

**"Evaluation of Pharmacy Syringe Access Linked to HIV Testing for
Injection Drug Users in New York City (Pharm-HIV)"
0920-09XX**

**Supporting Statement
Part B**

Contact Information

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B. Statistical Methods

1. Respondent Universe and Sampling Methods

The respondents providing the information for the proposed project are pharmacists and pharmacy staff and injection drug using (IDU) syringe customers at 12 of 958 New York City pharmacies registered with the Expanded Syringe Access Program (ESAP)¹ and located in Harlem, New York. New York Academy of Medicine (NYAM) will screen pharmacies for eligibility by administering a standardized screening instrument ("Pharmacy Telephone Screening and Enrollment Form", Attachment 3A) over the telephone to a randomly-ordered list of ESAP-registered pharmacies until 12 pharmacies have been recruited. Pharmacy inclusion criteria include:

1. Selling to at least three new IDU customers per month,
2. At least two new IDUs becoming regular syringe customers per month; and,
3. Allow the research staff to interview other pharmacy staff that sell syringes in the pharmacy.

Two pharmacists and 2 technicians from each of the 12 pharmacies recruited into this study will provide information.

The number of pharmacies to be enrolled is a convenience sample based on the resources available at the NYAM. Previous experience of the NYAM indicates that the target of 12 pharmacies may be reached by screening 24 pharmacies. This is the number used in calculating the burden hours (Exhibit A.12.1). Two kinds of pharmacies will be included in this study: 10 pharmacies refer syringe customers to an outside HIV testing facility and 2 provide HIV testing services on-site.

Two pharmacists and 2 pharmacy technicians (hereafter called 'technicians') from each of the 12 pharmacies will inform this project on the demographics of the clientele and the types of services provided on-site or collaborating referral facilities. This information will be collected at the start of the project, 6 months, 12 months, and 18 months, and as an exit survey at the end of the data collection period of this project. In addition, 1 pharmacist from each of the 12 pharmacies will provide status reports on a monthly basis on a standardized instrument (Attachment 3B).

In addition to the surveys, a technician will submit a daily log of syringe sales.

Table 1. Respondents and data collection instruments used in this study.

Respondent type	Number participating per Pharmacy per year	Data collection instrument (Attachment #)	Corresponding row(s) in Exhibit A.12.A
Pharmacists (Screening)	1	5	1
Pharmacists	2	3a, 3b, 3d, 3e	2, 3, 4, 5
Technicians	2	3a, 3c, 3d, 3e	6, 7, 8, 9
Syringe using customers	(221/12)	3f	10

Based on prior experience of pharmacies in Harlem, New York, screening 24 pharmacies are estimated to yield 12 eligible pharmacies for this study. The screening process will only be done in year 1.

Two pharmacists from each pharmacy will complete data collection instruments 3a, 3d, and 3e. One pharmacist from each pharmacy will complete data collection instrument 3c.

Two technicians from each pharmacy will complete data collection instruments 3a, 3d, and 3e. One technician from each pharmacy will complete data collection instrument 3c.

A total of 442 Injection drug using (IDU) customers will inform the project once each. Of these, 360 customers will be from pharmacies that refer customers to an external facility for HIV testing and 82 from pharmacies that provide on-site HIV testing. Annually, an anticipated 221 adult IDU customers will complete the survey.

The IDU customers are regular clientele of the pharmacy who have bought syringes without a prescription at least two times. Participation of the IDU customers will be entirely voluntary with a written consent. The target sample will be reached by engaging as many IDU customers as needed until the target for each year is reached.

2. Procedures for the Collection of Information

Recruiting pharmacies:

ESAP pharmacies must register with the New York State Department of Health. A current list of ESAP-registered pharmacies is available at the New York State Department of Health website¹.

Pharmacies will be screened for eligibility by telephone. Based on their earlier experience NYAM will call during specific hours and on certain days when business is likely to be slow. After five unsuccessful attempts, the pharmacy will be coded as "unavailable". The interviewer will request to speak to the managing pharmacist and, following a script, will introduce herself as an employee of the New York Academy of Medicine and ask if this is a good time to speak; if not, an effort will be made to arrange a good time. After establishing a convenient time to talk, the interviewer will ask the managing pharmacist if s/he is interested in participating in a research program that helps their IDU customers gain access to HIV testing. If interested, NYAM will administer the screening instrument over the telephone and determine whether the pharmacy and its staff may be included in this study.

Pharmacist and Technician surveys:

Two pharmacists will inform the project through baseline, 6 month, 12 month, 18 month, and an exit survey at the 24th month of the data collection period.

Two other data collection activities are included in this study. The first is a monthly survey regarding the project's progress at their facility. One of the 2 pharmacists from each pharmacy will participate in this monthly status review. The second is a completion of a daily syringe sale log sheets. A technician at each of the 12 pharmacies will submit the daily syringe sales log to project staff.

All surveys, will be administered by NYAM staff using a computerized survey tool, Questionnaire Development System (QDS) Version 2.5 R004 which is a Computer Assisted Personal Interview (CAPI), so information will be stored as it is collected. The baseline survey will be administered to 2 pharmacists and 2 technicians at each of the 12 pharmacies, at the initiation of the pharmacies' involvement in the collection of information. The Monthly Pharmacy Survey will be administered by NYAM staff during monthly visits to each pharmacy. It will be administered to whichever pharmacy staff person is present and available at the time of the visit.

The monthly survey will consist of qualitative and quantitative questions designed to gather information about the pharmacy's study-related activities over the past month and to track materials given out to syringe customers. It will serve as a tool for research staff to inquire about challenges and problems in order to help the pharmacy staff better carry out study.

