information and toxicology results. **Given the limited amount of patient information collected for the pilot study, these should be considered the minimum requirements for inclusion in the patient information survey.** The information contained in the toxicology results survey needs to be created in close consultation with the participating toxicology laboratory to ensure that all information is consistent (e.g., drug names are correct) and that the results can be imported directly into REDCap.

The procedure described below involves three primary steps:

- Create a new project
- Set up a new project
- Finalize a new project

CREATE A NEW PROJECT

1. At the top of the REDCap homepage, click the *New Project* button (Figure 10).

Figure 10. New Project button

2. In the Create a New REDCap Project dialog box (Figure 11), enter in the project title (e.g., Sentinel Surveillance System).

3. From the drop-down menu next to *Purpose of this project*, select *Research*.

4. From the templates options, click *Create an empty project*.

5. Click *Create Project*.

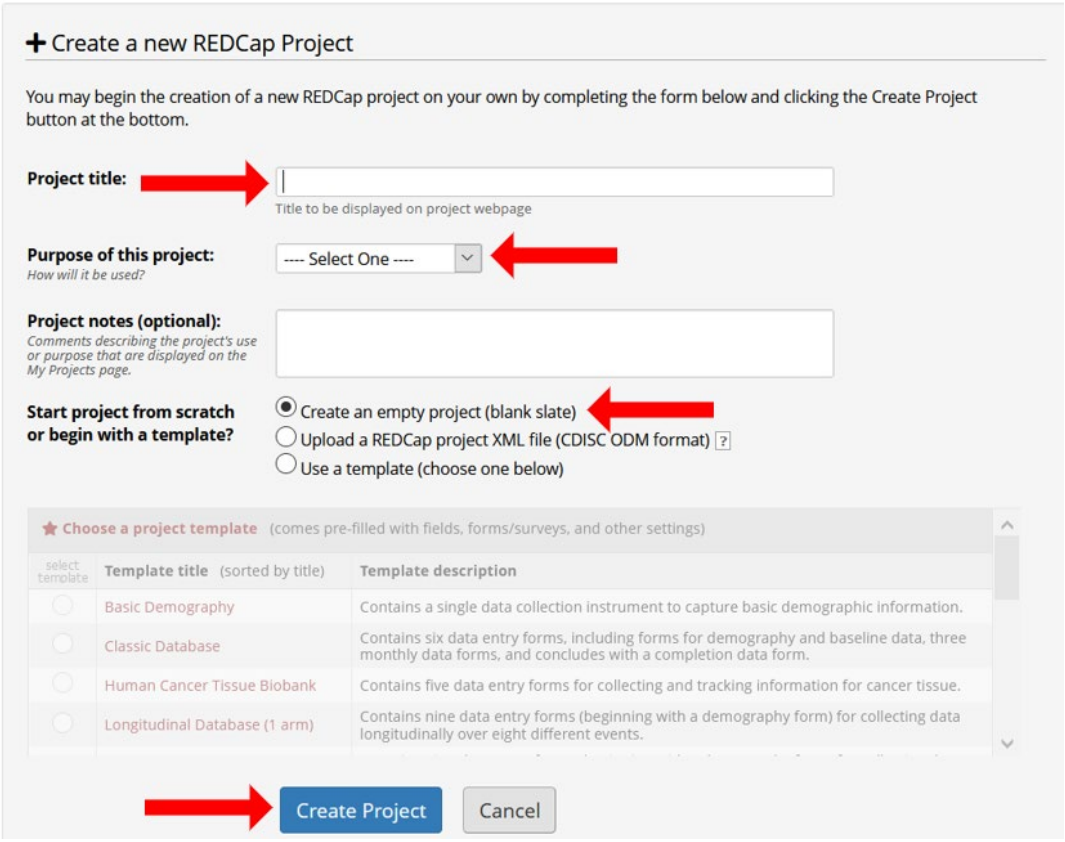


Figure 11. Create a new REDCap Project

SET UP A NEW PROJECT

Defining the data instruments used by a new project is accomplished in the *Project Setup* tab (Figure 12).

MAIN PROJECT SETTINGS

1. As mentioned above, data collection for the pilot sentinel survey involved two surveys. To employ surveys in your project, in the *Main project settings* section, click the *Enable* button next to *Use surveys in this project?*.

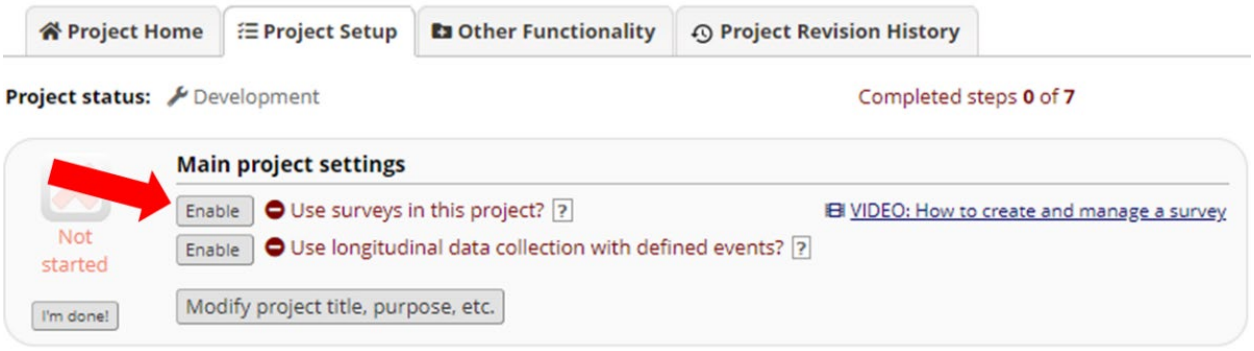


Figure 12. Main project settings: enable surveys

2. When finished, click *I'm done!* (Figure 13).

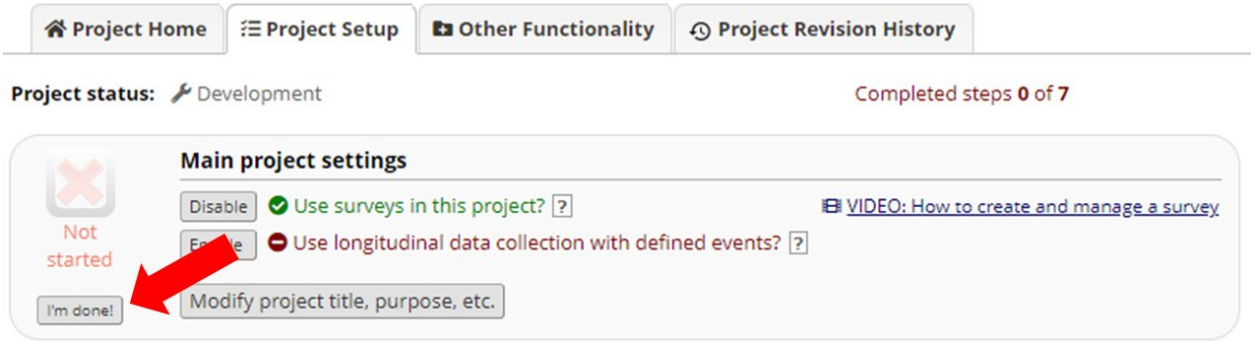


Figure 13. Main project settings: I'm done! button

DESIGN YOUR DATA COLLECTION INSTRUMENT AND ENABLE YOUR SURVEY

1. To begin building the surveys, scroll down the *Project Setup* page to *Design your data collection instruments* and click *Online Designer* (Figure 14).

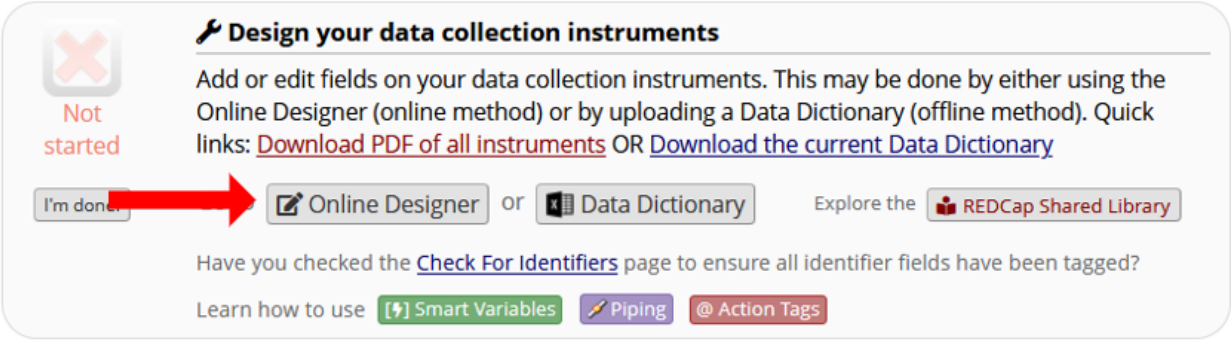


Figure 14. Button for the REDCap online survey designer

2. Rename your survey. On the *Online Designer* page, next to the default title of "My First Instrument," click *Choose action* and select *Rename* from the drop-down list (Figure 15). Change the name of this survey ("Patient Information" in this example) and click *Save*.

