Harm Reduction Toolkit for Non-Prescription Syringe Sales in Community Pharmacies

OMB No. 0920-New

Supporting Statement B

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B. Collections of Information employing statistical methods

1. Respondent Universe and Sampling Methods

The in-field demonstration is primarily designed to make comparisons between participants pre- and post-training, not to make generalizations to the larger population. As such, the sample will be a non-probability based convenience sample. The respondent universe is pharmacy personnel at 12 project sites. Project sites are anticipated to be a mix of community, retail and independent pharmacies. Each project site will enroll 5 participants for a total of 60 participants. No sampling methods will be used to choose project sites; both the project sites and project participants will represent convenience samples.

Persons who inject drugs (PWID) who purchase syringes at the project pharmacies, during the in-field demonstration, will be given the harm reduction kit and access to the resource website for PWID. Although no data will be collected directly from PWID, usage of the resource website will be collected.

Participant eligibility includes pharmacy personnel (e.g., pharmacists and pharmacy technicians) who work at one of the project pharmacies. CDC will work with the contractor (dfusion Inc.) to define additional eligibility criteria.

2. Procedures for the Collection of Information

Data collection methods

Three types of information will be collected for the project: online pre-test and post-test surveys; number of pharmacy syringe sales and service referrals and; website usage for the training website and the resource website for PWID.

Each pharmacy personnel who participates in the in-field demonstration will complete a one-time online pre-test survey and a one-time online post-test survey. Data from the pre-test and post-test surveys will be collected entirely online (**Att 6, Att 7 and Att 7a**). A one-time data collection of aggregated data on syringe sales and service referrals (**Att 8**) from the 30-day period before and after the training period will be collected; these data will be collected from pharmacy store or log records. Usage of the training website will be determined by downloading website administrative data and Google Analytics will be used to determine website usage of the resource website for PWID in the 30 days following the training period.(**Att 9**)

Data Transmittal

Aggregate level data will be electronically transmitted to CDC through the CDC Secure Data Network (SDN). All data transmissions are automatically encrypted by the software that generates the transfer files. Security certificates are used to control access to the SDN.

Analysis plan summary

Primary project outcomes include the following: the acceptability and usability of the online training videos for pharmacists and pharmacy personnel regarding NPSS; pharmacy personnel NPSS knowledge and skill before and after the online training period; and numbers of syringe customers and service referrals before and after the online training period. All outcomes will be compared pre- and post-online NPSS training.

MicroSkills™ scores will be calculated based on the short answer scenarios described in the pre-test and post-test surveys for pharmacy staff. The training website usage data will be paired

with the online pre-test and post-test surveys and MicroSkill™ scores and analyzed for correlations between usage and knowledge, comfort, and use of MicroSkills™. The number of syringe customers and service referrals (before and after the online training period) and usage of the resource website for PWID will be also described.

Analysis results are not meant to be generalizable; rather they are meant to describe participants' understanding and skills regarding NPSS before and after use of the contractor developed resources (e.g., online NPSS training).

Sample Size Justification

At the pharmacy level, to achieve an 80% power with an average effect size of 0.97, the project needs to be conducted in approximately 12 project sites. The average effect size was estimated using data analyzed during Phase I. At the individual level, a power of 80% with an effect size of 0.4 and p-value ≤0.05, a sample size of n=52 is required. Minimal attrition (13%) is expected due to the short study period bringing the total sample to n=60. All outcomes will be analyzed using a paired t-test.

3. Methods to Maximize Response Rate and Deal with Nonresponse

Attrition is expected to be minimal because the data collected directly from participants will take place over one six-week period. To enhance retention, a $20 token of appreciation will be given for completion of both the pre-test and post-test surveys. The contractor will work with the project sites to address any problems with data collection and to resolve data discrepancies.

4. Tests of Procedures or Methods to be Undertaken

The data collection forms were developed using questions from previous dfusion Inc projects with input from CDC and the project Advisory Panel which is comprised of pharmacists and harm reduction experts.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Project team members who were consulted on the aspects of project design and those who will be collecting and analyzing the data are listed below.

The contractor

CDC awarded a contract to dfusion Inc to conduct the project. The contract staff is involved with all aspects of designing and implementing the project. All data will be collected by contract staff. The contractor will analyze the data.

The following individuals were consulted on the statistical aspects of the project:

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The following contracted staff will analyze project data:

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CDC staff

The CDC staff members who are involved with the various aspects of designing and implementing the project are listed below. CDC staff will not be directly involved in the data collection, and will not be in contact with study participants. CDC will only receive aggregate-level data.

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