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**Final Report**

**"Investigation of the Reasons for the Increase in Reported Cases of Syphilis"**

**Data Collection Documentation**

**November 16, 1992**

Prepared for:

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## **I. INTRODUCTION**

The purpose of this report is to describe and document the data collection activities for a case-control study designed by investigators at the Centers for Disease Control (CDC) in Atlanta. A study questionnaire was administered to patients attending public health clinics located in seven cities, and to a sample of community residents living in the City of Philadelphia.

The principal activities conducted under this project to implement the study protocol included the following: (1) design data collection methods--including quality control measures, (2) manage the administration of the study questionnaire, (3) develop data bases, (4) code, clean and enter data, and (5) provide documentation for the database.

The CDC principal investigators for the study are Robert Rolfs, M.D. and George Schmid, M.D. A project Data Collection Team was responsible for designing, managing and documenting the data collection activities conducted for the study. A Data Collection Supervisor was responsible for overseeing the activities and conferring with Dr. Rolfs when necessary.

Following this introduction, Section II briefly describes the study for which data collection was conducted. Section III describes the data collection activities conducted at the clinics and Section IV provides the results those activities. Section V describes the community data collection activities and Section VI provides the results of the community data collection. Lastly, Section VII describes data management activities and the documentation for the data base.

## II. STUDY DESCRIPTION

CDC Investigators designed the study in response to an epidemic of syphilis that is occurring in many areas of the United States. Anecdotal reports from a number of these areas suggest a link between drugs or drug-related behaviors and the acquisition of sexually transmitted diseases, including syphilis, chancroid and PPNG. The purpose for the study is to investigate the relationship between drug use and the acquisition of sexual disease and to determine if this relationship is a possible reason for the increases in the number of reported cases of early syphilis. Drug-related behaviors may be an important factor in the increases in early syphilis seen in many areas of the United States between 1985 and 1988.

The study was designed to achieve the following objectives:

- (1) Assess the roles of drug use and related behaviors (particularly drug-related prostitution) as risk factors for the acquisition of syphilis;
- (2) Assess the importance of this association as a cause of the increases in syphilis occurring in the United States;
- (3) Determine the effect of drug use on the outcome of sexually transmitted disease (STD) partner referral activities; and
- (4) Further investigate the possibility of intravenous needle-related transmission of syphilis.

The unit of analysis for this case-control study is the individual with a clinical diagnosis of primary or secondary syphilis. Cases are patients who present voluntarily to the clinics participating in the study and who are diagnosed with primary or secondary syphilis. Controls are patients who present voluntarily to the same clinic, but who do not have syphilis. In one of the participating study sites, an additional control group was selected to represent the community in which the clinic cases reside.

A questionnaire on behavioral risk factors for STD acquisition was administered to the clinic patients selected as cases and controls. A similar questionnaire, identical to the clinic questionnaire except for the STD diagnoses and laboratory results section, was administered to the community-based controls. Results of partner referral activities for the syphilis patients enrolled in the study were also obtained. The protocol with the complete study design and original questionnaire appears in Attachment A.

### III. CLINIC DATA COLLECTION ACTIVITIES

#### A. Site Selection

Data was collected at the following seven public health clinics:

- Health Center Number One, Philadelphia, PA.
- Dallas County STD Clinic, Dallas, TX.
- Memphis and Shelby County STD Clinic, Memphis, TN.
- Delgado City Clinic, New Orleans, LA.
- Near South Specialty Clinic, Chicago, IL.
- Palm County Health Unit, West Palm Beach, FL.
- City of Long Beach Department of Health and Human Services, Long Beach, CA.

A list of the primary contacts at each site is provided in Attachment B.

In September 1989, a project start-up meeting was held in Atlanta with Dr. Rolfs and the CDC central office staff who were assigned as contact persons to each study site. CDC provided members of the Data Collection Team with a list of clinics that had been identified as potential study sites.

The Data Collection Team contacted staff at each of the potential clinic sites, usually the STD control program manager and clinic director, to introduce the study protocol and confirm clinic participation. Several discussions were necessary to answer questions and finalize the terms of participation.

Clinic staff considered the following issues when making the decision of whether or not to participate as a study site:

- Staffing: concern that participation would burden disease control staff busy with an overload of patients and required responsibilities and, in some cases, involvement other studies.
- Disruption: concern that the study would interfere with, or jeopardize, the disease control activities that the clinics routinely conduct.
- Space: concern that a shortage of space at some of the clinics would make conducting the interviews difficult.
- Patient Volume: some clinics did not meet the threshold of primary and secondary syphilis patients needed for timely completion of the study, (i.e., approx. 25 per month).

Based on one or more of these concerns, three sites (i.e., Atlanta, San Diego and Oakland) that originally stated a possible interest decided not to participate.

#### B. Study Interviewers

Clinics were asked to assign one or several of their Disease Intervention Specialists (DIS) to the study as interviewers responsible for administering the questionnaire to study cases and controls. The full DIS staff at the Chicago, Dallas and West Palm Beach clinics were responsible for administering the questionnaire, in addition to performing their routine activities. The Philadelphia and Long Beach clinics designated one DIS as the sole interviewer for the study.

Due to the unavailability of DIS staff at the Memphis clinic, CDC temporarily assigned one DIS to the clinic for the purpose of conducting interviews. In New Orleans, the clinic agreed to hire an outside interviewer for the study.

A designated on-site study coordinator was selected at each clinic to oversee data collection by the interviewers and to communicate progress and any problems to the

project Data Collection Supervisor. A list of key persons responsible for data collection at each site is provided in Attachment C.

### C. Review Of Study Questionnaire

The questionnaire included in the original study protocol was reviewed by the Data Collection Team and staff at the participating clinics to assess the reliability of the instrument and suggest any necessary improvements.

Data collection staff suggested an additional response category, “refused to answer,” to capture a possible response to some questions, particularly those related to sexual activity and drugs. Suggestions were also made to reword some questions for consistency and clarity. Desktop publishing software was used to format the questionnaire to make instructions and questions easy to read and follow.

A content review of the questionnaire was conducted by the disease control staff at the study sites who have firsthand experience with the nature of the problem being studied and the behaviors of the study population. Among their suggestions were to make cocaine distinct from crack and to better define categories of sexual activity.

These suggested revisions were submitted to Wilma Johnson, Office of Planning and Evaluation, CDC for her to judge whether the changes would require approval by OMB. (OMB had already approved the original study questionnaire.) She judged resubmission of the questionnaire as unnecessary since the suggested revisions were not substantive changes. A copy of the questionnaires used in the clinic and community data collection is in Attachment D. (Two versions of the clinic questionnaire exist as explained in Attachment L, Coding and Data Entry Guidelines for SYPHi .dbf and SYPH2.dbf.)

#### D. IRB Review

Each site submitted the study protocol and questionnaire to their local institutional review board (IRB) for review. Some IRBs required modifications to the consent form, such as: (1) requiring the study participant to sign the consent form (Memphis, Chicago, West Palm Beach); (2) adding a statement releasing the clinic from responsibility for any damages that may result from participation (Memphis); and (3) minor word changes. A copy of the consent form used by each clinic is in Attachment E.

#### E. Procedures Manual

To ensure the quality of the data, an implementation plan, or procedures manual, was developed for each clinic. Its purpose was to standardize the method of administration at the clinics and to serve as a reference document for study interviewers. To develop the procedures manual, discussions were held with clinic staff to outline the functional operation of the clinic and patient flow. Understanding each clinic's unique operational design was necessary for determining when potential cases and controls would be available for selection into the study. Emphasis was placed on designing selection and administration procedures that correspond with the patient flow to minimize disruption of routine activities.

For each clinic the manual contains the following:

##### Clinic Operations and Procedures

- Organization of the medical and disease control operations of the clinic within the local health departments.
- Patient flow through the medical and disease control activities of the clinic.

## Coerational Plan For Study Imolementation

- The roles and responsibilities related to study activities at the clinic and the persons performing them.
- The protocol criteria for determining cases and controls.
- The procedures for administering the questionnaire, logging participants, obtaining lab results and transferring data from the clinic to the Data Collection Team.
- Schedule for the data collection based on the estimated number of patients seen in the clinic per month who met study criteria and the number of interviewers administering the questionnaire.

A copy of the procedures manual for each site is in Attachment F.

### F. Site Visits and Enrollment

Data collection staff conducted a one- to three-day site visit to each clinic to finalize the data collection plans, train interviewers, begin data collection, and monitor the administration procedures. Specific site visit activities included:

- Orientation: using the procedures manual, medical and disease control staff who were directly and indirectly involved with study activities were informed about the purpose of study and the implementation procedures.
- Interviewer Training: data collection staff reviewed each item in the study questionnaire by defining concepts and explaining question skip-patterns. Each interviewer was observed administering the questionnaire to identify and resolve problems with individual methods of administration.
- Assessing Data Collection Procedures: participant selection and logging procedures were observed to assess effectiveness. Necessary adjustments were made.

The schedule of site visits is shown in Table 1, below. In most cases only one site visit was necessary, but some sites required additional site visits to ensure successful data collection. For example, in Chicago and Memphis, data collection at the clinics ceased due

to staff turnover, so another visit was necessary to train new interviewers and resume the study.

Table 1: Site Visits

SITE	SITE VISIT
West Palm Beach	March 14-16, 1990
Dallas	April 2-3, 1990
Chicago	April 10-11, 1990 April 19, 1991
Memphis	July 2-3, 1990 March 21, 1991
Philadelphia	July 5-6, 1990
New Orleans	January 28, 1991
Long Beach	March 4, 1991

Table 2, below shows the period of enrollment for cases and controls at each site. The length of the time needed to enroll the required number of cases and controls in the study varied with conditions at each site (e.g., the volume of eligible syphilis patients and staff availability). In Memphis, data collection ceased between August 17, 1991 and March 27, 1991. In Chicago, data collection ceased between February 16, 1991 and September 16, 1991 (despite another site visit on April 19, 1991 to restart activity). Overall, the study periods ranged from three months in Philadelphia to 21 months in Chicago.

Table 2: Enrollment Period By Cases and Control

SITE	CASES		CONTROLS	
	Starting	Ending	Starting	Ending
West Palm Beach	3/15/90	3/29/91	3/15/90	3/12/91
Dallas	4/03/90	2/27/91	4/02/90	4/23/91
Chicago	4/10/90	2/16/91	4/10/90	10/03/90
	9/16/91	1/31/92		
Memphis	7/06/90	8/15/90	7/05/90	8/17/90
	3/27/91	6/26/91	3/27/91	6/17/91
Philadelphia	1/29/91	6/07/91	1/28/91	6/13/91
New Orleans	7/06/90	9/29/90	6/10/90	9/19/90
Long Beach	3/06/90	5/23/91	3/04/91	6/03/91

**G. Data Tracking**

Study coordinators at each site were responsible for maintaining a logbook to record certain identifying information on the study cases and controls enrolled in the study. This information was necessary only for the purposes of: (1) collecting lab results that were not available at the time of the interview; and (2) collecting records of partner referral activities for study cases (see Section I, below). Patient anonymity has been preserved since the clinics maintain the study logbook and access by the project Data Collection Team is not possible. A sample page from the logbook is in Attachment G.

Upon receiving the completed questionnaires from the sites, project staff recorded each questionnaire by study number. Using study eligibility criteria, each questionnaire was classified as either a case or control. A tally was kept of the number of cases and controls collected at each site so clinics could be kept informed about how many were needed to complete the study.

#### **H. Partner Referral Information**

After sufficient time elapsed to ensure clinic staff completed the routine partner identification activities for syphilis patients, each clinic was given the study numbers of the study cases interviewed based on the study case/control determination made by data collection staff upon the receipt of the completed questionnaires. Using the information in the study logbook to identify the records for each study case, clinic staff collected the number of partners reported by the study case, the disposition of each partner, and whether the study case was reinterviewed. A copy of the data collection form used is in Attachment H.