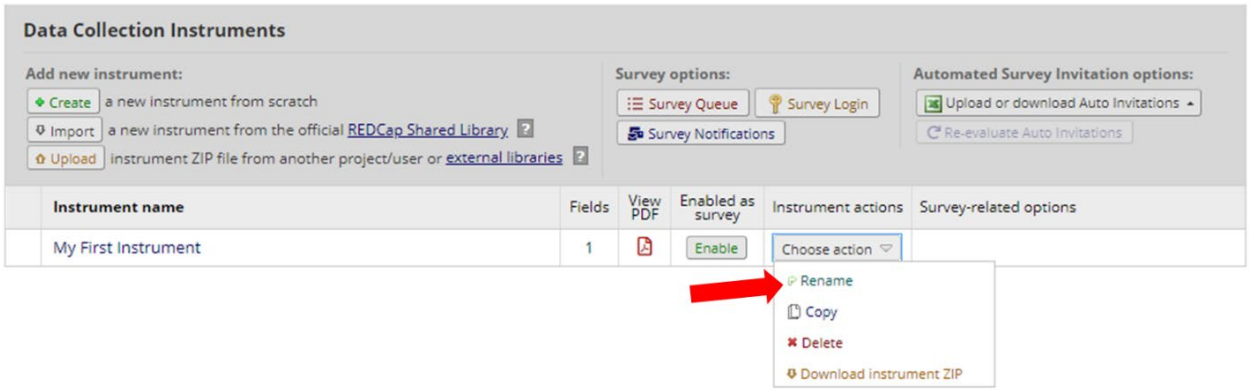


Figure 15. Rename action in Data Collection Instruments

3. Open the *Creation Tool* by clicking on the name of the instrument (shown in blue; in this case, "Patient Information").

4. Repeat the following steps to add each data collection field. In our example of the Patient Information survey, these include Sample ID, Sex, Age, Time of Crash, and Day of Crash. These data collection fields may vary by sentinel site/study and will depend on the variables approved by each site's IRB.

a. Click *Add Field* to add each new project field (Figure 16).

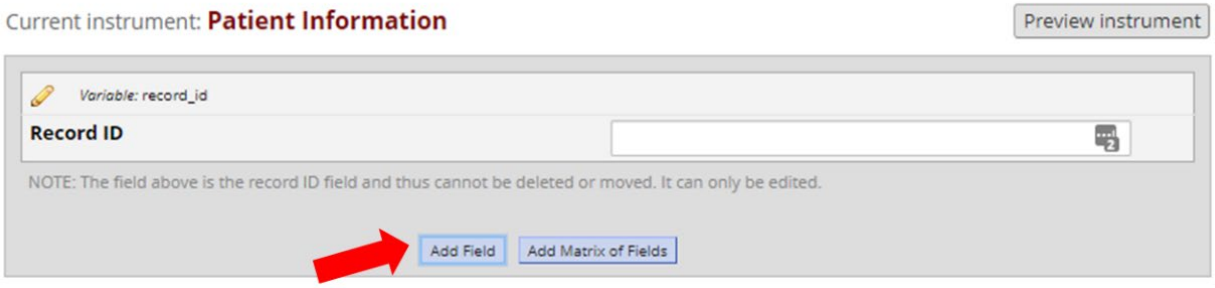


Figure 16. Add Field button

b. Fields are defined using the *Add New Field* dialog box (Figure 17). First, create a name for the new field and enter it in the *Field Label* box. Next, define the appropriate data type for each field using the *Field Type* drop-down list. The example shown is for the Sample ID Number, which requires a *Text Box (Short Text, Number, Date/Time….)* response option (e.g., "C9134" or "W2593").

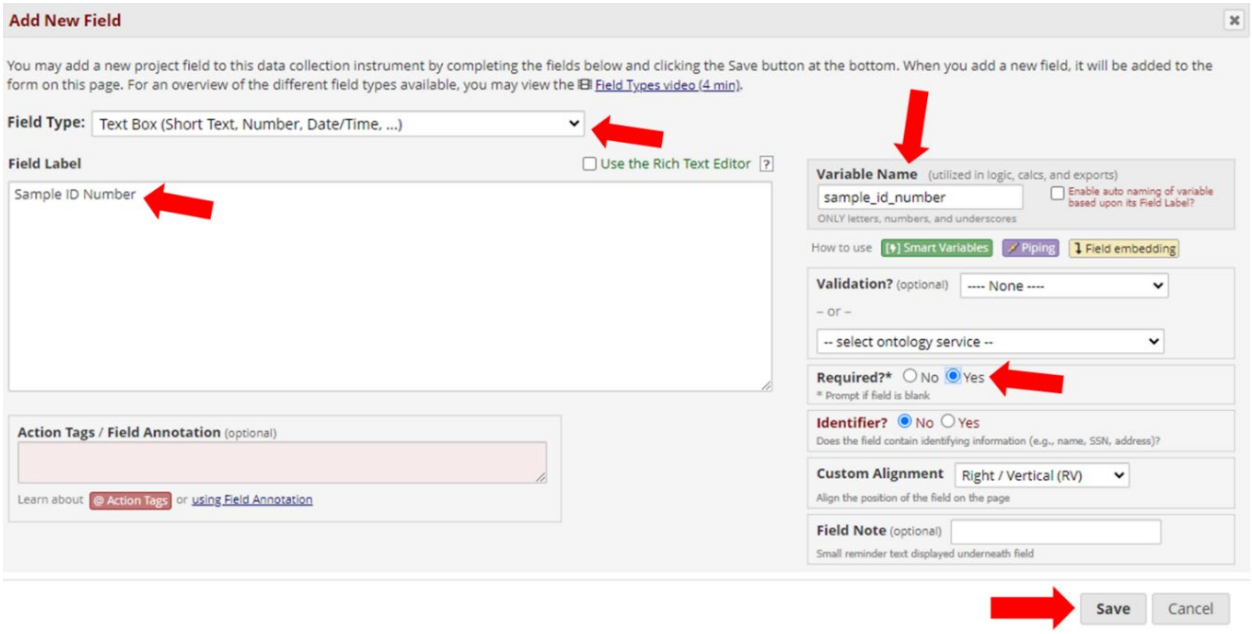


Figure 17. Completed Add New Field dialog box for the Sample ID Number

Other relevant *Field Type* options that were used in the sentinel surveillance pilot study included *Multiple Choice - Radio Buttons (Single Answer)* for the *Sex* field and *Multiple Choice - Drop-down List (Single Answer)* for the *Age Category* field. The response options for these fields are designated in the *Choices* box (Figure 18 and Figure 19).