Collecting this information less frequently would result in less timely improvements to the study conduct.

The 6, 12, and 18 month surveys will include an assessment of participating pharmacists' and technicians' support of the existing New York City Expanded Syringe Access Program, enhanced pharmacy services for IDUs, and information of the current and projected servicing of IDU syringe customers. This is necessary in order to determine how the knowledge, attitudes, and beliefs of pharmacy staff evolve over time while implementing this novel service.

The exit survey will be administered at the completion of the study. The exit survey includes both qualitative and quantitative measures of pharmacists' and technicians' experiences and insights on the expansion of pharmacy services. From these data we will learn the challenges, obstacles, and successes of implementing an HIV testing program in a community pharmacy in order to derive lessons learned for future programs should this pilot program be deemed useful. Collecting the information less frequently would result in a less robust assessment of these issues

Daily syringe sales log:

The daily syringe sales log sheet will be a scannable instrument completing the sales registered each day. The log sheets for the month will be collected by a NYAM researcher at the time of the monthly pharmacy visit. This is necessary to track the volume of business regarding syringe exchange so that we may learn the relative effort needed in order to identify syringe-customers in need of HIV testing. It is also needed to calculate the ratio of number of persons screened to number of persons tested for HIV. Collecting the information less frequently would render us unable to estimate this important variable for future program planning.

IDU customer surveys:

The pharmacist or technician in each of the 12 pharmacies will engage syringe-purchasing customers in light conversation and inform eligible IDU customers of the survey. If the customer expresses interest in taking part in the study the IDU customer will be offered an appointment time within the next two weeks and given a card reminding them of their appointment to return to the pharmacy for the 20-minute ACASI survey(Attachment #3f).

The pharmacist/ technician will also offer to remind the IDU customer of their appointment. If the customer agrees to be reminded of the appointment during the interim visits, the pharmacist/ technician will remind the customer discretely of the upcoming appointment during any pharmacy visits that occur before

the appointment date. This process of recruiting IDU customers for the survey will occur throughout the 24 months of the project's duration resulting in 221 interviews each year.

At each appointed day and time, NYAM staff will interview IDU customers at the pharmacies on previously scheduled days. The interview will be conducted using a computerized survey tool (ACASI - Audio Computer Assisted Self-Interviewing), and overseen by a trained NYAM researcher.

This software, provided by Questionnaire Data Systems (QDS), asks survey questions via headphones while the survey respondent provides the answers using a touch screen tablet PC.

NYAM research staff will train each participant using a tutorial prior to administering the survey. The ACASI system allows the participant to both read and hear each question, and is programmed so that questions must be answered in consecutive order. Skip patterns are automatic. Participant answers are automatically stored in the ACASI memory. If the participant is unable to access the ACASI system or if there is a technical problem, back-up paper questionnaires will be available

The IDU customer interview will last approximately 20 minutes.

In the 2 pharmacies providing on-site HIV counseling and testing pharmacy staff will inform IDU customers of the dates when HIV testing is offered. IDU customers who are willing to participate in the survey will be given an appointment for the survey as described above. In these sites, the surveys will be conducted on the dates of the HIV testing.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Selection of pharmacies for the collection of information will be made by calling down a randomly-ordered list of all ESAP-registered pharmacies. Based on earlier experience, calls will be made during specific hours and on certain days when business is likely to be slow (before 4pm Monday-Thursday excluding Monday morning). After five unsuccessful attempts, the pharmacy will be coded as "unavailable." If a pharmacist is contacted, but declines, he/she will be thanked for his/her time and the next pharmacy on the list will be called. If the pharmacist is busy on the first attempted call, he/she will be asked for a more convenient time.

In an August 2004 pharmacy telephone survey in NYC, NYAM examined opinions about drug treatment and other public health services for IDU syringe purchasing customers. Of the 151 ESAP registered pharmacies surveyed, 87% of pharmacists surveyed were willing to

take the time to offer drug abuse treatment and other health-related information to their IDU customers. These data suggest that pharmacists at ESAP registered pharmacies are highly likely to be interested in participation in the collection of information.

The pharmacies participating in the proposed project are assumed to be in business for the duration of the proposed project. NYAM staff will be in regular contact with pharmacists and pharmacy staff to conduct monthly surveys and to visit the pharmacy to conduct surveys with IDU syringe customers. However, contact information for IDU syringe customers will not be collected.

4. Test of Procedures or Methods to be Undertaken

This is a novel study for which previous data do not exist. The data collection instruments have not been used in previous studies. The NYAM has provided services and done other research among the Expanded Syringe Access Program in New York City. Surveys of pharmacists and syringe-customer attitudes toward syringe-exchange have been conducted by NYAM.

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

Individuals consulted on statistical aspects are the lead scientists on this project from The Center for Urban Epidemiologic Studies, New York Academy of Medicine, 1216 5th Avenue, New York, NY 10029

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Others consulted on the statistical aspects are the project officers from Centers for Disease Control and Prevention, 1600 Clifton Rd., MS E-45, Atlanta, GA 30333

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Individuals collecting and analyzing the data are from The Center for Urban Epidemiologic Studies, New York Academy of Medicine, 1216 5th Avenue, New York, NY 10029

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References

- (1) New York State Department of Health. Directory of ESAP providers in New York State. January 2008; Available at http://www.health.state.ny.us/diseases/aids/harm_reduction/needles_syringes/esap/provdirect.htm. Accessed Jan 29, 2009.