### **IV. CLINIC DATA COLLECTION RESULTS**

#### **A. Enrollment**

The total number of patients enrolled in the study for each clinic site are shown in Table 3, below. Of the total patients, the estimated number of cases and controls are also shown. The classification of cases and controls is subject to change based on the expert determination by Dr. Rolfs.

**Table 3: Enrollment By Case and Control**

<b>SITE</b>	<b>TOTAL ENROLLMENT</b>	<b>CASES (est.)</b>	<b>CONTROLS (est.)</b>	<b>EXCLUDED<sup>1</sup> (est.)</b>
1. West Palm Beach	487	124	317	46
2. Dallas	399	135	247	17
3. Chicago	455	140	311	4
4. Memphis	348	120	224	4
5. New Orleans	430	135	284	11
6. Philadelphia	375	107	247	21
7. Long Beach	274	9	242	23
<b>TOTAL</b>	<b>2,768</b>	<b>770</b>	<b>1,872</b>	<b>126</b>

**B. Refusal Rate**

The number of eligible individuals who refused to participate in the study when asked are shown by clinic in Table 4, below. Of the total 219 refusals shown, 43 (19.6%) were known to be cases, i.e., diagnosed with primary or secondary syphilis. Interviewers recorded refusals (gender, race, age, and syphilis diagnosis) using a designated section of the consent form. Data on the refused are contained a separate database (refer to Section VII, Part B, Data Entry and Documentation).

**Table 4: Refusal Rates**

<b>SITE</b>	<b>TOTAL ENROLLMENT</b>	<b>NUMBER REFUSALS</b>	<b>REFUSAL RATE</b>
1. West Palm Beach	487	70 (cases= 13)	14.3%
2. Dallas	399	44 (cases= 17)	11.0%
<b>3. Chicago</b>	<b>455</b>	<b>64</b> <b>(cases =3)</b>	<b>15.2%</b>
<b>4. Memphis</b>	<b>348</b>	<b>(</b> <b>(cases = 1)</b>	<b>2.3%</b>

SITE	TOTAL ENROLLMENT	NUMBER REFUSALS	REFUSAL RATE
5. New Orleans	430	13 (cases=4)	3.0%
6. Philadelphia	375	16 (cases=5)	4.3%
7. Long Beach	274	( (cases=0)	1.6%
TOTAL	2,768	219 (cases=43)	7.9%

## V. COMMUNITY DATA COLLECTION

### A. Methodology

In designing the community comparison group data collection activities, the Data Collection Team reviewed the current literature to identify any existing sampling approaches and data collection methods that would be useful for implementing this study protocol. Advice was also sought from investigators--some are sponsored by CDC and National Institute of Drug Abuse--experienced in employing sampling techniques and administration methods in studies with a similar scope. Dawn Upchurch, Ph.D., a demographer from the Johns Hopkins University, School of Public Health made significant recommendations for improving the sampling design and data collection methods for the study. Drs. Rolfs and Upchurch considered important design issues such as whether to “frequency match” or “individually match” the controls to the cases and how to define the unit of analysis and the method of data collection (telephone interviews versus face-to-face interviews).

1. Definition of Community Comparison Group

The community comparison group was defined as residents of the same geographically-defined area as syphilis patients enrolled in the study at Health Center Number One in Philadelphia<sup>1</sup> (N = 107). Community controls were recruited from the same census tracts in which the study cases reside and were individually matched to the study cases on age, gender, and race.

2. Catchment Area of Clinic Study Cases

To determine the geographic catchment area of the clinic study cases, Philadelphia census tract numbers were assigned to the addresses of the study cases. With the cooperation of STD Program staff at Health Center One and staff at the Division of Information Management, Philadelphia Department of Health, the Data Collection Team obtained two automated data bases. One data base contained addresses of the study cases; the other contained the Philadelphia census tract numbers with the corresponding street names and address ranges. The appropriate census tract number was matched with each address and plotted on census tract maps to show the distribution.<sup>2</sup>

The clinic catchment area for study cases was comprised of 74 census tracts within the Philadelphia city limits. The study cases reside in census tracts surrounding the

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<sup>1</sup>Although the protocol was designed for two community sites, data was collected in only one – Philadelphia. This was due in part to resource and time constraints, and in part to local circumstances at the second selected community site.

<sup>2</sup> Anonymity was ensured since no records linking the patient's name or address to the census tract were maintained.

the clinic, but not in the tract in which the clinic is located (Tract 12). The distribution of cases among census tracts is shown in Attachment I.

### 3. Block Group Sampling

Using 1980 Census Block Statistics, a computer-generated random sample of block groups was selected within each of the 74 census tracts defining the catchment area for study cases. To meet the protocol requirement that two community controls be selected for each clinic case, the number of block groups sampled from each census tract equaled two times the number of study cases in that census tract. One community control was selected from each sampled block group.

For example, since one study case resides in census tract 13, two block groups from census tract 13 were randomly selected. Interviewers recruited and interviewed one person from each of the two block groups. If respondents were not obtained from a sampled block group, sampling (with replacement) of the block groups was repeated.

### 4. Matching Controls to Cases

Each community control was selected as an “individual match” to the study cases. The controls were matched to the gender, race and the age group of the clinic cases from the same census tracts. For example, in census tract 13 mentioned above, the case is a 35-39 year-old black male. The two controls, selected from two block groups in census tract 13, are both 35-year-old black males.

Table 5, shows the gender, age range and race of study cases and community controls. For a breakdown of the individual match refer to Attachment K.

**Table 5: Demographics of Study Cases and Community Controls**

Age:	Clinic Cases		Community Controls	
	No. Males	No. Females	No. Males	No. Females
15-19	1	10	3	26
20-24	11	7	33	22
25-29	11	6	31	12
30-34	18	2	49	5
35-39	11	0	26	0
40-44	18	1	44	4
45-49	3	0	8	0
50-54	2	1	2	1
55-59	2	0	3	1
60-64	1	0	3	0
65+	0	0	2	0
Total	80	27	207	71
<b>Race:</b>				
Black	78	27	203	69
White	1	0	2	1
Hispanic	1	0	2	0
Unknown	0	0	0	1
Total	80	27	207	71

**B. Data Collection Plan**

To prepare for administration of the community survey the following activities were conducted:

- Gained Local Approval. Submitted the community control protocol to the Philadelphia institutional review board (IRB); determined no other local approvals were needed.

- Recruited Interviewers. Recruited and hired seven Health Center One disease intervention specialists (DIS) as study interviewers; develop a schedule of available hours.
- Developed Administration Materials. Developed rules for selecting households in each block group and logs to track progress and ensure the sex and age distribution match. Produced 300 copies of questionnaires with study ID numbers.
- Developed Participant Payment Disbursement System: A checking account was established in Philadelphia for convenient check cashing for participants and to eliminate the danger of having interviewers carry cash.
- Developed Quality Control and Monitoring Procedures: Three on-site team leaders were appointed to conduct and monitor data collection. They were responsible for ensuring that interviewers strictly adhered to established procedures and for communicating progress to the project Data Collection Supervisor.

In addition, the project Data Collection Supervisor led a field test of preliminary data collection methods and conducted a data collection orientation to train all interviewers.

#### 1. Field Test

A one-day field test of the administration procedures with two study interviewers was conducted to assess the following: (1) the reaction of community residents to being interviewed in an interviewer's car, and (2) the effect of compensation on participation (\$10.00 per respondent). In general, the results showed that individuals requested that they be interviewed in their own homes, but agreed to sitting in the car if there was no privacy in the home. Also, the amount of compensation was deemed adequate to provide incentive to participate.

#### 2. Interviewer Orientation

Just prior to beginning data collection, the project Data Collection Supervisor conducted an intensive study orientation with the interviewers. The orientation covered

the purpose of the study and thorough specification of procedures for recruiting and enrolling study respondents. Use of data collection field rules was also explained and the importance of adhering to them stressed. The Data Collection Supervisor observed each interviewer recruit and administer the questionnaire to identify and resolve any problems.

### C. Administration Procedures

The project Data Collection Supervisor provided the on-site supervisor of the interviewers with census tract assignment sheets and with census block maps that corresponded to the assigned tracts. The assignment sheets, distributed among the interviewers, provided the eligibility information for the recruitment of controls, i.e., census tract number, block group numbers, age range and gender of each control to be selected. The assignments were updated each day based on the results of the previous day.

To ensure the safety of the interviewers, respondent recruitment was conducted by two interviewers per block group. Interviewers went door-to-door in the sampled block groups to recruit eligible residents using the field rules developed for selecting households and individuals in each block group. The field rules are provided in Attachment J. Prior to going into the field each time, the interviewing team would randomly choose one of eight field rules for beginning the selection of households in a block. The interviewers were instructed to use the following procedures to handle the various circumstances arising from selecting households and individuals:

- If a resident of the selected household was at home, the interviewer greeted the resident, stated that they were conducting a survey and established whether someone in the household met the eligibility criteria for that block.
- If another resident of the selected household reported that the eligible person was not home at the time, the interviewer would return to that household as necessary until that person was contacted.

- If after selecting a household, no one was at home, the interviewers returned to the house again on a different day, and if possible, at a different time. A total of two visits were made attempting to contact someone in the household. After the second unsuccessful attempt, interviewers moved along the block clockwise and selected the next household.
- If the selected household was an abandoned building, or if no one in the household was eligible, the interviewers moved clockwise along the block and selected the next household.
- If there was more than one household (i.e., an apartment building), or if more than one eligible individual lived in a selected household, a systematic process using a table of random numbers was used. Apartments were numbered using the apartment number where available or they were assigned sequential numbers if the apartments were identified using letters. When more than one eligible respondent was available, the individuals were numbered from youngest to oldest.

To use the table of random numbers, interviewers would arbitrarily select the following every time they went out into the field: (1) a column on the table, (2) the  $n$ th digit in the five digit series, and (3) the top or bottom of the column to begin. To illustrate, an interviewer may have chosen to begin at the top of the third column and to use the fourth digit in the five digit series. If the fourth digit in row one was inappropriate for the circumstance, the interviewer moved down the column selecting the fourth digit in row two, and so on. Each time a random number needed to be selected, the interviewer would go to the row from which the last number was selected and begin with the following row. If double digits were in the range of selection possibilities, for example an apartment complex containing fifteen apartments, interviewers would go up or down a column using two  $n$ th digits such as the fourth and fifth digits to select the random number.

Eligible residents who agree to participate were asked to sit in the interviewer's car for the interview to ensure privacy. If the individual refused to be interviewed in the car, interviewers administered the questionnaire in another place (e.g., home, park bench) only if privacy could be assured. The consent form was read before the questionnaire was administered. Upon completion, interviewers provided the respondents with a check for \$10.00. Although the respondent's name was needed to write the check, the respondents' anonymity was preserved by not maintaining names and by linking only the check numbers with the questionnaire ID numbers for record keeping purposes.

## VI. COMMUNITY DATA COLLECTION RESULTS

### A. Enrollment

Eligible community residents were enrolled in the study within a 12-week period (June 8 to September 1, 1991). The results of the enrollment which was based on matching to the study cases is shown in Attachment K.

### B. Community Recruitment Encounters

The types of situations encountered by study interviewers in the recruitment of community respondents are shown in Table 6, below. A response rate of 74 percent was obtained based on the total number of individuals eligible to participate.

**Table 6: Community Recruitment Encounters**

<b>SITUATION</b>	<b>TOTAL</b>
No Answer	401
Vacant/Business/Empty Lot	555
No One Eligible	2,442
Other/Unknown Situations	192
Refused to Participate	95
Participated	277
TOTAL ELIGIBLE	372
RESPONSE RATE	74%

## VII. DATA MANAGEMENT

### A. Study Numbers

Each questionnaire received a unique study number with the first digit of the study number denoting the clinic site as shown in Table 6, below. The range of study

numbers is shown, but within these ranges study numbers are missing and therefore are not completely consecutive.