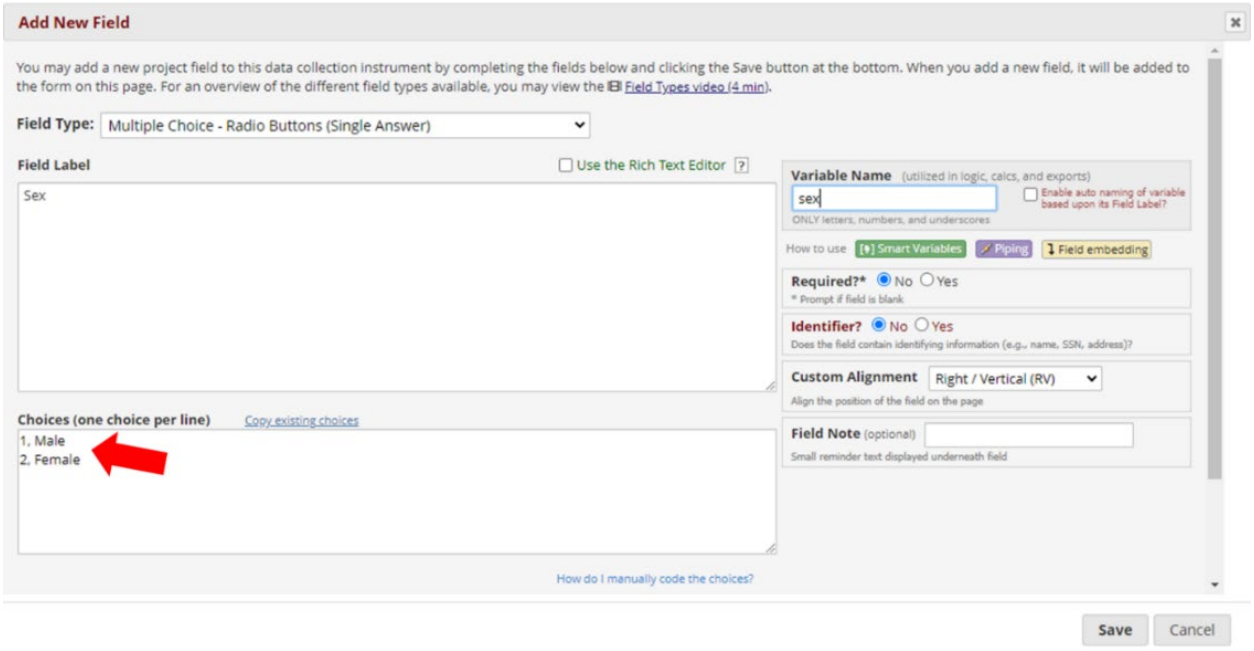


Figure 18. Configuring the Sex field for the Patient Information survey

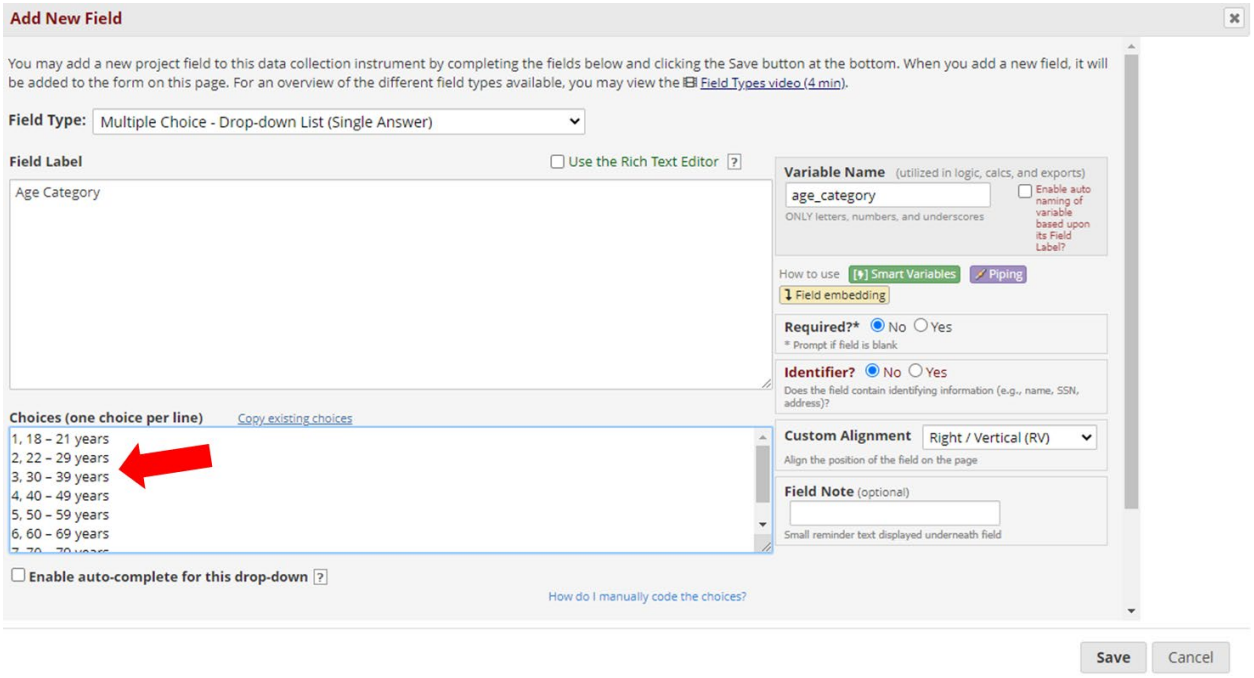


Figure 19. Configuring the Age Category field for the Patient Information survey

c. Mandatory fields need to be identified. If completion of a field is mandatory, select *Yes* next to *Required?* (Figure 17). For example, in the case of the sentinel pilot survey, the Sample ID Number is the random unique ID number assigned to the blood specimen and the patient information obtained by the trauma team during the data collection phase.

This is a critical piece of information required to match the patient information to the toxicology results and must be marked as a required field.

d. Create a *Variable Name* (Figure 17). This variable name can be the same as the *Field Label* or something different. The variable name will be shown in place of the field label in data exports and analyses.

e. Click *Save*. The data field will be added to the Patient Information survey. Repeat these steps for all additional fields that need to be added to the survey. After each field is complete, click *Save.*

The sentinel pilot study survey also captured EMS-administered medications. To include this information, click *Add Field,* select the *Text Box (Short Text, Number, Date/Time….)* field type, and assign a *Field Label* and *Variable Name*, such as Medication_1. Then, click on *select ontology service* and choose *BioPortal Ontology Service* (Figure 20). In the box directly below *Enable searching within a biomedical ontology?*, select *MDDB - Master Drug Data Base Clinical Drugs* from the drop-down list (Figure 21). This will create a prepopulated list of drug names, which can be selected from a drop-down list as the name is typed into the survey. The drop-down list also includes a variety of dosages for each drug. Thus, when entering EMS-administered medication into REDCap, the researcher selects both the drug name and corresponding dosage from the list. This feature greatly reduces spelling errors of drug names or differences in annotations between researchers.

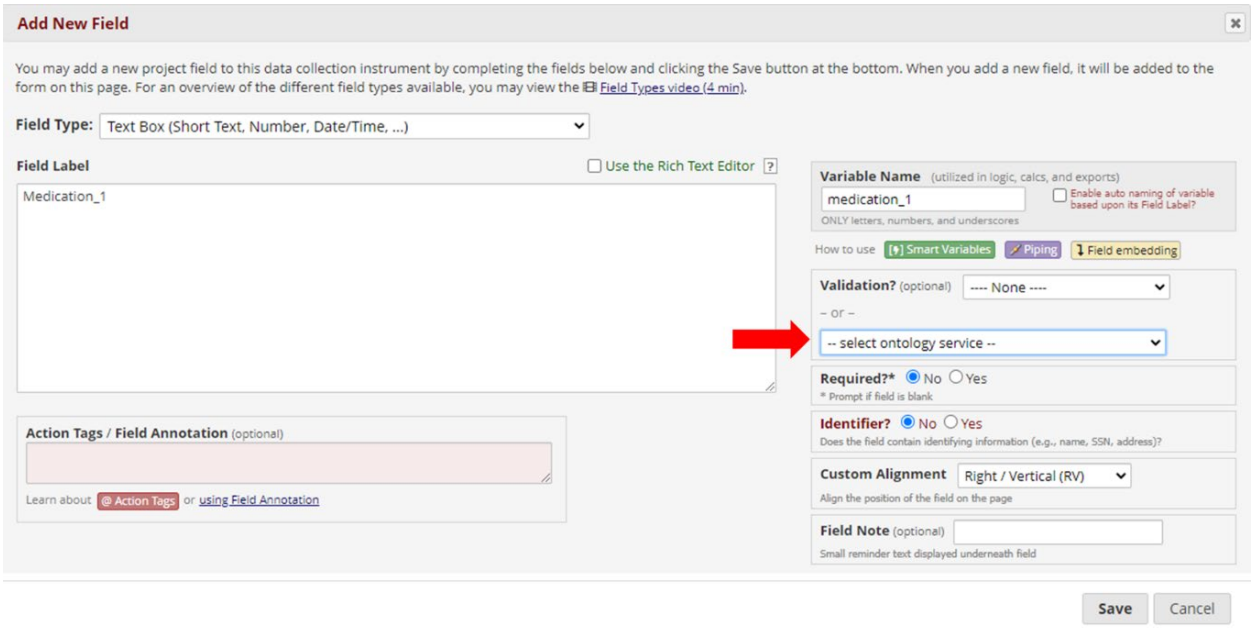


Figure 20. Select ontology service highlighted in Add New Field dialog box

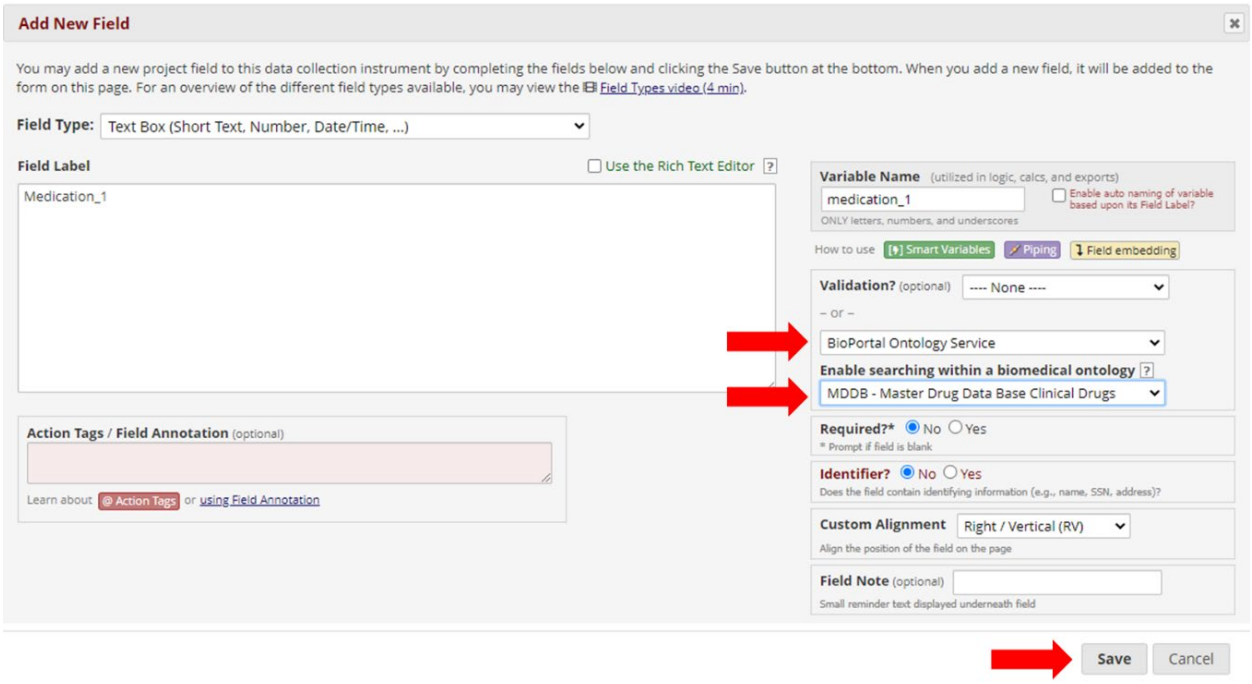


Figure 21. Settings used for configuring the EMS-administered medications field

5. Once all data collection fields have been added and saved, enable the survey on the Data Collection Instruments page by clicking the *Enable* button (Figure 22) for the instrument.

