Enhancing NFLIS – Implementing an Medical Examiner/Coroner Office and Toxicology Laboratory Data Collection

Background: Currently, the National Forensic Laboratory Information System (NFLIS) is a DEA program that systematically collects results from drug chemistry analyses of seized substances conducted by state, local, and federal forensic laboratories across the country. NFLIS presents the laboratory results validated by chemical analysis. NFLIS provides scientifically verifiable forensic analysis data to support drug control actions under the CSA, as well as to support international scheduling actions. NFLIS information is also used for monitoring and understanding drug abuse and trafficking in the United States, including the diversion of legally manufactured drugs into illegal markets.

Overall Project Goal: Establish a data coordination center that will design, implement, and maintain a continuous program for providing DEA with current information on drug-related mortality and toxicology findings supplied by medical examiner/coroner (ME/C) offices and toxicology laboratories to supplement the NFLIS drug seizure data.

Such a data coordination center could provide a range of tasks including, but not limited to, the following:

- **Data collection design**
  - Define data requirements (e.g., drug types, date of death, manner of death, etc.); select measures; protocol development; analysis planning.
- **ME/C Recruitment**
  - Establish relationships and negotiate data reporting procedures, agreements, and incentives
  - Secure MOU's with ME/C and toxicology laboratory participants.
- **Assess ME/Cs Testing Protocols and Populations Referred to ME/Cs**
  - Assess/evaluate toxicology testing protocols; define populations referred to ME/Cs and toxicology labs; anticipate differences in protocols and populations referred.
- **Data Capture and Management**
  - Perform electronic data capture from ME/C offices nationwide (as well as toxicology labs if decision is made to include them in final data collection); harmonize data inputs; build ancillary systems; ensure data security.
- **ME/C Data Coordination**
  - Provide guidance to sites about the core data elements, reporting options, and any resources available; provide technical assistance where needed.
- **Statistical Analysis and Reporting**
  - Develop a nationally representative sample in the short-term that will enable establishment of national estimates on drug-related deaths.
  - In the long-term, develop statistical design and analytic methods for reporting from incomplete or partial data in census; imputation; assess data use protocols; prepare publications and presentations; and provide statistical consultation where needed.
- **Project Management and Logistics**
  - Project coordination; communications; progress reports; site incentives
  - Institutional review board coordination

- Data privacy monitoring
- Regulatory filings and submissions

Phase 1

September, 2015 – January, 2016

Short Term Objective: Build project foundation to support Phase 2 objectives and tasks

Core foundational activities:

1. Build the ME/C and toxicology lab frames.
2. Identify topics to be discussed with key stakeholders and consultants.
3. Identify and recruit key stakeholders.
4. Identify core data items for data collected from ME/C and toxicology labs
5. Begin modifying existing readiness assessments for pilot site visits.
6. Begin identifying and recruiting pilot sites for Phase 2.
7. Initiate preliminary discussions regarding potential sampling approaches.
8. Tap internal data processing expertise for innovative ways to parse narrative data.

Task 1 – ME/C and Toxicology Lab Universe and Sampling

1. **Establish the universe of ME/C offices and toxicology labs in the United States**
2. **Evaluate potential sampling approaches that take into consideration key factors for sites selected**

Task 2 – Outreach and Communications

1. **Identify topics that will need to be discussed with key stakeholders and consultants**
2. **Identify (and possibly recruit) 5-6 key stakeholders for work in Phase 2**
3. **Begin identifying and recruiting pilot sites for Phase 2 (Task Lead: Katherine Moore)**

Task 3 - Develop Project Design

1. **Identify core data items for data collected from ME/C and toxicology labs**
2.

Task 4 - System Assessment and Data Collection

1. **Begin modifying existing readiness assessments for pilot site visits (Task Lead: Hope Smiley-McDonald).**
   Assessments would include the following dimensions: data system infrastructure (including type of information management system), caseloads, data availability, data quality, data timeliness, agency willingness to participate, incentives/barriers to participation, overlap between current drug labs and ME/C offices, and relationships between ME/C offices and toxicology labs. These readiness assessments could be

conducted on-site at ME/C officers and toxicology labs or potentially could be conducted remotely by phone.

   a. Instruments could be pre-tested at the North Carolina Office of the Medical Examiner in Raleigh, NC during Phase 1.

2. **Tap internal data processing expertise for innovative ways to parse narrative data (Task Lead: Mark Pope).**
   Evaluate methods, software, and staff that could be leveraged since many of the death records may be in PDF/paper format.

3. **Initiate communications with key LIMS providers (Task Lead: Jeff Ancheta).** Such efforts will facilitate ME/C and forensic laboratory participation and reporting.
4. **Determine the costs and timeline for Phase 2 implementation (Task Lead: Hope Smiley-McDonald).**
   RTI will develop a methodological approach for estimating the cost of Phase 2 implementation including incentives, data extraction, data processing, analysis, and possibly, reporting. Forecast timeline for Phase 2 implementation.

Phase 1 Products

1. A universe of ME/C offices and forensic toxicology laboratories.
2. Summary of recommended sampling approaches.
3. Recommendations for core data items for ME/C and toxicology lab data collection
4. Recommendations for external and internal infrastructure needed to process data
5. Forecasted labor hours (by CLIN) needed for Phase 2 implementation.
6. Timeline for key milestones for Phase 2 implementation.
7. Regular progress reports on all project phases via the monthly progress reports.