Table 7: Study Numbers

SITE NUMBER	SITE	STUDY # RANGES
1	West Palm Beach	1001 - 1505
2	Dallas	2001 - 2475
3	Chicago	3001 - 3582
4	Memphis	4001 - 4378
5	New Orleans	5001 - 5430
6	Philadelphia	6001 - 6375
7	Long Beach	7001 - 7294
A	Philadelphia Community Controls	AI002 - AI 286

B. Databases & Documentation

The following five databases have been developed using Dbase III for the data collected under this study:

- SYPHi .DBF: contains all responses for the first half of the questionnaire (questions 1 through 46 in the Florida version<sup>3</sup> of the survey, and questions 1 through 47 in all other versions).
- SYPH2.DBF: contains all responses for the second half of the questionnaire (questions 47 through 61 in the Florida version, questions 48 through 62 in all other versions).
- REFERRAL.DBF: contains all responses on the data collection instrument used to obtain the results of partner referral activities.
- REFUSED.DBF: contains demographic data collected on individuals who refused to participate in the study.

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<sup>3</sup>See the code manual for an explanation of the “Florida version” of the questionnaire.

SYPHA.DBF: contains all responses to the questionnaire administered to Philadelphia community residents.

The coding and data entry guidelines for these data bases are in Attachment L. The field names of the data base are listed and are matched with the corresponding question and coding instruction.

Project staff coded each questionnaires before entering them into the appropriate database. Coding and data entry were supervised by the project manager.

### C. Quality Checks

Samples of questionnaires were routinely reviewed to ensure that all questions were answered, and to identify any administration issues. In addition, an SPSS computer program was developed to conduct periodic quality checks on the data bases. Problems with interviewer administration of the questionnaire such as missed questions or inconsistent responses to multi-part questions were identified and communicated to interviewers as soon as possible. To minimize data entry error, all database entries were verified against hardcopy survey instruments and incorrect entries were corrected.

# **ATTACHMENT A**

## **Study Protocol**

Document 6897e

April 19, 1989

Study Protocol: Case-control study of drug use and syphilis

### 1.0 Background

In 1987, the reported incidence of primary and secondary syphilis in the United States was 14.6 cases per 100,000 persons, an increase of 25% compared to 1986. Syphilis incidence increased again in 1988 to 16.4 cases/100,000 persons, the highest rate since 1950. While over 50% of all cases were reported from Florida, New York and California which accounted for a large part of the overall increase, a number of other areas also reported increases. In general, areas with high incidence experienced the greatest increases, however Oregon and Connecticut which had 1986 annual incidence rates of 4.7 and 5.3 per 100,000 persons, respectively, increased more than 100% in 1987. Texas was a notable exception to the overall pattern of increase.

Table 1. States with 1987 reported incidence of primary and secondary syphilis greater than 7 per 100,000 persons and an increase in incidence between 1985 and 1987.

	Primary and secondary syphilis Rate per 100,000 persons					
	Cases	Rate	Cases	Rate	Cases	Rate
District of Columbia	342	55.3	425	69.1		
Florida	3679	32.6	7453	62.5	8378	68.2
California	4326	16.6	7718	28.2	6572	23.6
New York	2530	14.2	5004	28.1	5788	32.4
Nevada	64	6.9	180	18.1	564	53.7
North Carolina	672	10.9	752	11.9	840	13.1
Oregon	112	4.2	310	11.4	324	11.8
Delaware	39	6.3	71	11.1	104	15.9
Connecticut	215	6.8	334	10.5	724	22.4
Pennsylvania	513	4.3	941	7.9	1462	12.2

An analysis of data through the first 8 months of 1987, from 14 areas experiencing increases, indicated that the increases were greatest for females and heterosexual males (1) (table 2). Several studies have indicated that the increase has primarily been confined to persons of black and hispanic race/ethnicity (1,2,3).

Reviews of syphilis interview records from two areas with increases in syphilis incidence during this period – Connecticut and Philadelphia, PA – documented that syphilis patients were increasingly likely to be drug users (especially of cocaine) and either prostitutes (females) or sexual contacts of prostitutes (males) (5). A review of syphilis records in Oregon, from the first 3 months of 1986 and 1987, revealed similar increases in the proportion of cases which were associated with drug use and prostitution (CDC, unpublished data).

Data on an appropriate comparison group are not available, therefore, it is not possible to determine whether these changes were unique to syphilis patients or whether they reflect changes in populations with high syphilis incidence rates.

Anecdotal reports from a number of areas in the United States have suggested a link between drugs or drug-related behavior and acquisition of sexually transmitted diseases, including syphilis, chancroid and PPNG. These reports and the above data suggest that these behaviors may be an important factor in the increases in early syphilis seen in many areas in the United States between 1985 and 1988.

It has been suggested that drug-users are less cooperative and studies have shown that traditional STD control methods, such as, partner referral are less effective for drug users and for persons who have exchanged sex for money or drugs (4,6). It has also been suggested that sexual activity related to drug use, particularly prostitution, leads to greater syphilis transmission. In addition, an association between IV cocaine use and syphilis in a case-control study in Philadelphia (6), has raised the possibility of direct transmission due to IV needle sharing.

## 2.0 Objectives of study

- 2.1 Assess the roles of drug use and drug use-related behaviors, particularly drug use-related prostitution, as risk factors for acquisition of early syphilis.
- 2.2 Assess the importance of this association as a cause of the increases in syphilis occurring in the United States.
- 2.3 Determine the effect of drug use on the outcome of STD partner referral activities.
- 2.4 Further investigate the possibility of IV needle-related transmission of syphilis.

## 3.0 Study design

- 3.1 Case-control study of behavioral risk factors for acquisition of syphilis. The unit of analysis for this study is the individual with syphilis. The study will be carried out in several communities to provide an adequate sample size and to increase the generalizability of the results.
- 3.2 Comparison of the prevalence of the above defined risk factors in different communities which have increases in syphilis to the prevalence in communities which do not. In addition, it may be possible to compare the extent to which syphilis is associated with these behaviors between the different communities.

3.3 Evaluation of the effect of drug use and drug-related behaviors on the outcome of the partner referral process in syphilis patients.

#### 4.0 Case definition

4.1 Cases will be patients seen in the participating STD clinics who have a **clinical diagnosis of either primary or secondary syphilis.**

4.2 **In addition, information on prior syphilis, and results of non-treponemal serologic testing (VDRL, RPR), treponemal serologic testing (FTA-ABS, HHA-TP) and dark field examination of lesion material will be collected and used to apply the following case definitions during analysis.**

##### 4.21 primary syphilis -

a) **dark field positive chancre**

or

b) **characteristic lesion of early syphilis plus positive non-treponemal (RPR, VDRL) and treponemal (FTA-ABS, HHA-TP) test for syphilis in a patient without a previous history of syphilis.**

or

c) **characteristic lesion of early syphilis plus non-treponemal (RPR, VDRL) tests showing a 4-fold increase from previous result and positive treponemal (FTA-ABS, HHA-TP) test in a patient with previous history of syphilis.**

##### 4.22 secondary syphilis -

a) **characteristic lesion of secondary syphilis which is dark field positive.**

or

b) **clinical picture compatible with secondary syphilis plus positive non-treponemal and treponemal tests for syphilis in a patient with no previous history of syphilis**

or

c) **clinical picture compatible with secondary syphilis plus non-treponemal tests showing a 4-fold increase from previous result and positive treponemal tests for syphilis in a patient with a previous history of syphilis**

4.3 Patients who receive the diagnosis of syphilis and are treated elsewhere and seen at the STD clinic only for partner referral interviews will be excluded from analyses which compare syphilis patients to STD clinic controls. They will be included for analyses which utilize community controls.

4.4 Patients who were recruited for examination or treatment by public health disease intervention specialists, because they were a sexual contact of a syphilis patient will be excluded from analyses of the case-control study.

## 5.0 Control selection

In most sites there will be one control group chosen from among patients seen in the same STD clinic as the syphilis patients/cases. There are potential biases in this comparison, due to the fact that the majority of these patients are infected with another STD. This other STD could itself be related to the exposures of interest. In addition, these exposures could be related to the probability that a person with either syphilis or the other infections will receive care at the STD clinic (rather than self-medicating or seeking care elsewhere). To address these biases, an additional, community-based control group will be chosen in 2 of the study sites. An additional benefit of this comparison group, will be greater understanding of the prevalence of these behaviors in the community in which much of syphilis transmission occurs.

5.1 STD clinic comparison group – Patients who present voluntarily for diagnosis or treatment to the same clinic as the syphilis cases, but who are free of syphilis will be eligible to be controls. This group will include patients with other STD (eg. gonorrhea, genital herpes, genital warts and chlamydia-related diseases) and patients who either have other diseases with similar symptoms and signs, but which are not sexually transmitted (eg. vaginal candidiasis, bacterial vaginosis) or who are free of disease. It will be important to assure that there are sufficient patients in each group to allow for exclusions in the analyses..

5.11 To prevent selection bias, controls should be selected consecutively or by an appropriate random selection procedure from among persons seeking care at the same clinics as those from which the cases are recruited, during the same time period. An example of selection bias, would be if the most cooperative patients were selected and if drug users tend to be uncooperative.

5.12 Sufficient controls will be enrolled to allow efficient analysis stratified by race and sex and to allow the prevalence of risk factors among controls with different STD diagnoses to be examined. The number of controls necessary in each site will be determined by examining existing data on the frequency of diagnoses made in the STD clinic and demographic characteristics of syphilis patients and other STD clinic attendees. It is expected, based on preliminary work with a similar study performed in Philadelphia, that this will require between 2 and 3 controls for each case. A stratified selection procedure based on diagnosis and gender may be necessary.

5.13 All controls should have had a serologic test for syphilis and culture for gonorrhea performed at the enrollment visit.

5.14 Exclusions:

- a) diagnosis of early syphilis at the enrollment visit or within the past 12 months.
- b) patients seen only for HIV testing, in sites where RIV testing is offered by the STD clinic.
- c) patients brought to the STD clinic through the efforts of disease intervention specialists, because of an infected sex partner.

4.5.2 Community-based comparison group – In two of the participating study sites, an additional comparison group will be selected to represent the community in which the study patients reside. If possible, one site should be in a community with a syphilis increase and one site in a community with either stable or declining incidence. Community-based controls will be selected so that they are comparable to syphilis patients enrolled in the study at that study site, except for having syphilis. Controls should be selected as follows:

**5.21 Two controls should be enrolled for each syphilis patient.**

**5.22 Controls** should be matched to cases on gender, and be within 5 years of age.

5.23 Controls should be selected based on geographic proximity to **the patient they are matched with. To prevent overmatching, it is desirable that controls not be socially associated with the syphilis patients. Confidentiality will prevent explicitly** addressing this with the control/subject, instead, controls should be selected from a geographic unit large enough to minimize this possibility, while maintaining adequate match of socio-demographic factors.

5.24 Community controls will be reimbursed to compensate them for time required to participate in the study and? for transportation costs (\*15–25).

#### 6.0 Data -

6.1 Prior to the usual partner referral/counseling interview, the attached questionnaire on behavioral risk factors for SID acquisition will be administered to patients with early syphilis. The same interviewers will also administer the questionnaire to SID clinic controls. A questionnaire, which is identical except for the STD diagnoses and laboratory results section, will be administered to the community-based controls.

6.2 A log book will be kept in the facility conducting the study, containing a unique study number for each patient, along with information necessary to link that number with the patients medical and laboratory records. The questionnaires will be labeled with the patients unique study number, but not with any other unique identifier. This will maintain confidentiality and allow retrieval of lab results and other information not available at the time of the interview, and prevent duplicate patient enrollment. Questionnaires for community-based controls will be labeled only with a unique study number, linking them to the matched syphilis patient. This log book will be destroyed as soon as data collection is complete.