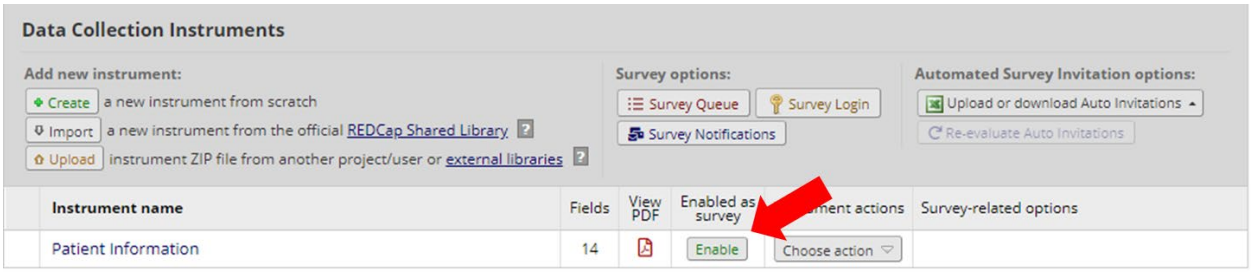


Figure 22. Enable survey button for Patient Information survey

6. Enabling the survey activates the *Set Up My Survey* page, which allows instructions to be added (if needed) and provides options for survey design, customization, and access, all of which can be tailored to the needs of the specific project.
7. Once the survey is set up accordingly, click *Save Changes*.
8. Repeat this process for any additional surveys. For the sentinel pilot study, two separate surveys were created within REDCap to capture the two data sources (Figure 23). Larger projects including additional sources of data (e.g., crash reports) may need additional surveys.

The second survey instrument used in the sentinel pilot study, called *Toxicology*, was used to store, link, and manage the toxicology results. **It is important to consult with the collaborating toxicology laboratory to obtain a list of all the drugs that will be included in the drug panel.** Within the Toxicology survey, create a corresponding text box for each drug listed using the exact spelling for both the *Field Label* and *Variable Name.* Click *Save* after each entry to add the data field to the Toxicology survey.

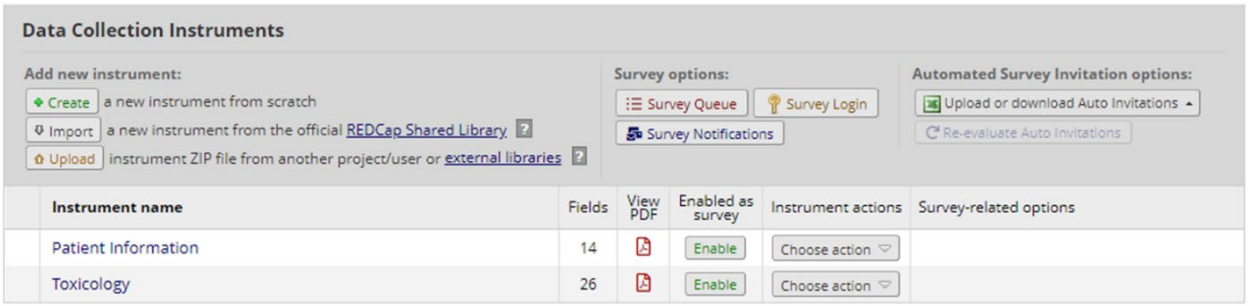


Figure 23. Data Collection Instruments screen with Patient Information and Toxicology surveys listed

DISTRIBUTE THE SURVEY

After all survey instruments are finished, navigate to *Survey Distribution Tools* in the menu on the left of the page (Figure 24).

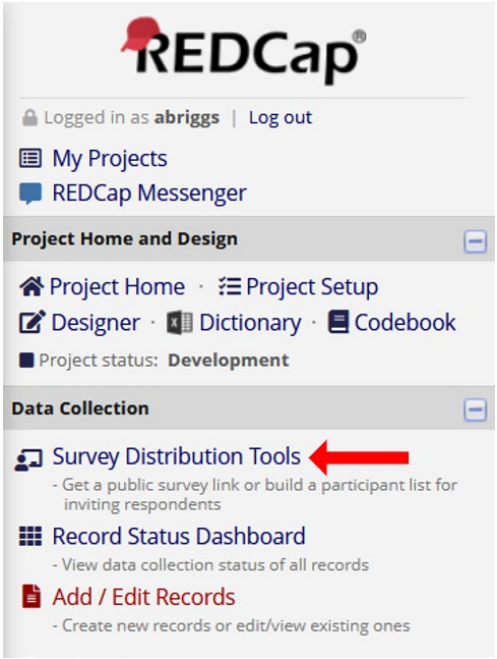


Figure 24. Survey Distribution Tools on main menu.

The *Survey Distribution Tools* menu (Figure 25) will provide the URL for the survey, as well as options to create a short link or a customized survey link that can be circulated to members of the research team responsible for data entry (if there is more than one designated data entry person) or each participating sentinel site (if there is more than one site) to allow for quick and easy data entry of patient information.

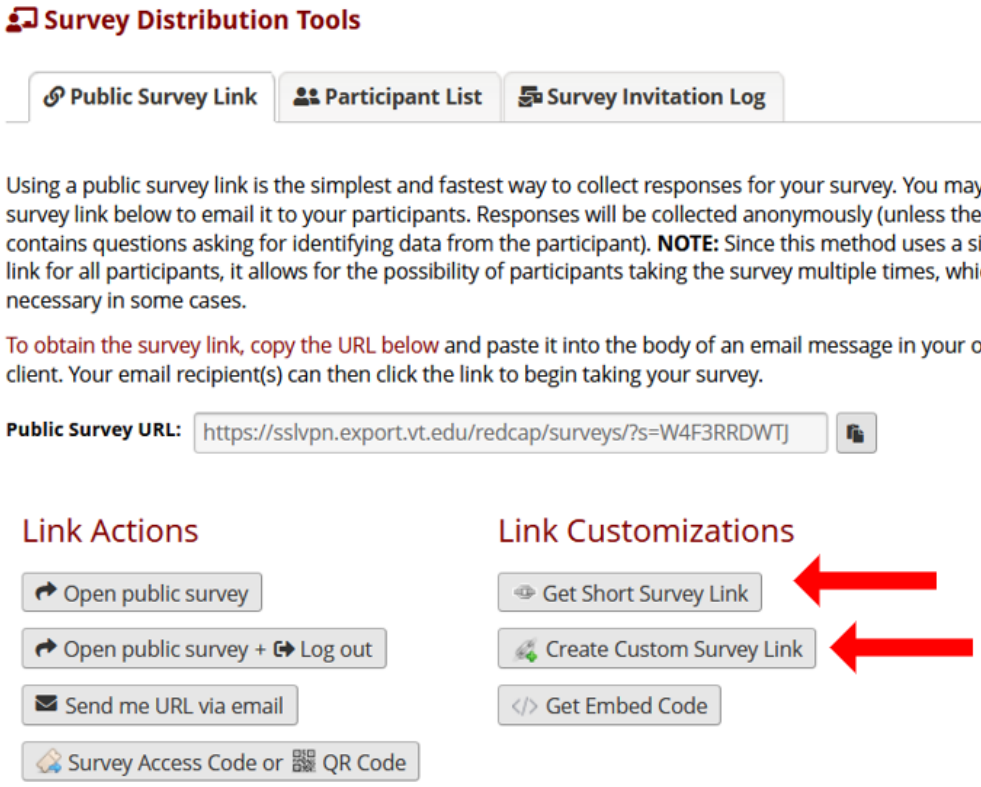


Figure 25. Survey Distribution Tools with link options highlighted

FINALIZE THE PROJECT

REDCap divides the workflow on the Project Setup page into seven steps:

- Main project settings
- Design your data collection instruments and enable your survey
- Enable optional modules and customizations
- Set up project bookmarks (optional)
- User rights and permissions
- Test your project thoroughly
- Move your project to production status

Once the data collection instruments are finalized, click *I'm done!*, and work through the other relevant steps to finalize them (Figure 26). Enable *Auto-numbering for records* in optional

modules and customizations. Some steps, such as *Set up project bookmarks,* are optional. As each step is finalized, click the *I'm done!* button and move on to the next step.

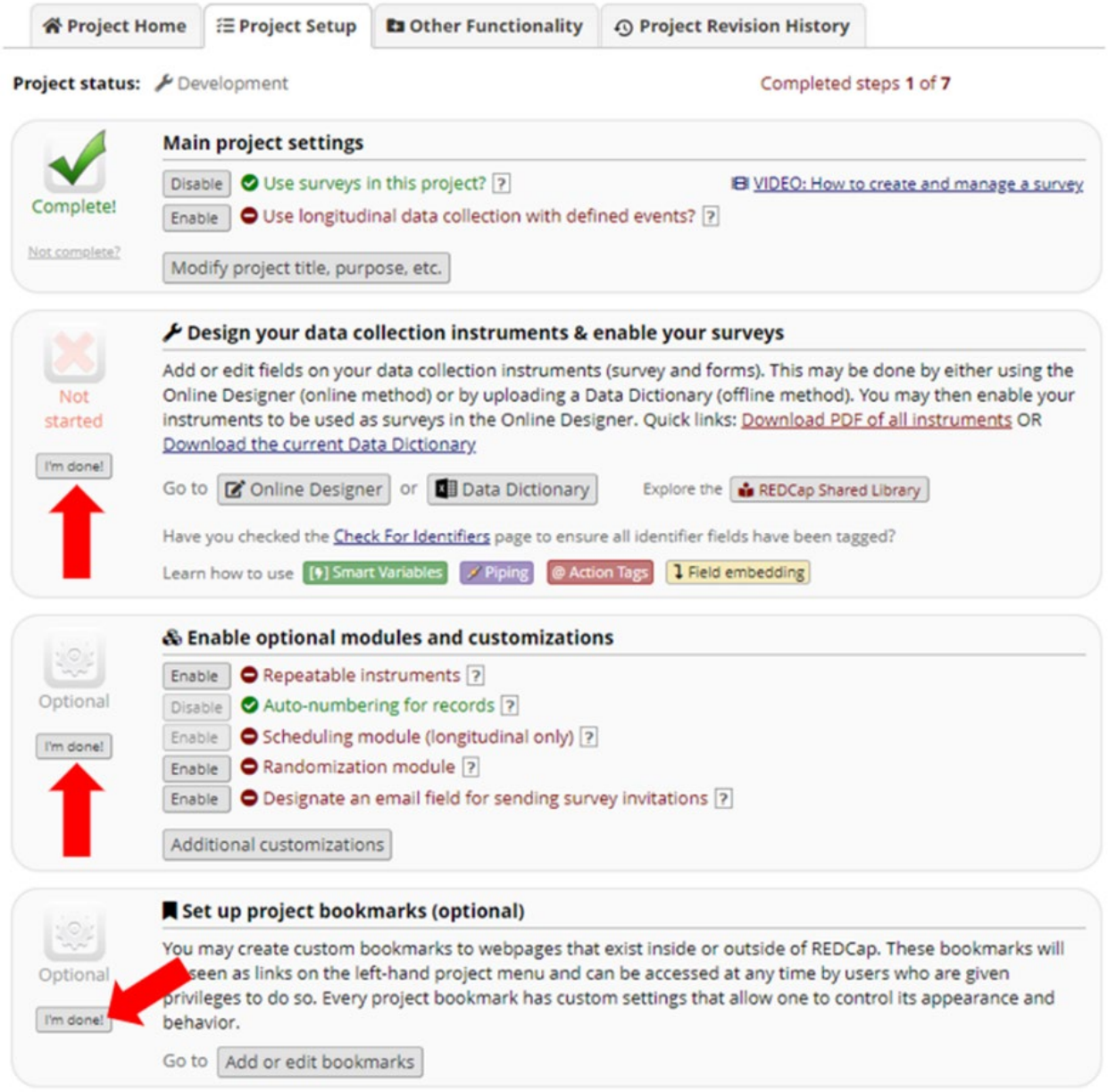


Figure 26. Project Setup tab: first four steps of workflow with I'm done! Buttons highlighted.

The last step before testing the survey is to add or limit any user rights or additional permissions required for the project (Figure 27). Follow relevant institutional and IRB guidelines on data access and retention requirements.

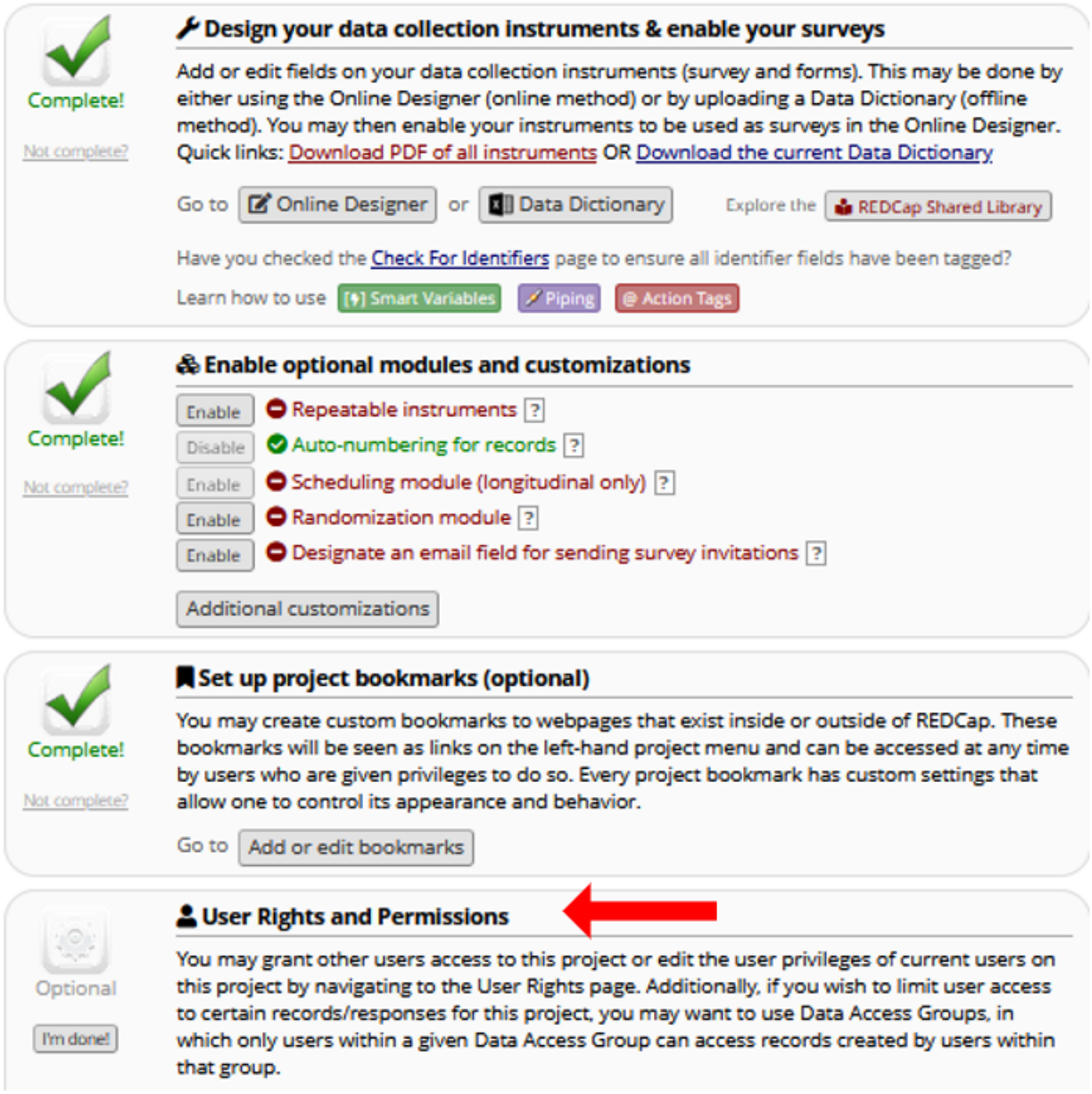


Figure 27. Project Setup tab: User Rights and Permissions

It is crucial to test the survey instrument before publishing. Once satisfied with the project, click *Move project to production* (Figure 28). The project can still be edited after this point if necessary.

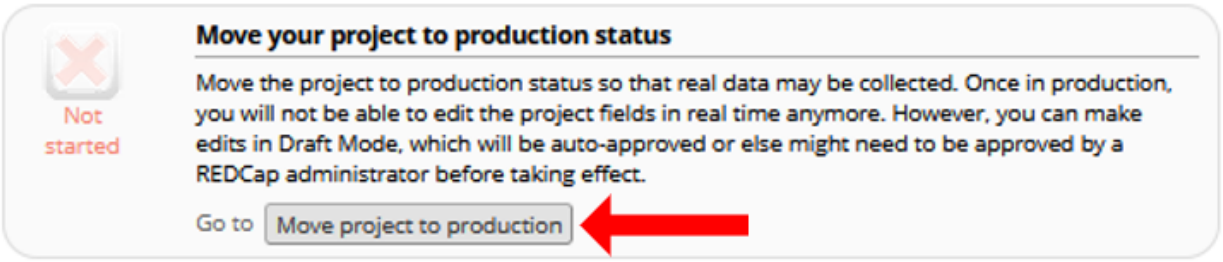


Figure 28. Project Setup tab: Move project to production button.

DATA COLLECTION, IMPORTS, AND EXPORTS

Once data collection is underway, REDCap provides easy access to track the data in real-time. As soon as patient information is entered at a sentinel site it is available on REDCap. There will be a lag associated with toxicology information, as the toxicology laboratory needs time to complete the drug testing and report the results. In the pilot study, toxicology results were reported in monthly batches; however, results could be reported more frequently if needed. This detail would need to be clarified with the chosen toxicology laboratory. In the pilot, the lab compiled the results in an Excel spreadsheet, which was sent to the PI from VTTI. REDCap provides a data import tool, which also links imported data to existing data in REDCap. Thus, the toxicology results could be linked to the associated patient information using the unique Sample ID numbers. This created one record for each patient that included all relevant information.