6.3 Records of partner referral activities for the syphilis patients enrolled in the study will be abstracted when the activities have been determined to be complete. A form will be developed for this purpose after review of interview record forms used in all study sites.

## 7.0 Data management

Completed questionnaires will be sent to Atlanta for editing, coding and analysis.

## 8.0 Analyses

- 8.1 Aggregate case-control-study of risk factors for acquisition of syphilis – Data from different study sites will be combined to compare (separately) syphilis patients with LTD clinic controls and with community-based controls. Standard methods will be used to calculate odds ratios and confidence limits for the various behavioral risk factors. Differences between study sites will be examined. Stratification and logistic regression modeling will be used to adjust for confounding. Methods for matched analyses including conditional logistic regression will be used for analyses including community controls.
- 8.2 Comparisons between different sites – The associations between syphilis and drug-related behavior, and prevalences of these behaviors in individual study sites will be compared. Existing surveillance data on syphilis and gonorrhoea incidence will be used **to help interpret these data.**
- 8.3 In sites with two comparison groups, the results of the comparison with STD clinic controls will be compared to the results of the comparison with community-based controls.
- 8.4 STD clinic patients will be compared to the community-based controls according to the specific disease of the LTD clinic patients. The associations between different diseases and the different behaviors will be compared.
- 8.5 Results of partner referral (number of contacts named, number with locating information, number examined, number infected, etc.) in syphilis patients who report drug use, prostitute contact, etc. will be compared to results in patients not reporting these behaviors. The comparisons will be made for the aggregate data and also for individual study sites, and differences between study sites will be examined. These results will be used to help STD control personnel at the individual study sites develop patient profiles which predict success or failure in disease intervention and to identify individuals requiring more intensive disease intervention efforts.

## 9.0 Sample size

A sample of 120 syphilis patients and 240 controls, at each study site, will provide 80% power to detect an odds ratio of 2.4, if the prevalence of the risk factor in the control group is at least 10% ( $\alpha=5\%$ ). In analyses of aggregate data, we will be able to detect odds ratios of 1.5 or less (assuming 10 sites with 1200 cases and 2400 controls. In aggregate data, this number of controls should allow evaluation of the appropriateness of the STD clinic control group, by comparing prevalence of risk factors among controls with different STD diagnoses and with no STD and should also assure our ability to control for confounding. For these reasons, 2-3 STD clinic controls (300) and 2 community-based controls (240, in 2 sites only) will be enrolled for each

Table 4.  
Minimum Odds Ratio Detectable at each Site\*

		Power	
		80%	90%
<b>Proportion of</b>	<b>10%</b>	<b>2.4</b>	<b>2.7</b>
<b>Controls with</b>	<b>20%</b>	<b>2.0</b>	<b>2.3</b>
<b>Risk Factor</b>	<b>30%</b>	<b>1.9</b>	<b>2.1</b>

\*assumes 120 cases and 240 controls at each site,  
alpha=5%..

#### 10.0 Resource requirements

It is expected that the questionnaire will add 5-10 minutes to the length of each syphilis partner-referral interview and that 10-15 minutes will be needed to explain and administer the questionnaire to each SID clinic control. Two hours are expected to be needed for each community-based control, in the sites enrolling community controls. See appendix 1 for budget calculations.

#### 11.0 Principal investigators (CDC-

Robert Rolfs, M.D.

George Schmid, M.D.

#### 12.0 Study sites (tentative):

Areas with increasing incidence of syphilis during 1987:

Florida - 1 site

New York City

Long Beach, California

Los Angeles County, California

Areas with stable or decreasing incidence of syphilis during 1987:

Little Rock, Arkansas

Dallas, Texas

New Orleans, LA

Chicago, IL

### 13.0 Informed Consent

The following statement must be read to all potential participants:

The Centers for Disease Control is doing a study to see why people get sexually transmitted diseases. We're doing this because there has been a large increase in the number of people getting sexually **transmitted diseases this year and we don't know why. We think that some** of the increase might be due to things people do, such as sexual behavior **or drug use. If it's okay with you, I'd like to ask you some questions** about sex and drugs to help us understand why sexually transmitted **diseases are increasing. No one will know how you answered the questions** because the form that I'll put your answers down on will not have your name on it and no one will be able to identify you. We are not here to judge you or your behavior; all we want to do is make sure you are healthy and don't get infected again. It's very important to us that you be in our study because we need your answers to our questions. You don't have to be in our study and if you don't want to be, this won't change your treatment today or your future treatment in this clinic. We'd like you to be, though, because if everyone participates, we are more likely to find the answers. Would you be part of our study and answer my-questions; it'll take no more than 10 minutes?

**Good. Now, it's very important that you be honest with me.**

Remember, I won't judge you or what you have been doing, but we need to get honest answers.

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Questionnaire for Syphilis Risk Factor Study  
 STD Clinic Ca-sea and Controla

Form Approved

~IB No. 09200242

Expiration date: \_\_\_\_\_ 3/91

2) IfltOXVLCW date ..... 44444.5

3) ni.ai~ ..... S S PP~@---C S-----4\*4644~\*e  
 4) Sex S.... \*4544\*SS 5564545554 \*SS.C.6S\* Male~] Fezz~.Je [2]

Infoz~nticn far qyesticxm 6-27 to be obtained frc~i clini~l records.

Diagnosis at ~nroUinent Visit (check 1=yes, 2~no,  
 3~not Bure, iznless otherwise specified)

6a.) Syplilli.s [1] [2]  
 5b) Syphilis stage  
     primary (1)  
     secondary (2)  
     early latent [3]  
     late latent (4)  
     othei' (8)  
     w~kno~ (93)

6) CC ..... (1) (2)  
 7) 464444 4444444444444444 44 444 44 444 4444 4-446444 (1) (2)  
 8) (1) (2)  
 9) 44444445. 644\*5444 4.444544464464 PP.44.44P4444 (1) (2)

K~

10) (1) (2)  
 11) c3enita.1. War-ts ..... (1) (2)  
 12) Ohanoroid ..... (1) (2)  
 13) Triclicxmoniesis 446-64P\*4 44444 4\*4 4. 6 444 44445544 (1) (2)  
 14) Bacteria). vaginosis (Nonspecific vaginitis) (1) (2)  
 15) Vagirisi. caz~d~.di.e.gi~ 44444 ..... 6 ..... 4 ..... 44444446 (1) (2)  
 16) Genital lice (crs~ba). (13) (23)  
 17) (1) (23)  
 18) Other (Specify: \_\_\_\_\_) (1) (2)

Le~boratory Results at Enrollment Viait

(check 1~positive, 2negative, 3not done, , unless otherwise  
 irzAicated~

19) RPR/VLJRL (please enter titer, or -'0" if negative) 444.... \_\_\_\_\_

20) F'12A/1'SIA. \*444444..44.44.t.qt 444..44..4.64464.p466 (1) (2) (3) Not B2~ U!~ ~S  
 21) (1) (2) (3)  
 22) GonA,rziiea gram stain ..... \*~ 444 44444444 (1) (2) (3)  
 23) Gonorz4aea cn2ltUI'e 4444446.p4 (1) (2) (3)  
 23) pp~~X] 4-444444444 4446444444446 [1] [2] [33]  
 24) C~ilamydia (test or culture) [1] [2] [33]  
 25) Herpes lAaboratory Confirmation (Tzanck smear, culture, Fluorescent antibody, latex a~glutinntion) 64444444444 [1] (23) [3]  
 26) Wet Mount for Trichomonas vaginalis [1] [2] [3]  
 27) Other (13) [2]

Specify \_\_\_\_\_



Don't  
Yes No Know

- 38) Why did you come to clinic today?
- a) voluntarily because of symptoms [1]. [2] [3].
  - b) for check-up (1) [2] (3) \
  - a) referred by another doctor or clinic (1) [2] (3) ~
  - d) voluntarily because my partner was infected (1) (2) (3)
  - e) referred by public health worker because of contact with an infected person (1) [2] (3)
  - f) other (1) [2] [3]

39) IF ANSWER TO 38 d) or e) WAS YES, what kind of infection did your sex partner have? (check one from list below)

- a) Syphilis (1)
- b) Gonorrhea (2)
- c) Chlamydia, non-gonococcal urethritis (3)
- d) mucopurulent cervicitis (NGU, NSTI, MFC) (3)
- e) Don't know what the infection was (4)
- f) Other (8)

Specify \_\_\_\_\_

40) How many men have you had sex with in the last year?  
(By sex we mean vaginal, oral or anal sex.)

41) How many women have you had sex with in the last year?  
(By sex we mean vaginal, oral or anal sex.)

42) How many men have you had sex with in the last 3 months?  
(By sex we mean vaginal, oral or anal sex.)

43) How many women have you had sex with in the last 3 months?  
(By sex we mean vaginal, oral or anal sex.)

44) In the last 3 months, how often have you or your partner used a condom (rubber) when you had sex? 5645455E.

1-never (1) (2) (3) (4)

2-sometimes (less than half) 3-usually (half the time or more)

4-every time

N\*~ I AM GOING TO ASK YOU 8 QUESTIONS AND I WILL ASK YOU

45) In the last 3 months have you used any of the following drugs?

	Yes	No	Unsure	Don't know	in last 2 weeks
45a) Crack	(1)	(2)	(3)	(4)	46a) _____
45b) Cocaine, not crack	(1)	(2)	(3)	(4)	46b) _____
45c) Marijuana	(1)	(2)	(3)	(4)	46c) _____
45d) Heroin (or other opiates)	(1)	(2)	(3)	(4)	46d) _____
45e) Alcohol	(1)	(2)	(3)	(4)	46e) _____
45f) Other drugs	(1)	(2)	(3)	(4)	46f) _____

Specify other: \_\_\_\_\_

IF YOU ANSWERED YES TO ANY OF THE ABOVE DRUGS: (IF NO TO ALL OF 45 GO TO 47)

46) how many times have you used that drug in the last 2 weeks?

(Record number of times above)

47) Have you taken any drug by needle ("shot up". "skin popped" in the last 2 months? Yes ~ 1/2i ~ Refu'

IF Y~ to 47, what drugs? -(IF ~\$J, a-c to 49)

47a) cocaine	(1)	(2)	[3]	(4)
47b) heroin (or other opiate)	[1]	[2]	[2]	[4]
47c) amphetamine (speed)	(1)	(2)	(3)	(4)
47d) other	[1]	(2)	(3)	(4)
Specify other				

48) Have you shared a needle with another person while taking drugs in the last 3 months? (1) [2] [3] (4)

49a) In the past 3 months, have you given drugs or money (including alcohol) to someone to have sex with you? (1) (2) [3] (4)

IF Y~ It) 49a, did you give them: (IF ~, go to 61)  
 49b) money? 556666 (1) (2) [3] (4)  
 49c) drugs? [1] [2] (2) [4]

IF Y~ TO 49c ("drugs"), which drug?  
 49d) oral (1) (2) [3] (4)  
 49e) cocaine, not crack [1] [2] (3) [4]  
 49f) heroin -6 -6-5...5-6-6 6 [1] (2) (3) [4]  
 49g) marijuana (1) (2) (3) (4)  
 49h) alcohol [1] [2] (3) (4)  
 49i) other [1] [2] (3) (4)  
 IF OTHER, specify

How many times, in the past two weeks, have you given someone sex (fill in according to above answers) to have sex with you?