The *Data Exports, Reports, and Stats* tab (Figure 29) within REDCap provides a way to view reports of the data, create plots and descriptive statistics, and export data for analysis using statistical software packages, such as SAS or SPSS. The *Data Exports, Reports, and Stats* page has a video that provides helpful information on how to use this REDCap feature (VIDEO: How to use Data Exports, Reports, and Stats). One of the benefits of using REDCap is the array of options available for viewing, exporting, and reporting data.

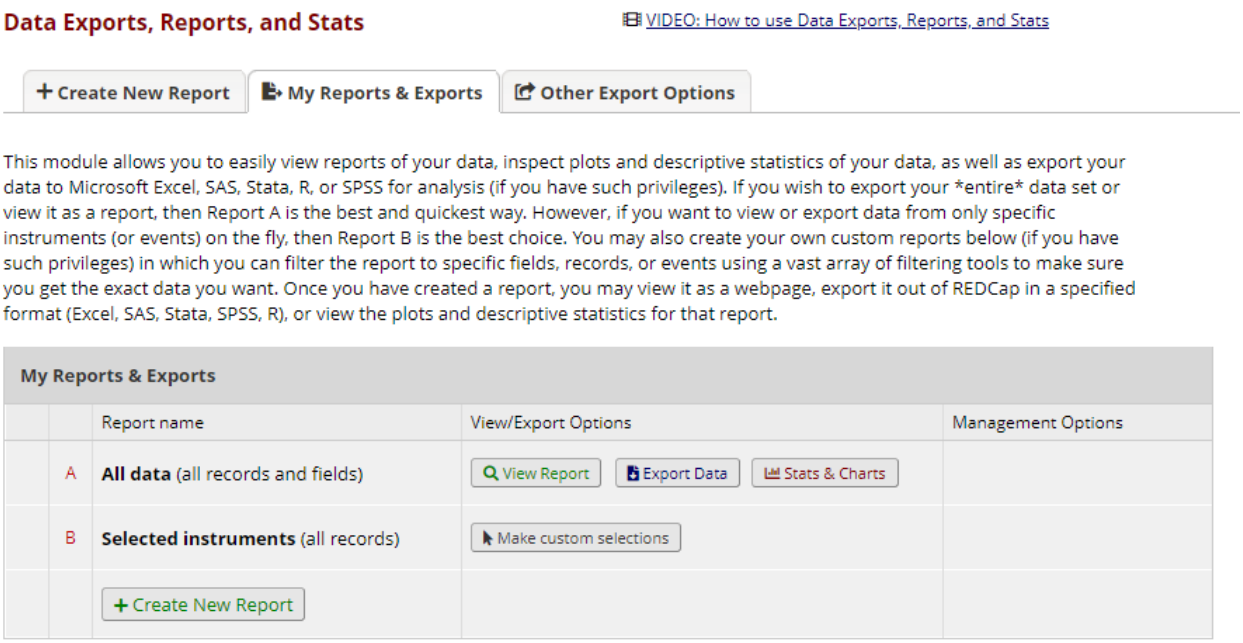


Figure 29. My Reports & Exports tab.

OPTIONS OTHER THAN REDCAP

A range of other database management solutions are available if REDCap is unappealing or unavailable. As mentioned above, the decision to use REDCap was largely based on the prior experience of the pilot sites, and REDCap also made it easier to manage incoming data from multiple sites. Depending entirely on the needs of the study, something as simple as an Excel spreadsheet could work. Other options may require more effort on the data entry side but are easier to create and set up. Guidance from an IT expert who understands any associated security requirements for data storage would be helpful.

CHAPTER HIGHLIGHTS

- ✓ At a minimum, a sentinel surveillance system data repository should have the following characteristics:
    - Have a user-friendly interface
    - Store data in an easily exportable and readable format
    - Offer sufficient data protection
- ✓ When choosing a data repository solution, the following is of note:
    - REDCap is not the only option.
    - Advice from an IT expert is strongly recommended to determine the most feasible option that fits the needs of the study.
- ✓ The following is of note when creating the data repository:
    - It is important to consult with the collaborating toxicology laboratory to obtain a list of all the drugs that will be included in the drug panel.

CHAPTER 8: DATA ANALYSIS

Data analysis techniques will depend on the data collected by each participating sentinel site. If there is more than one participating sentinel site, such as in the pilot study, an initial assessment of the data is necessary in order to determine if it is appropriate to combine data across sites. **If there are fundamental differences between how the data were collected at each site, or what data were collected, then it will likely be more appropriate to analyze data on a site-by-site basis.** For example, during the pilot study, WFMC collected patient specimens around-the-clock, whereas, due to staff availability, CRMH was limited to collecting specimens on weekdays between the hours of 8 a.m. and 6 p.m. Thus, combining these data would give an inaccurate picture of drug prevalence during late night/early morning hours and on weekends, as only one site was collecting specimens during those times. There may be statistical methods to account for differences between sites; however, the guidance of a statistician is strongly encouraged.

Analyses will mainly focus on the prevalence of drug class/category stratified across other variables collected. For example:

- Sex
- Age category
- Weekday vs weekend
- Daytime vs nighttime

Sample size will determine the specificity of the analyses. For example, the prevalence of a specific drug (e.g., methamphetamine) vs a broad drug category (e.g., stimulants)

Analyses will largely revolve around comparing drug class/category prevalence across a range of other variables, such as sex, age category, weekday/weekend, and daytime/nighttime. Sample size will play a role in determining how much the data can be pulled apart in terms of prevalence of specific drugs (e.g., cocaine or heroin), or combinations of drugs (e.g., alcohol and stimulants). Chi square tests of independence and z-tests of proportions are applicable statistical tests for categorical variables (e.g., drug presence by age category or sex). Descriptive statistics (e.g., mean, standard deviation, median, and range) and t-tests may also be useful to quantify alcohol and drug concentration data (e.g., mean BAC of men vs. women).

Depending on the data collected, there may be other issues that need to be considered prior to data analysis. For example, the drug panel used by the toxicology laboratory in the sentinel pilot study included a number of inactive metabolites (e.g., 11-COOH-THC, BZE, norfentanyl, EDDP). The presence of inactive metabolites in the blood show that the driver used the parent drug at some point in the past (e.g., the inactive metabolite of THC can be detected in the blood for days or even weeks after use). However, this does not give an indication of when the corresponding

drug was consumed or that the driver had the active drug in their system at the time of the crash (Thomas et al., 2020). **A decision needs to be made about the inclusion of drug test results that test positive for inactive metabolites only** (i.e., no corresponding drug or active metabolites present) and **this decision needs to be applied across the board at all sites to ensure consistency**.

Another issue relates to specimens that tested positive for EMS-administered drugs but at a higher concentration than what would be expected given the dose administered by EMS personnel (e.g., a low dose of fentanyl was administered by EMS but toxicology results reveal a higher concentration of fentanyl in the specimen than would likely result). This may be indicative of recreational use prior to the crash on top of therapeutic administration by EMS personnel. The conservative approach to this issue would be to exclude all positive results attributed to therapeutic drug administration, regardless of the drug concentration in the toxicology results. Unfortunately, this approach would also result in an underestimation of the prevalence of certain drugs that are commonly administered by EMS to MVC trauma patients that are also drugs of abuse (e.g., fentanyl, morphine, benzodiazepines). **Input and guidance from a toxicologist is strongly advised in order to determine if these data can be included in the analysis.** Decisions will likely be made on a case-by-case basis as toxicology results become available. In the pilot study, the VTTI team arranged a meeting with the toxicologist towards the end of the data collection period and reviewed all cases where EMS drugs were administered that subsequently showed up in the drug test results. After comparing the EMS dosage with the drug concentrations from the toxicology testing, the decision was made to exclude all positive test results associated with a corresponding EMS drug administration for that particular drug category only. Meaning, if a patient was administered morphine and tested positive for morphine and THC, only the morphine result was excluded from the analysis.

Table 2 provides an example summary table of drug category prevalence at each of the sentinel pilot sites, as well as the totals from the two sites combined. Depending on the sample size, some of these categories can be broken out further for more detail. Sedatives, for instance, includes benzodiazepines (e.g., midazolam), barbiturates (e.g., phenobarbital), and sleep drugs (e.g., zolpidem). The results in Table 2 exclude cases where EMS drugs were administered. **The presentation of these preliminary results is for illustrative purposes to provide an example of summary table formatting.** The "Other Drugs" category in Table 2 included drugs such as PCP, ketamine, and Alpha-PVP; however, the only positive test results in the pilot study related to ketamine.

Table 2. Pilot Study: Positives for Drug Category by Trauma Center

Drug Category	CRMH (N = 56)		WFMC (N = 82)		Total (N = 138)	
	n	%	*n*	%	*n*	%
Alcohol	5	8.93	22	26.83	27	19.57
Cannabinoids	10	17.86	20	24.39	30	21.74
Stimulants	4	7.14	7	8.54	11	7.97
Sedatives	5	8.93	9	10.97	14	10.14
Opioids	11	19.64	12	14.63	23	16.67
Antidepressants	1	1.78	3	3.66	4	2.90
OTC Drugs	2	3.57	2	2.44	4	2.90
Other Drugs	2	3.57	3	3.66	5	3.62
At Least 1 Drug Category	29	51.79	49	59.76	78	56.52
Non-Alcohol Drug Use (i.e., excluding alcohol)	28	50.00	39	47.56	67	48.55
Polydrug Use (i.e., including alcohol)	9	16.07	23	28.05	32	23.19

The results in Table 2 indicate that, 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. Cannabinoids and alcohol were the most prevalent drug categories across the two sites combined, followed closely by opioids. 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. Other analyses of interest may include polydrug use, such as alcohol plus other drugs (e.g., alcohol plus cannabinoids) or multiple non-alcohol drugs (e.g., cannabinoids plus opioids). **Due to the large number of possible combinations of drugs, preliminary analyses of the data are advised to look for trends in positive results before deciding on specific combinations or drug categories to focus on**. As mentioned earlier, the data analyses will depend on many factors, including the sample size and the specific research questions being addressed. The pilot study dataset was small, which limits the potential analyses.

IMPACT OF PILOT SITE DIFFERENCES ON RESULTING DATA

Differences in the results from the two pilot sentinel sites highlight the importance of understanding how these data were collected and the impact this can have the interpretation of the data. One result that stands out is the low prevalence of alcohol-positive results from CRMH. Only 9 percent of seriously injured drivers tested positive for alcohol, compared to 27 percent from WFMC. The ongoing NHTSA trauma center study, which uses a similar methodology to that presented in this guidebook, found similar alcohol prevalence to that of WFMC (Thomas et al., 2020). However, it is critical to factor in the lack of weekend and late night/early morning specimens from CRMH, which could account for these differences. Lack of staff to cover these hours at CRMH meant that no specimens were collected during times that would coincide with a higher likelihood of alcohol-positive drivers being on the road. The same reasoning may also account for the lower prevalence of cannabinoids from CRMH compared to WFMC. Thus, the results from CRMH should be considered an underestimation of drug prevalence in seriously injured drivers.

CHAPTER HIGHLIGHTS

- ✓ If there are fundamental differences between how the data were collected at each site, or what data were collected, then it will likely be more appropriate to analyze data on a site-by-site basis.
- ✓ When determining what data should be included, the following are of note:
    - Decide if results that are positive for inactive metabolites only will be included or excluded.
    - Ensure this decision is applied across the board at all sites to ensure consistency.
    - Input and guidance from a toxicologist are strongly advised in order to determine the exclusion criteria for EMS administered drugs.
- ✓ Preliminary analyses of the data are advised to look for trends in positive results before deciding on specific combinations or drug categories to focus on.

CHAPTER 9: CONCLUSIONS & LESSONS LEARNED

Drug-involved driving is a complex and evolving issue for a multitude of reasons, many of which stem from inconsistencies and limitations to the non-alcohol drug data currently available (e.g., FARS). This lack of high-quality, consistent data makes it difficult to understand the scope of the drug-involved driving problem, including the prevalence of drugs other than alcohol in crashes and in general everyday driving. A potential solution is to create a sentinel surveillance system for drug use by drivers involved in crashes. The steps covered in this Guidebook follow the path from the initial identification of potential sentinel sites through implementation of the data collection protocol to data analysis, implications, and applications for findings.

The development of the Guidebook was based on the pilot implementation of a sentinel surveillance system at two participating study sites, CRMH in Roanoke and WFMC in Winston-Salem. Other sites may be different and have varying procedures and processes in place. Despite this potential variability, **the lessons learned by the coordinating agency and the research teams from each pilot site provide an invaluable resource for other interested agencies or teams and a solid foundation on which to build and create a nationwide sentinel surveillance system.** Data from such a system is critical to further understanding the contribution of non-alcohol drugs and polydrug use to crashes and would facilitate the monitoring of changing drug trends in drivers. As a result, more effective countermeasures to prevent drug-involved driving may be developed, helping to ensure that the limited resources available to states to address drug-involved driving are put to good use.

LESSONS LEARNED

Members of the coordinating agency, VTTI, learned a great deal during the development and implementation of the pilot sentinel surveillance system. However, one factor stood out above any other as the crucial element for success. **Effective communication is always important, but in this case, it was absolutely vital and would become even more so if the sentinel network grew to incorporate a greater number of hospitals** (i.e., sentinel sites). Each sentinel site may have an array of personnel involved in the study, so communication within each site is necessary for reliable and effective data collection. An open line of communication between the coordinating agency and each sentinel site needs to be established early-on in the process so all issues and problems can be identified as soon as they emerge, and steps can be taken to rectify them. Problems that arise at each sentinel site may be vastly different and require distinct solutions; however, a "go it alone" attitude at a sentinel site will invariably create more problems than it solves. This is due to the fact that, in order **to create a sentinel surveillance system that collects accurate and representative data comparable across sites, the same data collection protocol and procedures need to be in place and adhered to at all times.** For example, if all sentinel sites were collecting blood specimens from patients and one site decided urine specimens were sufficient, this would

automatically exclude that site from the sentinel network as toxicology results using two different testing matrices are not comparable, which would greatly affect the usability and interpretation of the drug results. Similarly, if all sentinel sites were sending blood specimens to the same toxicology laboratory for testing and one (or more) sites decided it was more cost-effective to use the hospital's in-house toxicology laboratory, this would also greatly impact the results due to the potentially different equipment, protocols, and procedures in place at each toxicology laboratory. If the PI or project manager at a sentinel site needs to make changes to the data collection protocol, for whatever reason and at any point in time, this needs to be discussed and agreed upon with the coordinating agency. It is strongly advised to set up regular meetings between the coordinating agency and the PI at each sentinel site at the beginning of the study. Meetings could be held every 2 weeks or once a month, depending on the needs of the study and site. Trauma surgeons, doctors, and medical personnel typically work irregular hours, so identifying a mutually agreeable time early on will make things easier and more streamlined moving forward. Once a regular meeting is scheduled, it can be skipped or postponed if not needed at that particular time. It is far easier to skip a prescheduled meeting than to arrange a new one each time the research teams need to meet to discuss the project.

> Set up regular meetings early in the preparation phase of the project. Communication is critical to success of the sentinel surveillance system. It is easier to skip or postpone a pre-scheduled regular meeting than to find a mutually agreeable time once a meeting is deemed necessary

While the criteria to join a sentinel surveillance network may be strict (i.e., a minimum standard for participation is necessary to ensure the collection of consistent, high-quality data), **the coordinating agency needs to be flexible and work with potential sentinel sites to identify the barriers to their joining the sentinel network and devise solutions and/or improvements to procedures and processes that will create a smoother path forward**. For example, during the initial discussions with the two pilot sites, the PI from the coordinating agency had to make the case for using blood specimens over urine, as both sites currently used urine for toxicology screening. By laying out the reasons for requiring blood specimens, rather than urine, the PI at each pilot site agreed that collecting an additional vial of blood from a qualifying patient fell within the "standard care" for level 1 and level 2 trauma patients. Thus, it was not necessary to change any existing patient treatment protocols in order for the pilot sites to participate in the study.

Streamlining the data collection and storage process as much as possible also reduces the chance of errors or mix-ups, particularly if there are a large number of people involved in data collection. WFMC, for example, had medical students and residents involved in data collection, so the project manager created individual patient packets comprising the data collection form and blood vial,

both of which were prelabeled with Sample ID numbers. This reduced the risk of research personnel incorrectly assigning, or forgetting to assign, an ID number to the blood specimen and patient information. Due to the nature of the de-identification process, most errors that may have occurred during data collection would not be rectifiable as the information and blood specimen could not be linked or traced back to the patient. Thus, in the context of this study protocol, errors would have resulted in lost data. However, the data collection protocol that was put in place during the pilot study mitigated any potential errors and no data were lost.

Creating a sentinel surveillance system for drug use by drivers in crashes would go a long way toward helping researchers and policy makers truly understand the scope of the drug-involved driving problem. There are so many limitations on the currently available drug-involved driving data that the role non-alcohol drugs play in crashes, injuries, and fatalities is still unknown. **In order to address these limitations, high-quality consistent drug data needs to be collected and the most viable method to do so is to partner with Level 1 trauma centers.** The high-quality 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. The data collection protocol developed for the sentinel pilot study was created in close collaboration with the PI from each trauma center, meaning every decision was based on a solid line of reasoning regarding what would work at their facility. The outcome was a fully functioning protocol that should be easily applicable (with minor modifications) to other trauma centers across the country. Building the protocol from the ground up presented many challenges and lessons, each of which has been presented in this Guidebook in the hopes of making the path forward easier to navigate.

CHAPTER HIGHLIGHTS

- ✓ Effective communication is vital and would become even more so as the sentinel network grows to incorporate a greater number of hospitals.
- ✓ To ensure the collection of accurate and representative data that is comparable across sites, the same data collection protocol and procedures need to be in place and adhered to at all times.
- ✓ The coordinating agency needs to be flexible and work with potential sentinel sites to identify the barriers to their joining the sentinel network.
    - Devising solutions and/or improvements to procedures and processes will create a smoother path forward.
- ✓ Streamlining the data collection and storage process as much as possible reduces the chance of errors or mix-ups, particularly if there are a large number of people involved in data collection.

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APPENDIX A – TRAINING PRESENTATION

Developing a Sentinel Surveillance System for Drug Use by Drivers in Crashes: Pilot Implementation

What is the Challenge?

- Impaired driving continues as a significant public health challenge
  - Approximately 10,000 individuals lose their lives each year in *alcohol-involved* traffic crashes.
  - Yet, little is known about the prevalence of drugs in traffic crashes.
- Why don't we have good data on drug-involved crashes?
  - There is no "breathalyzer" for drugs.
  - Drug testing is complex, time consuming, and expensive.
  - Laboratory drug testing practices vary greatly across and within jurisdictions.
  - Toxicology results are handled across numerous types of locations (e.g., hospitals, police stations, coroner's offices)
  - There may be little legal incentive to test for other drugs when alcohol is detected.