49j) mon.ay? 5666 65  
 49k) drugs? 5666 65

50) ~C~LY  
 The last time you gave someone drugs or money to have sex with you, did you use a condom? 4565656.56 (1) [2] (3) (4)

51a) In the past 3 months, has someone given you drugs or money (including alcohol) to have sex with them? 65456666... (1) (2) [3] (4)

IF Y~ 51a, did they give you: (IF NO, go to 53)  
 51b) money? [1] [2] (3) [4]  
 51c) drugs? [1] [2] (3) [4]

IF It) 51c ("drugs"), which drug:  
 51d) oral (1) (2) (3) [4]  
 51e) cocaine, not crack [1] (2) [3] (4)  
 51f) heroin (1) [2] [3] [4]  
 51g) fl~ijuarui [1] [2] [3] [4]  
 51h) alcohol [1] [2] [3] [4]  
 51i) other (1) (2) [3] [4]  
 If other, specify

61 (cant)

How many times, in the past 2 weeks, have you given someone drugs/money (ifl. in soording to answers to Sib and Sic) to have sex with you?

51j) -money? \_\_\_\_\_  
 51k) drugs?

-What type of sex did you have with the last person who gave you money or drugs to have sex with then?

	Yes	NQ.	Refu~
51l) oral sex	[1]	[2]	[4]
51m) vaginal intercourse	[1]	[2]	[3]
51n) anal intercourse	[11]	[21]	[3]

YARN a~LY

52. The last time someone gave you drugs or money to have sex with then, did they wear a condom? (1) (2) (3) (4)
- 53) Do you think that anyone you have had sex with in the last 3 months ever takes money or drugs from other people for sex? (1) (2) (3) [4]
- 64) In the past 3 months, have you had sex with, someone you met at a crack house or place where people go to buy or use crack? [1] [2] [3] (4)
- 55) In the past 3 months, have you had sex with someone on the same day that you met them? [1] [2] (3) (4)
- 56) In the past 3 months, have you had sex with more than one person in a 24 hour period? (1) [2] [3] [4]
- 57a) In the past 3 months, have you shared drugs (including alcohol) with someone before having sex with them (on the same day)? (1) (2) [3] (4)  
 IF Yes, what drug(s)?
- |                         |      |      |     |     |
|-------------------------|------|------|-----|-----|
| 57b) crack              | (13) | [2]  | [3] | (4) |
| 57c) cocaine, not crack |      | [21] | [3] | (4) |
| 57d) heroin             | (13) | (2)  | (3) | (4) |
| 57d) marijuana          | [11] | [2]  | [3] | [4] |
| 57e) alcohol            | (1)  | (2)  | (3) | (4) |
| 57f) other              | [1]  | (2)  | [3] | [4] |
- If other, specify \_\_\_\_\_

- 58a) In the past 3 months, have you had sex with someone only one time, how did you meet that person or persons? (1) [2] [3] [4]

IF Yes '10 GSa:

If, in the past 3 months, you have had sex with someone only one time, how did you meet that person or persons?

- |                        |     |      |     |     |
|------------------------|-----|------|-----|-----|
| 58b) At a bar?         | [1] | [2]  | [3] | [4] |
| 58c) On the street?    | [1] | (2)  | (3) | (4) |
| 58d) At a crack house? | (1) | (2)  | (3) | (4) |
| 58e) At work?          | [1] | (2)  | [3] | [4] |
| 58f) At school?        | [1] | (2)  | [3] | (4) |
| 58g) Other             | [1] | [2]  | [3] | (4) |
| 58h) Don't remember    | (1) | [21] | (3) | (4) |
- If other, specify \_\_\_\_\_

Interviewer's mission:

54) Answers seem valid? **65.....44064644644s16566644444445**  
ISS) If no, which type of questions?

The flow  
(1) [2]  
Check if not valid

number of partners  
en  
other

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“CASE CONTROL COMPARISON OF PRIMARY AND SECONDARY  
SYPHILIS WITH COMMUNITY CONTROL GROUP”

Conducted by  
The Centers for Disease Control

Study Protocol

1991

Prepared by:

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Study Protocol:

Case - Control Comparison of Primary and Secondary Syphilis with Community Control Group

Background:

In 1987, the reported incidence of primary and secondary syphilis in the United States was 14.6 cases per 100,000 persons, an increase of 25% compared to 1986. Syphilis incidence increased again in 1988 to 16.4 cases/100,000 persons, the highest rate since 1950. While over 50% of all cases were reported from Florida, New York and California which accounted for a large part of the overall increase, a number of other areas also reported increases. In general, areas with high incidence experienced the greatest increases, however, Oregon and Connecticut which had 1986 annual incidence rates of 4.7 and 5.3 per 100,000 persons, respectively, increased more than 100% in 1987. Texas was a notable exception to the overall pattern of increase. Data indicate that the increases were greatest among females and heterosexual males of black and hispanic race/ethnicity.

Anecdotal reports *from* a number of areas in the United States have suggested a link between drugs or drug-related behavior and acquisition of sexually transmitted diseases, including syphilis, chancroid, and PPNG. These reports and the above data suggest that these behaviors may be an important factor in the increases in early syphilis in many areas in the United States between 1985 and 1988.

To investigate the reasons for the increase in the reported cases of syphilis, a case-control study of risk factors for syphilis is being conducted at STD clinics in seven cities: West Palm Beach, FL; Dallas, TX; Chicago, IL; Philadelphia, PA; Memphis, TN; New Orleans, LA and Long Beach, CA.

In two of these cities (Philadelphia and Chicago), comparison will also be made to community control groups to evaluate the possibility of bias in the principle comparison with the STD clinic control group. This is a proposal for the community comparison group portion of this study.

Objectives:

- (1) Assess the roles of drug use and drug use-related behaviors, particularly drug use-related prostitution, as risk factors for acquisition of early syphilis.
- (2) Evaluate potential for bias in comparison with STD clinic controls being conducted at the same sites.
- (3) Evaluate community prevalence of behaviors determined as risk factors by the study to aid in attributable risk estimates.

#### Study Design:

This is a case-control study of risk factors for primary and secondary syphilis. Cases will be patients with primary or secondary syphilis who are interviewed by staff of the Philadelphia STh Control Program at Health Center Number One. Controls will be persons who are residents of the geographically-defined community as the cases, matched on age and gender. The results of this study will also be part of the larger seven-city study of risk factors for syphilis and will assist in the analysis and interpretation of its results. Risk factors examined include sexual behavior (number of partners, partner selection factors), IV and non-IV drug use and related behavior, and health care behavior.

#### Case Definition:

Cases will be persons with a diagnosis of primary or secondary syphilis interviewed by two Disease Intervention Specialists (DIS), Kimberly West and Darrin Brown, at Health Center Number One. In addition, information on prior syphilis and results of non-treponemal serologic testing (VDRL~ RPR), treponemal serologic testing (FTA-ABS, MHA-TP) and dark field examination of lesion material will be collected and used to apply the case definitions during analysis.

#### Control Selection:

Persons residing in the same geographically-defined community as the clinic population and without a history of syphilis in the last six months of 1990 will be eligible to be controls. At least two controls will be selected for each case, or a minimum of 240 controls.

The geographic location of potential community controls will be defined by the census tracts which represent the catchment area of syphilis patients seen at the clinic. Census tracts will be assigned to addresses of a sample of syphilis patients seen within the last six months of 1990 (7/1/90 to 12/31/90). Anonymity will be ensured since no records linking the patient's name or address to the census tract will be maintained. Within these defined areas, community controls will be matched on age and gender of the syphilis patients.

Interviewers will conduct face-to-face interviews with the selected participants in a suitable public location in the community. This environment ensures participant privacy and interviewer safety. Approximately ten minutes will be taken to obtain informed consent and administer the questionnaire. Controls will be compensated \$15.00 for their participation.

Study interviewers will be individuals with training and experience interviewing similar populations about sensitive topics such as sexual activity and drug-use behaviors.

In addition to administering the study questionnaire, interviewers will inform participants that syphilis testing is being offered at the STD clinic. Agreeing to a syphilis test is not required for study enrollment, however.

#### Data Collection:

To collect information on cases, interviewers will administer a questionnaire on behavioral risk factors for STD acquisition to patients with early syphilis prior to the usual partner referral/counseling interview. An identical questionnaire (except for the STD diagnosis and laboratory results section) will be administered to the community-based controls.

No personal identifiers will be used on data collected from cases and community controls; all questionnaires will be labeled with a unique number only. The unique study number on the questionnaires for community-based controls will link them to the matched syphilis patient. A log book will be kept by interviewers to track the matching process and prevent duplicate respondent enrollment. For clinic cases a log book will be kept containing the unique study number for each patient along with the information necessary to retrieve medical and laboratory information. Log books will be destroyed after data collection is complete.

#### Data Management:

Completed questionnaires will be sent to the independent management consulting firm under contract to collect, edit, code and enter data. Data bases will be sent to CDC for analysis.

#### Analysis:

Odds ratio and 95 percent confidence intervals will be calculated using standard methods. Conditional logistical regression considering matching factors will be used for multivariate analysis.

Data will be analyzed separately for this specific study comparison being performed in Philadelphia, and in addition, data will be incorporated into a larger data set from the seven-city study.

#### Sample Size:

The target sample of at least 120 cases and 240 controls will provide 80 percent power to detect an odds ratio as small as 2.4 if the prevalence of a risk factor in the control group is at least 10 percent. The statistical power of the aggregated data from all study sites will be substantially greater which will assist in multivariate

analysis.

Principal Investigators:

**Robert T. Rolfs, M.D., Clinical Research Branch, Division of STD/HIV Prevention, Centers for Disease Control.**

**Martin Goldberg, Senior Public Health Advisor, Philadelphia STD Control Program, Philadelphia Department of Health.**

**James Bell, Director, James Bell Associates, Inc., CDC contractor assisting with coordination of study and performing data entry and management.**

ATTACHMENT B

List of Clinic Contacts

## Clinic Contacts

1. Florida

Jadis Porter-  
Robinson  
407-845-4407

Palm Beach Health Unit  
3701 Broadway  
West Palm Beach, FL 33407

2. Dallas

Don Hutcheson  
214-920-7975

Dallas County STD Clinic  
1936 Amelia Court  
Dallas, TX 75235

3. Chicago

Louise Galaska  
312-435-5432

Chicago Department of Health  
1306 S. Michigan Ave.  
Chicago, IL 60605

4. Memphis

Dr. Edwin Thorpe  
901-576-7793

Shelby County Health Department  
STD Control Program  
814 Jefferson  
Memphis, TN 38105

5. New Orleans

Van Jenkins  
504-568-5508

HIV/AIDS Services  
325 Loyola Ave. Rm618  
New Orleans, LA 70112

6. Philadelphia

Marty Goldberg  
215-875-5637

Philadelphia DoH  
Division of STDs  
500 South Broad St.  
Philadelphia, PA 19146

7. Long Beach

Ruth Bundy  
213-427-7421  
x4340

DHHS  
2655 Pine Ave.  
Long Beach, CA 90806

## ATTACHMENT C

Key Persons Responsible For Data Collection

## Key Persons On Site Responsible For Data Collection

	<p>Kimberly West, DIS: Clinic Interviewer/Coordinator and Supervisor of Community Interviewers</p> <p>Darrin Brown, DIS: Clinic Interviewer/Coordinator</p> <p>Sonia Johnson, DIS: Supervisor of Community Interviewers</p> <p>Alexander Phillips, DIS: Supervisor of Community Interviewers</p>
Memphis	<p>Tracy Luster, STD Control Program Manager: Study Coordinator</p> <p>Yolanda Spencer, TDY Federal Assignee: Interviewer</p> <p>Vonetta Leatherwood, DIS: Interviewer</p>
New Orleans	<p>Abid Mehmood, M.D., MPH: Interviewer/Study Coordinator</p> <p>Frank Meyers, Senior Public Health Advisor: Study Supervisor</p>
Chicago	<p>Joe Betros, DIS Supervisor: Study Coordinator</p>
Long Beach	<p>Tony Bustamante, DIS Supervisor: Study Coordinator</p> <p>Suzanne Lebovit, DIS: Interviewer</p>

**ATTACHMENT D**  
**Study Questionnaires**

ORIS /t: 09200242

ExpJres: 3/31

Study#:

## **~EVALUATION OF THE REASONS FOR THE INCREASE IN REPORTED CASES OF SYPHILIS"**

### **Questionnaire**

**1990**

Conducted by:

The Centers for Disease Control

Principal Investigators: Robert Rolfs, M.D. & George Schmid, M.D.