2

Why is this Important?

- Rapidly shifting cannabis legalization environment
- Evolution of the opioid epidemic
- Greater understanding of drug combinations and complexities
- Accurate data is critical to understanding the drug-impaired driving problem and developing effective solutions

3

We Need To Improve What's Currently Available!

U.S. Department of Transportation
National Highway Traffic Safety Administration

TRAFFIC SAFETY FACTS
Research Note

DOT HS 812 072 | Behavioral Safety Research | November 2014

Understanding the Limitations of Drug Test Information, Reporting, and Testing Practices in Fatal Crashes

Amy Berning & Dereece D. Smither

Since 1975, the National Highway Traffic Safety Administration (NHTSA) has collected data from all 50 States, the District of Columbia, and Puerto Rico on all police-reported fatal crashes on public roadways. NHTSA's National Center for Statistics and Analysis (NCSA) includes data from these fatal crashes in the Fatality Analysis Reporting System (FARS). This dataset provides a wealth of information on fatal crashes, the roadways, vehicles, and drivers involved.

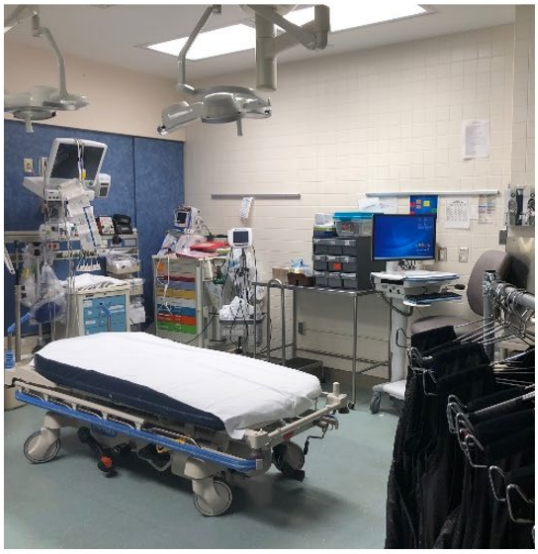
In addition, while the impairing effects of alcohol are well-understood, there is limited research and data on the crash risk of specific drugs, impairment, and how drugs affect driving-related skills. Current knowledge about the effects of drugs other than alcohol on driving performance is insufficient to make judgments about connections between drug use, driving performance, and crash risk (Compton, Vegega, & Smither, 2009).

- The use and misuse of drug data in FARS is prevalent
- NHTSA has published a research note documenting the limitations of drug data in FARS

4

Why Level I Trauma Centers?

- Representative sample of severely injured drivers
- Controlled environment for conducting standardized toxicology testing
- Highly trained staff of medical professionals and researchers



5

Objectives

- Pilot implementation of a Sentinel Surveillance System at two Level 1 Trauma Centers
  - Carilion Roanoke Memorial Hospital in Roanoke, VA
  - Wake Forest Baptist Health Medical Center in Winston-Salem, NC
- Develop a guidebook, resources, and materials to facilitate the growth of this sentinel surveillance network to other trauma centers across the country

6

Overview of Procedure

- Target population:
  - Trauma patients identified by EMS as the driver involved in a motor vehicle or motorcycle crash
- As part of their standard care, trauma patients have multiple vials of blood collected upon arrival
- An additional vial of blood and basic demographics will be collected at this time for inclusion in the study
- This research blood vial will be de-identified and stored then sent to an independent laboratory for comprehensive drug testing

7

Data Collection Protocol

- Patient information collected at time of admission
  - Sample Number
    - Recorded from the label attached to the research blood vial and entered into REDCap
    - The blood vial number MUST match the sample number assigned to the patient information
  - Sex of patient
  - Age category of patient
  - Medications administered by EMS personnel at crash site or en route to hospital
    - Drug type/class and dosage
    - VERY important information to enable researchers to eliminate these drugs from the toxicology test results

8

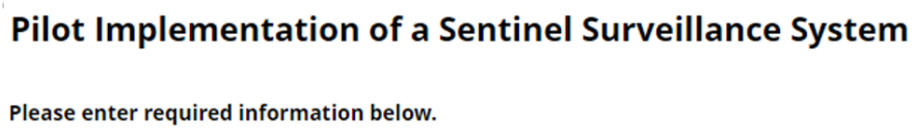
Data Collection Steps

1. Collect additional vial of blood from the patient on admission to the trauma bay using gray cap research blood vial
2. Take a "Sample Number" label from the label sheet on the clipboard and attach it to the research blood vial
   - NO OTHER patient information is to be recorded on the vial of blood designated for this study

9

Data Collection Steps

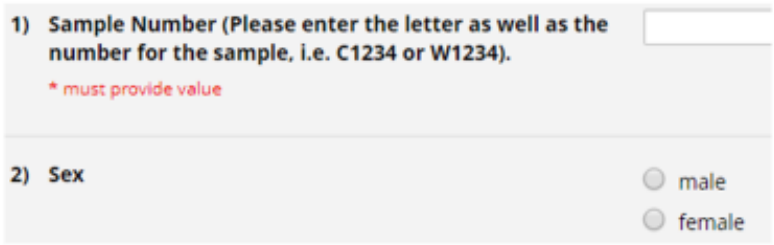
3. Use the REDCap system generated link to log into the Sentinel data collection application
   - Link: *https://insert.redcap.link/xxxx*
   - This link will take you directly to the data entry page



10

Data Collection Steps

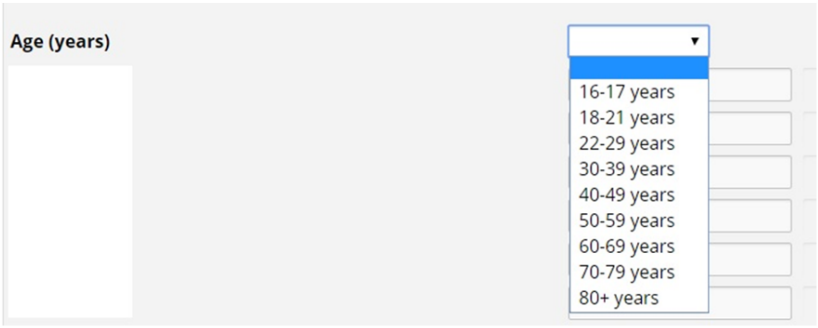
4. Record the same Sample Number that is written on the research blood vial, include the letter & numbers
   - E.g., C7337 or W1543
5. Indicate the sex of the patient



11

Data Collection Steps

6. Select the appropriate age category for the patient from the drop-down list



12

Data Collection Steps

7. Use EMS records to choose specific medications and dosages for each drug administered to the patient by EMS
   - Each medication needs to be recorded separately
   - E.g., medication 1, medication 2, etc.
   - Type in the first three letters of the medication then choose from the drop-down list with the corresponding correct dosage

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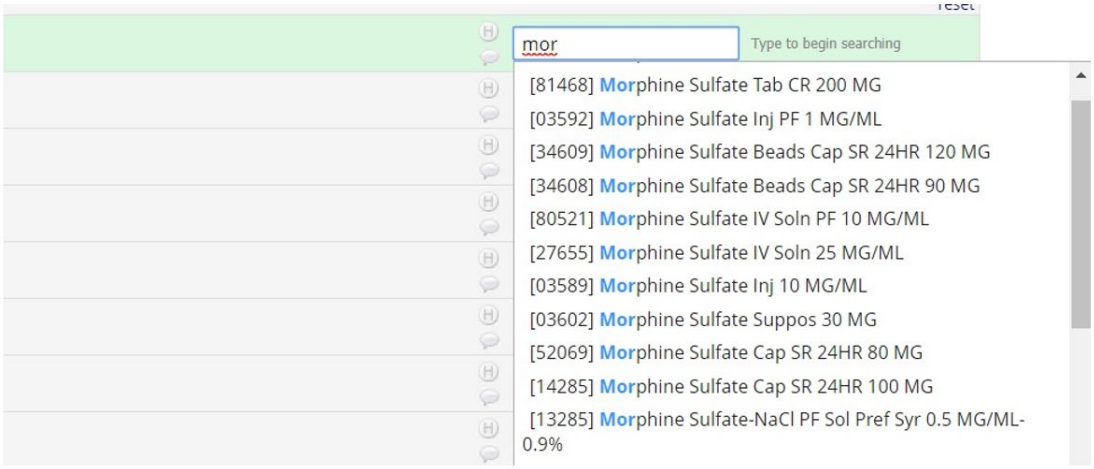
Example of Medication Data Entry



14

Data Collection Steps

8. Save the patient record in REDCap
9. Deliver the research blood vial to the lab for storage in the designated space in the fridge
    - Inform the lab the blood vial is for VTTI Sentinel study
10. Blood samples will be packed each week by a designated team member using the packing materials provided. The samples will then be shipped via FedEx to the toxicology lab for testing.

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Important Discussion Points

- Who will be the main point of contact and/or managing the study?
- Need gray top blood vials *very important*
- Coverage in terms of research staff availability?
- Record of missed patients?
- Usual FedEx pickup day?
    - Who will be responsible for packing and shipping?

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