Public reporting burden for this collection of information is estimated to be 10 minutes per response. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: P1(5 Reports Clearance Office) (TN: PRA Humphrey Bldg., Rm 721-H, 200 Mudge Road, Ave. SW; Washington, DC 20201; and to the Office of Management and Budget Paperwork Reduction Project (0920-0242); Washington, DC 20503.

1) Interviewer ID. Number .

2) Interview date . \_\_\_\_\_I

### **Patient Diagnosis**

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Obtain information for questions 3-26 from clinical records.

Indicate the patient's diagnosis at the enrollment visit.

(Check appropriate number.)

3a) Syphilis [13] N~Un~r~ [23] [3]

3b) IF YES, What is the syphilis stage? (Check only one)

- [1] primary
- [2] secondary
- [3] tertiary latent
- [4] latent
- [8] other
- [9] unknown

- 4)GC [1] [2] [3]
- 5)PID [1] [2] [3]
- 6)NGU [1] [2] [3]
- 7)MPC [2] [3]
- 8) Genital HSV ~Vj [2] [3]
- 9) Genital Warts [1] [2] [3]
- 10) Chancroid [1] [2] [3]
- 11) Trichomoniasis [1] [2] [3]
- 12) Bacterial va p.noSis (Nonspecific vaginitis) [13] [2] [3]
- 13) Vaginal candidiasis Eli [2] [3]
- 14) Genital lice (crabs) [13] [2] [3]
- 15) No diagnosis made [1] [2] [3]
- 16) Other diagnosis [13] ~2] [~1]

Specify: \_\_\_\_\_

## Lab Results

Indicate the patients laboratory test results at enrollment visit.

	P	N	Peudinp	Not
17) RPR/VDRL (enter 1-1er, or ~-0f'negative)				
18) FTNMHA	[1]	[2]	[3]	[4]
19) Dark.field exam	[1]	[2]	[3]	[43]
20) Gonorrhea gram stain	[1.]	[2]	[3]	[4]
21) Gonorrhea culture	[1]	[2]	[3]	[4]
22) PPNG assay	[1]	[2]	[3]	[4]
23) Chlamydia (test or cultur~)	[1)	[2]	[3]	[4]
24) Herpes Laboratory Confirmation (Tzanck s~n~ar, culture fluorescent antibody,latex agglutination)	[1]	[2]	[3]	[43]
25) Wet Mount for Trichomonas vaginalis	[1]	[2]	[3]	[4]
26) Other lab test	[1]	[2]	[3]	[4]
Specify: _____				

## Demographics

27) Home zip code

28) Sex

- [1] Male
- [2] Female

~TdInterviewer; Please ask each question on the (ollowing pages as they at~  
Written. Afler using standard wording, you may use other wording (o explain  
it .

29) What is your age?

\_\_\_\_\_ years

30.1 What is your marital status? (*Check only one*)

- Married
- Never married
- [3] Divorced
- [5] Separated
- Widowed

31) What is your race? (*Check only one*)

- [13] White
- [2] Black
- [3] American Indian/Alaskan Native
- [4] Asian/Pacific Islander
- Other

32) Are you Hispanic or Spanish?

Yes [1] No [2] Unsure [3]

33) Are you currently employed?

[1] [2] [3]

34) Are you currently in school?

[1] [2] [3]

35) What is the highest grade you completed in school?

\_\_\_\_\_ years

36) Do you have a telephone?

[1] [2] [3]

### History of STD and Sexual Activity

37a) Have you ever been told you had syphilis? (*Prior to the current episode, if applicable*)

[1] [2] [3]

37b) IF YES, What was the date of most recent episode?

\_\_\_/\_\_\_/\_\_\_

38a) Have you ever been told you had gonorrhea? (*Prior to the current episode, if applicable*)

[1] [2] [3]

38b) IF YES, What was the date of most recent episode?

\_\_\_/\_\_\_/\_\_\_

L1~IITh

39a) [ Have you had an ulcer/sore in your genital area in the last 6 months? (In addition to an ulcer present at this visit) ... [1] [2] [3]

39b) IF YES, Did you seek medical care for it" [1] [2] [3]

39c) IF CARE WAS SOUGHT, Where did you seek care? (Check oh' that apply)

- [1] STD clinic  
 [2] Private physician  
 [3] Emergency room  
 [8] Other, specify: \_\_\_\_\_

39d) IF NO CARE WAS SOUGHT, Why didnt you seek care? (Check all that apply,

- [1] Didn't have enough money  
 [2] Didn't have the time  
 [3] Didn't think it was important  
 [4] Took antibiotics without seeking care  
 [8] Other, specify: \_\_\_\_\_

40) Why did you come to clinic today? (Check only one)

- [1] Voluntarily because a sex partner was infected  
 [2] Referred by public health worker because of contact with an infected sex partner  
 [3] Voluntarily because of symptoms  
 [4] Referred by another doctor or clinic  
 [5] For check-up  
 [8] Other, specify: \_\_\_\_\_

41) IF ANSWER TO 40 WAS 1 or 2, What kind of infection did your sex partner have? (Check only one)

- [1] Syphilis  
 [2] Gonorrhea  
 [3] Chlamydia, non-gonococcal urethritis, mucopurulent cervicitis (NGU, NSU, NIPC)  
 [4] Don't know  
 [8] Other, specify: \_\_\_\_\_

42) [n the past year. how many men have you had sex with? (By sex we mean ~ ~ 'aght oral or WWI Sex) \_\_\_\_\_

43) In the past 3 months, how many women have you had sex with~

44) In the past year, how many women have you had **sex with**?  
(By sex we mean ~'aginal/oral or a,ioJsex)

\_\_\_\_\_

45) In the past 3 months, how many women have you had sex with?"

\_\_\_\_\_

46) In the past 3 months, how often have you or your partner used a condom (rubber) when you had sex? (Check only one)

- [1] Never
- [2] Sometimes (less than half)
- [3] Usually (half the time or more)
- [4] Every time

## Drugs and Drug Use

Now! am going to ask you some questions about drugs and drug use.

47a) In the past 3 months, have you used any of the following drugs?

	~i~S	Nn	Unsui~	R~~eA
47b) Crack		[2]	[3]	[4]
47c) Cocaine, not crack		[2]	[3]	}
47d) Marijuana	[1]	[2]	(3)	
47e) Heroin (or other opiates)	[1]	[2]	[3]	
47f) Alcohol		[2]	[3]	

48a) IF YES TO ANY OF THE ABOVE DRUGS, How many times have you used that drug in the last 2 weeks?

### LoLi~

- 48b) Crack \_\_\_\_\_
- 48c) Cocaine, not crack \_\_\_\_\_
- 48d) Marijuana \_\_\_\_\_
- 48e) Heroin (or other opiates) \_\_\_\_\_
- 48f) Alcohol \_\_\_\_\_
- 48g) Oth~ drugs \_\_\_\_\_

OMB #: 09200242

Expires: 6/31/91

Study#:

**“EVALUATION OF TILE REASONS FOR THE  
INCREASE IN REPORTED CASES OF SYPLULIS”**

**Questionnaire**

**1991**

Conducted by:

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The Centers for Disease Control

Principal Investigators: Robert Rolfs, M.D. & George Schmid, M.D.

1) Interviewer I.D. Number \_\_\_\_\_

2) Interview date \_\_\_\_/\_\_\_\_/\_\_\_\_

**Patient Diagnosis: obtain information for questions 3-26 from clinical records**

Indicate the patient's diagnosis at the enrollment visit.

(Check appropriate number.)

	<u>Yes</u>	<u>ti~</u>	<u>Un~</u>
3a) Syphilis	[1]	[2]	[3]
3b) IF YES, What is the syphilis stage? ( <i>Check only one</i> )			
[1] primary			
[2] secondary			
[3] early latent			
[4] late latent			
[8] other			
[9] unknown			
4)GC	[1]	[2]	[3]
5)PID	[1]	[2]	[3]
6)NGU	[1]	[2]	[3]
7) MPG	[1]	[2]	[3]
8) Genital HSV	[1]	[2]	[3]
9) Genital Warts	[1]	[2]	[3]
10) Chancroid	[1]	[2]	[3]
11) Trichomoniasis	[1]	[2]	[3]
12) Bacterial vaginosis (Nonspecific vaginitis)	[1]	[2]	[3]
13) Vaginal candidiasis	[1]	[2]	[3]
14) Genital lice (crabs)	[1]	[2]	[3]
15) No diagnosis made	[1]	[2]	[3]
16) Other diagnosis	[1]	[2]	[3]

Specify: \_\_\_\_\_

17a) In the past, was patient ever diagnosed with syphilis? [1] [2] [3]

17b) IF YES, enter date diagnosis was made (*Prior to curreta episode, if applicable*): \_\_\_\_/\_\_\_\_/\_\_\_\_

49a) In the last 3 months, have you taken any drug by needle (“shot up” or “skin popped”)?	[ii]	[2]	[3]	[4]
IF NO, Go to 51a				
IF YES, Which drugs?				
49b) Cocaine	[1]	[2]	[3]	[4]
49c) Heroin or other opiate	[1]	[2]	[3]	[4]
49d) Amphetamine (speed)	[1]	[2]	[3]	[4]
49e) Other drugs	[1]	[2]	[3]	[4]

50) In the past 3 months, have you shared a needle with another person while taking drugs?	[1]	[2]	[3]	[4]
--	-----	-----	-----	-----

51a) In the past 3 months, have you given money or drugs, including alcohol, to someone so they’ll have sex with you?	[1]	[2]	[3]	[4]
---	-----	-----	-----	-----

IF NO, Go to 52a

IF YES, Did you give them:

51b) money	[1]	[2]	[3]	[4]
51c) drugs	[1]	[2]	[3]	[4]

IF PATIENT GAVE MONEY,

51d) In the past two weeks, how many times did you give someone money so they’ll have sex with you?

# of times: \_\_\_\_\_

IF PATIENT GAVE DRUGS,

51e) In the past two weeks, how many times did you give someone drugs so they’ll have sex with you?

# of times: \_\_\_\_\_

Which drugs did you give? (Check all that apply)

51f) Crack	[1]	[2]	[3]	[4]
51g) Cocaine, not crack		[1]	[2]	
51h) Heroin		[1]	[2]	
51i) Marijuana	[1]	[2]	[3]	[4]
51k) Other drug: specify _____				

51l) The last time you gave someone drugs or money to have sex with you, did you use your partner’s drug?	[2]	[3]	[4]
---	-----	-----	-----

52a) In the past 3 months, has someone given you: money or drugs, including alcohol, to have sex with them? [1] [2] [3] [4]

**IF NO, Go to 53**

[F YES, Did they give you:

52b) money" [1] [2] [3] [4]  
 52c) drugs" [1] [2] [3] [4]

**IF MONEY WAS GIVEN TO PATIENT,**

52d) In the past 2 weeks, how many times has someone given you money so you'll have sex with them?

# of times: \_\_\_\_\_

**IF DRUGS WERE GIVEN To PATIENT,**

52e) In the past 2 weeks, how many times has someone given you drugs so you'll have sex with them?

# of times: \_\_\_\_\_

Which drugs did they give you? (*Check all that apply*)

52f) Crack	[1]	[2]	[3]	[4]
52g) Cocaine, not crack	[1]	[2]	[3]	[4]
52h) Heroin	[1]	[2]	[3]	[4]
52i) Marijuana	[1]	[2]	[3]	[4]
52j) Alcohol	[1]	[2]	[3]	[4]
52k) _____	[1]	[2]	[3]	[4]

**IF EITHER MONEY OR DRUGS WERE GIVEN~**

What type of sex did you have with the last person who gave you money or drugs to have sex with them?

52l) oralsex [1] [2] [3]  
 52m) vaginal intercourse [1] [2] [3]  
 52n) anal intercourse [1] [2] [3]

52o) The last time someone gave you drugs or money to have sex with them, did you or your partner use a condom? [1] [2] [3] [4]

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	Mi	Unsi1.L~	R~Lis~	
53) Do you think that anyone you have had sex with in the last 3 months ever takes money or drugs from other people for sex?"	[1]	[2]	[3]	[4]
54) In the past 3 months, have you had sex with someone you met at a crack house or place where people go to buy or use crack?"	[1]	[2]	[3]	[4]
55) In the past 3 months, have you had sex with someone on the same day that you met them?"	[1]	[2]	[3]	[4]
56) In the past 3 months, have you had sex with more than one person in a 24-hour period <sup>9</sup>	[ii]	[2]	[3]	[4]
57a) In the past 3 months, have you shared drugs, including alcohol, with someone before having sex with them (on the same day)?"	[1]	[2]	[3]	[4]
IF YES, Which drugs?				
57b) Crack	[1]	[2]	[3]	[41]
57c) Cocaine, not crack	[1]	[2]	[3]	
57d) Heroin	[1]	[2]	[3]	
57e) Marijuana	[1]	[2]	[3]	
57f) Alcohol	[1]	[2]	[3]	
57g) Other drug specify: _____	[1]	[2]	[3]	[4]

58a) In the past 3 months, have you had sex with someone only one time and never again?" [1] [2] [3] [4]

IF YES, How did you meet that person or persons?

58b) At a bar?"	[1]	[2]	[3]	[4]
58c) On the street <sup>9</sup>	[1]	[2]	[3]	
58d) At a crack house"	[1]	[2]	[3]	
58e) At work <sup>9</sup>	[1]	[2]	[3]	
58f) At school"	[1]	[2]	[3]	
58g) Don't remember	[1]	[2]	[3]	
58h) Other ~ .....	[1]	[2]	[3]	

Interviewer's Impressions

59) Do all answers seem valid<sup>9</sup>

1] Yes

[2] No

60) **IF NO**, Which type of questions? (*Check those no valid*)

[1.] Drugs

[2] Number of partners

[3] Other, specify: \_\_\_\_\_

61) Express any additional comments about the interview **in the space** below.

## Lab Results

Indicate the patient's laboratory test results at enrollment visit.

18) RPR/VDRL ( <i>enter titer, or "0" if negative</i> )	<u>1</u> _____			Not
	P.Q~	~kg	udip	
19) FTA/MI-IA	[1]	[2]	[3]	[4]
20) Dark-field exam	[1]	[2]	[3]	[4]
21) Gonorrhea gram stain	[1]	[2]	[3]	[4]
22) Gonorrhea culture	[1]	[2]	[3]	[4]
23) PPNG assay	[1]	[2]	[3]	[4]
24) Chlamydia (test or culture)	[1]	[2]	[3]	[4]
25) Herpes Laboratory Confirmation (Tzanck smear, culture Fluorescent antibody, latex agglutination)	[1]	[2]	[3]	[4]
26) Wet Mount for Trichomonas vaginalis	[1]	[2]	[3]	[4]
27) Other lab test	[1]	[2]	[3]	[4]
Specify: _____				

## Demographics

28) Home zip code

29) Sex

[1] Male  
[2] Female

**if** interviewer. Please ask each question on the following pages as they are written. After using standard wording, you may use other wording to explain

e~ss~y.

30) What is your age?

\_\_\_\_\_ years

Study #:

31) What is your marital status? (*Check only one*)

- [1] married
- [2] never married
- [3] divorced
- [4] separated
- [5] widowed

32) What is your race? (*Check only one*)

- [1] White
- [2] Black
- [3] **American Indian/Alaskan Native**
- [4] Asian/Pacific Islander
- [8] Other

33) Are you Hispanic or Spanish<sup>9</sup>

Y~s

[1] [2] [3]

34) Are you currently employed?"

[1] [2] [3]

35) Are you currently in school?"

[1] [2] [3]

36) What is the highest grade you completed in school?

\_\_\_\_\_ years

37) Do you have a telephone?"

[1] [2] [3]

### History of STD and Sexual Activity

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38a) Have you ever been told you had syphilis? (*Prior to the current episode, ~~~i~~applicable*)

[1] [2] [3]

38b) IF YES, What was the date of most recent episode?

— / —

39a) Have you ever been told you had gonorrhea? (*Prior to the current episode, **if** applicable*)

[1] [2] [3]

39b) IF YES, What was the date of most recent episode?

— / —

40a) Have you had an ulcer/sore in your genital area in the last 6 months? *(In addition to any ulcer present at this visit)* ...

	Ye~	N~	Unsu~
	[1]	[2]	[3]

40b) IF YES, Did you seek medical care for it~

	[1]	[2]	[3]
--	-----	-----	-----

40c) IF CARE WAS SOUGHT, **Where** did you seek care? *(Check all i-hat apply)*

- [1] STD clinic
- [2] Private physician
- [3] Emergency room
- [8] Other, specify: \_\_\_\_\_

40d) IF NO CARE WAS SOUGHT, **Why** didn't you seek care? *(Check all that apply)*

- [1] Didn't have enough money
- [2] Didn't have the time
- [3] Didn't think it was important
- [8] Took antibiotics without seeking care
- [8] Other, specify: \_\_\_\_\_

41) Why did you come to clinic today? *(Check only one)*

- [1] Voluntarily because a sex partner was infected
- [2] Referred by public health worker because of contact with an infected sex partner
- [3] Voluntarily because of symptoms
- [4] Referred by another doctor or clinic
- [5] For check-up
- [8] Other, specify: \_\_\_\_\_

42) IF ANSWER TO 41 WAS 1 or 2, What kind of infection did your sex partner have? *(Check only one)*

- [1] Syphilis
- [2] Gonorrhea
- [3] Chlamydia, non-gonococcal urethritis, mucopurulent cervicitis (NGU, NSU, MPC)
- [4] Don't know
- [8] Other, specify: \_\_\_\_\_

43) In the past year, how many men have you had sex with?

*(Bys&t we mean vaginal oral or anal set)* \_\_\_\_\_

Study #:

44) In the past 3 months, how many men have you had sex with<sup>9</sup> \_\_\_\_\_

45) In the past year, how many women have you had sex with? (By sex we mean vaginal, oral or anal sex) \_\_\_\_\_

46) In the past 3 months, how many women have you had sex with” \_\_\_\_\_

47) In the past 3 months, how often have you or your partner used a condom (rubber) when you had sex? (Check only one)

- (1) Never
- [2] Sometimes (less than half)
- [3] Usually (half the time or more)
- [4] Every time

### Drugs and Drug Use

Now I am going to ask you some **questions about drugs and drug use.**

48a) In the past 3 months, have you used any of the following drugs?

	Y~	Na.	Un~ui~	R~fus~ii
48b) Crack	(1)	[2]	[3]	[4]
48c) Cocaine, not crack	[1]	[2]	[3]	[4]
48d) Marijuana	[1]	[2]	[3]	[4]
48e) Heroin (or other opiates)	[1]	[ 2 ]	[ 3 ]	[4]
48Q Alcohol	[1]	[ 2 ]	[ 3 ]	[ 4 ]
48g) Oth~r drugs specity: _____	[1]	[2]	[ 3 ]	[ ~ ]

49a) IF YES TO ANY OF THE ABOVE DRUGS, How many times have you used that drug in the last 2 weeks?

	LQflim~
49b) Crack	_____
49c) Cocaine, not crack	_____
49d) Marijuana	_____
49e) Heroin (or other opiates)	_____
49Q Alcohol	_____
49g) Oth~r drugs _____	_____

	Y~	NIL	IJnauL~	ReIus~
50a) In the last 3 months, have you taken any drug by needle (“shot up” or “skin popped”)	[1]	[2]	[3]	[4]
<b>IF NO, Go to 52a</b>				
<b>IF YES, Which drugs?</b>				
SOB) Cocaine	[1]	[2]	[3]	[4]
SOc) Heroin or other opiate	[1]	[2]	[3]	[4]
SOd) Amphetamine (speed)	[1]	[2]	[3]	[4]
	[1]	[2]	[3]	[4J]
51) In the past 3 months, have you shared a needle with another person while taking drugs”	[1]	[2]	[3]	[4]
52a) In the past 3 months, have you given money or drugs, including alcohol, to someone so they’ll have sex with you”	[1]	[2]	[3]	[4]
<b>IF NO, Go to 53a</b>				
<b>IF YES, Did you give them:</b>				
52b) money <sup>9</sup>	[1]	[2]	[3]	[4]
52c) drugs <sup>9</sup>	[1]	[2]	[3]	[4]
<b>IF PATIENT GAVE MONEY,</b>				
<b>52d) In the past two weeks, how many times did you give someone money so they’ll have sex with you?</b>				
# of times: _____				
<b>IF PATIENT GAVE DRUGS,</b>				
<b>52e) In the past two weeks, how many times did you give someone drugs so they’ll have sex with you?</b>				
# of times: _____				
Which drugs did you give? (Check all that apply)				
52f) Crack	[1]	[2]	[3]	[4]
52g) Cocaine, not crack	[1]	[2]	[3]	[4]
52h) Heroin	[1]	[2]	[3]	[4]
52i) Marijuana	[1]	[2]	[3]	[4]
52j) Alcohol	[1]	[2]	[3]	[4]
52k) Other drug: specify, _____	[1]	[2]	[3]	[4]
52l) The last time you gave someone drugs or money to have sex with you, did you or your partner use a condom?	[1]	[2]	[3]	[4]

Study #:

	Y~s	No	IInsur~	R~fus~
53a) In the past 3 months, has someone given you money or drugs, including alcohol, to have sex with them”	[1]	[2]	[3]	[4]

IF NO, Go to 54

IF YES, Did they give you:

53b) money”	[1]	[2]	[3] <sup>1</sup>	[4]
53c) drugs”	[1]	[2]	[3]	[4]

**IF MONEY WAS GIVEN TO PATIENT,**

53d) In the past 2 weeks, how many times has someone given you money so you’ll have sex with them?

# of times: \_\_\_\_\_

**IF DRUGS WERE GIVEN TO PATIENT,**

53e) In the past 2 weeks, how many times has someone given you dnigs so you’ll have sex with them?

# of times: \_\_\_\_\_

Which drugs did they give youL? (*Check all that apply*)

530 Crack	[1]	[2]	[3]	[4]
53g) Cocaine, not crack	[1]	[2]	[3]	[4]
53h) Heroin	[1]	[2]	[3]	[4]
53i) Marijuana	[1]	[2]	[3] <sup>1</sup>	[4] <sup>1</sup>
53j) Alcohol	[1]	[2]	[3]	[4]
53k) Other drug specity: _____	[1]	[2]	[3]	[4]

**IF EITHER MONEY OR DRUGS WERE GIVEN,**

**What type of sex did you have with the last person who gave you money or drugs to have sex with them?**

53l) oral sex	[1]	[2]	[3]	[4]
53m) vaginal intercourse	[1]	[2]	[3]	[4]
53n) anal intercourse	[1]	[2]	[3]	[4]

53o) The last time someone gave you drugs or money to have sex with them, did you or your partner use a condom? ..	[ii]	[2]	[3]	[4] <sup>1</sup>
--	------	-----	-----	------------------

Study #:

	Y~	No	IJsurr~	B~Ths~j
54) Do you think that anyone you have had sex with in the last 3 months ever takes money or drugs from other people for sex”	[1]	[2]	[3]	[4]
55) In the past 3 months, have you had sex with someone you met at a crack house or place where people go to buy or use crack’	[1]	[2]	[3]	[4]
56) In the past 3 months, have you had sex with someone on the same day that you met them’	[1]	[2]	[3]	[4]
57) In the past 3 months, have you had sex with more than one person in a 24-hour period”	[1]	[2]	[3]	[4]
58a) In the past 3 months, have you shared drugs, including alcohol, with someone before having sex with them (on the same day) <sup>9</sup>	[1]	[2]	[3]	[4]
IF YES, Which drugs?				
<sup>58b)</sup> Crack	[1]	[2]	[3]	[4]
58c) Cocaine, not crack	[1]	[2]	[3]	[4]
58d) Heroin	[1]	[2]	[3]	[4]
58e) Marijuana	[1]	[2]	[3]	[4]
58Q Alcohol	[1]	[2]	[3]	[4]
58g) Oth~ drug	[1]	[2]	[3]	[4]
<hr/>				
59a) In the past 3 months, have you had sex with someone only one time and never again”	[1]	[2]	[3]	[4]
IF YES, How did you meet that person or persons?				
59b) At a bar”	[1]	[2]	[3]	[4]
59c) On the street <sup>9</sup>	[1]	[2]	[3]	[4]
59d) At a crack house <sup>9</sup>	[1]	[2]	[3]	[4]
59e) At work”	[1]	[2]	[3]	[4]
59Q At school’	[1]	[2]	[3]	[4]
59g) Don’t remember	[1]	[2]	[3]	[4]
59h) Other specify: _____	[1]	[2]	[3]	[4]

## Interviewer's Impressions

---

60) Do all answers seem valid<sup>9</sup> [1] Yes  
[2] No

61) IF NO, Which type of questions? (*Check those not valid*)

- [1] Drugs
- [ 2 ] Number of partners
- [3] All
- [8] Other, specify: \_\_\_\_\_

62) Express any additional comments about the interview in the space below.

Public reporting burden for this collection of information is estimated to be 10 minutes per response. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: PHS Reports Clearance Officer; ATIN: PRA. Humphrey Bldg., Rm 721-1-1,200; 200 Independence Ave. SW; Washington, DC 20201; and to the Office of Management and Budget; Paperwork Reduction Project (0920-0242); Washington, DC 20503.

OMB #: 09200242

Expires: 6/31/91

Study#:

**“EVALUATION OF THE REASONS FOR THE  
INCREASE IN REPORTED CASES OF SYPHILIS”**

**Questionnaire  
1991**

Conducted by:

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**The Centers for Disease Control**

**Principal Investigators: Robert RoWs, M.D. & George Schmid, M.D.**

STUDY #

- |   | Y~s | ND  | Unsure |
|---|-----|-----|--------|
| 11) Are you currently in school?"                                     | [1] | [2] | [3]    |
| 12) What is the highest grade you completed in school?<br>_____ years |     |     |        |
| 13) Do you have a telephone?"   | [1] | [2] | [3]    |

**History of STD and Sexual Activity**

---

- 14a) Have you ever been told you had syphilis" [1] [2] [3]
- 14b) IF YES, What was the date of most recent episode?  
\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_
- 15a) Have you ever been told you had gonorrhea" [1] [2] [3]
- 15b) IF YES, What was the date of most recent episode?  
\_\_\_\_\_/\_\_\_\_\_
- 16a) Have you had an ulcer/sore in your genital area in the last 6 months? (*In addition to any ulcer present*) [1] [2] [3]
- 16b) IF YES, Did you seek medical care for it~ [1] [2] [3]
- 16c) IF CARE WAS SOUGHT, Where did you seek care? (*Check all that apply*)
- [1] STD clinic
  - [2] Private physician
  - [3] Emergency room
  - [8] Other, specify: \_\_\_\_\_
- 16d) IF NO CARE WAS SOUGHT, Why didn't you seek care? (*Check all that apply*)
- [1] Didn't have enough money
  - [2] Didn't have the time
  - [3] Didn't think it was important
  - [4] Took antibiotics without seeking care
  - [8] Other, specify: \_\_\_\_\_

STUDY #

	Y~s	NIL	IUnsur~	Ikfus~A
24a) In the last 3 months, have you taken any drug by needle (“shot up” or “skin popped”)	[1]	[2]	[3]	[4]
<b>IF NO, Go to 26a</b>				
<b>IF YES, Which drugs?</b>				
24b) Cocaine	[1]	[2]	[3]	[4]
24c) Heroin or other opiate	[1]	[2]	[3]	[4]
24d) Amphetamine (speed)	[1]	[2]	[3]	[4]
24e) Other drugs specify: _____	[1]	[2]	[3]	[4]
25) In the past 3 months, have you shared a needle with another person while taking drugs”	[1]	[2]	[3]	[4]
~ In the past 3 months, have you given money or drugs, including alcohol, to someone so they’ll have sex with you”	[1]	[2]	[3]	[4]
<b>IF NO, Go to 27a</b>				
<b>IF YES, Did you give them:</b>				
26b) money”	[1]	[2]	[3]	[4]
26c) drugs”	[1]	[2]	[3]	[4]
<b>IF PATIENT GAVE MONEY,</b>				
26d) In the past two weeks, how many times did you give someone money so they’ll have sex with you? # of times: _____				
<b>IF PATIENT GAVE DRUGS,</b>				
26e) In the past two weeks, how many times did you give someone drugs so they’ll have sex with you? # of times: _____				
Which drugs did you give? ( <i>Check all that apply</i> )				
26f) Crack	[1]	[2]	[3]	[4]
26g) Cocaine, not crack	[1]	[2]	[3]	[4]
26h) Heroin	[1]	[2]	[3]	[4]
26i) Marijuana	[1]	[2]	[3]	[4]
26j) Alcohol	[1]	[2]	[3]	[4]
26k) Other drug: specify, _____	[1]	[2]	[3]	[4]

STUDY #

	Y~s	NIL	UnsuL~	R~fu~1
28) Do you think that anyone you have had sex with in the last 3 months ever takes money or drugs from other people for sex <sup>7</sup>	[1]	[2]	[3]	[4]
29) In the past 3 months, have you had sex with someone you met at a crack house or place where people go to buy or use crack”	[1]	[2]	[3]	[4]
30) In the past 3 months, have you had sex with someone on the same day that you met them”	<b>[1]</b>	[2]	[3]	[4]
31) In the past 3 months, have you had sex with more than one person in a 24-hour period”	[1]	[2]	[3]	[4]
32a) In the past 3 months, have you shared drugs, including alcohol, with someone before having sex with them (on the same day)”	[1]	[2]	[3]	[4]
IF YES, Which drugs?				
32b) Crack	[1]	[2]	[3]	[4]
32c) Cocaine, not crack	[1]	[2]	[3]	[4]
32d) Heroin	[1]	[2]	[3]	[4]
32e) Marijuana	[1]	[2]	[3]	[4]
32f) Alcohol	[1]	[2]	[3]	[4]
32g) Other drug (specify): _____	[1]	[2]	[3]	[4]
33a) In the past 3 months, have you had sex with someone only one time and never again”	[1]	[2]	[3]	[4]
IF YES, How did you meet that person or persons?				
33b) At a bar”	[1]	[2]	[3]	[4]
33c) On the street <sup>7</sup>	[1]	[2]	[3]	[4]
33d) At a crack house”	[1]	[2]	[3]	[4]
33e) At work <sup>9</sup>	[1]	[2]	[3]	[4]
33f) At school”	[1]	[2]	[3]	[4]
33g) Don't remember	[1]	[2]	[3]	[4]
33h) Other (specify): _____	[1]	[2]	[3]	[4]

Interviewer's Impressions

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34) Do all answers seem valid<sup>9</sup> [1] Yes  
[2] No

35) IF NO, Which type of questions? (*Check those not valid*)

- [1] Drugs
- [2] Number of partners
- [3] All
- [8] Other, specify: \_\_\_\_\_

36) Express any additional comments about the interview in the space below.

Public reporting burden for this collection of information as estimated to be 10 minutes per response. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: PHS Reports Clearance Officer; ATTN: PRA; Humphrey Bldg., Rm 721-H,200; 200 Independence Ave. SW; Washington, DC 20201; and to the Office of Management and Budget; Paperwork Reduction Project (0920-0242); Washington, DC 20503.

## **ATTACHMENT E**

### **Consent Forms**

“Evaluation of the Reasons for the Increase in Reported Cases of Syphilis”

Conducted by CDC

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The Centers for Disease Control (CDC) in conjunction with The Chicago Department of Health, STD Program is doing a study to see why people get sexually transmitted diseases. We are doing this because there has been a large increase in the number of people getting sexually transmitted diseases during the past year (1989) in the city and we don't know why. If it is okay with you I will ask you some questions about sex and drugs to help us understand why sexually transmitted diseases are increasing. Information will be kept confidential and your name will not be written on the form. If you decide to help in this study, please remember that I am not here to judge you or your behavior. You are free to refuse to answer any of these questions. If you have questions now you may ask them. Participation in this project is voluntary, and refusal to participate will not affect your visit today or in the future. This will require only a few minutes of your time. If you think of questions after you leave the clinic today, you may call 435-5400 for assistance.

The information collection will be coded and sent to CDC for them to analyze, Your name and address are not part of the information sent to CDC. We will not identify any of the people who take part in this study to CDC or any unauthorized personnel in the Department of Health.

I, \_\_\_\_\_ have been informed as to the purpose of this study and agree to participate.

Signed: \_\_\_\_\_ Date: \_\_\_\_\_

Witness: \_\_\_\_\_ Date: \_\_\_\_\_

**CONSENT FORM**  
**CDC SYPHILIS SURVEY**

---

The Centers for Disease Control (CDC) and the New Orleans Department of Health, is doing a study to see why people get sexually transmitted diseases. We are doing this because there has been a large increase in the number of people getting sexually transmitted diseases during the past year and we don't know why.

If it is okay with you., I will ask you some questions about sex and drugs to help us understand why sexually transmitted diseases are increasing. No one will know how you answered, the questions because your name will not be written on the questionnaire so no will be able to identify you.

Your participation is voluntary, and if you refuse to participate this will not affect your visit today or in the future. If you decide to help in this study, please remember that I am not here to judge your behavior. We need honest answers from you so that we can learn more about sexually transmitted diseases and keep people healthy.

Will you participate? It will take about 10 minutes of your time.

## INTEORMED CONSENT

### “Evaluation of the *Reasons* for the Increase in Reported Cases of Syphilis” Conducted by CDC

The following statement must be read to all potential participants at Health Center No. 1:

**The** Centers for Disease Control and Health Center No. 1 is doing a study to see why people get sexually transmitted diseases. We’re doing this because there has been a large increase in the number of people getting sexually transmitted diseases this year and we don’t know why. If it’s okay with you, I’d like to ask you some questions about sex and drugs to help us understand why sexually transmitted diseases are increasing. No one will know how you answered the questions because the form that I’ll put your answers down on will not have your name on it and no one will be able to identify you. We are not here to judge you or your behavior; all we want to do is make sure you are healthy and won’t get infected again. It’s very important to us that you be in our study because we need your answers to our questions. You don’t have to be in our study and if you don’t want to be, this won’t change your treatment today or your future treatment in this clinic. We’d like you to be, though, because if everyone participates, we are more likely to find the answers. Would you be part of our study and answer my questions; it’ll take no more than 10 minutes?

Good. Now, it’s very important that you be honest with me. Remember, I won’t judge you or what you have been doing, but we need to get honest answers.

To interviewez-- If patient does not agree to participate in the study, please indicate:

- 1) Sex [1] Male 121 Female
  
- 2) Race:  
[1] White  
[2] Black  
[3] American Indian/Alaskan Native  
[4] Asian/Pacific Islander  
[8] Other
  
- 3) Age
  
- 4) Does the patient have a diagnosis of primary or secondary syphilis?  
(Check only one) [1] Yes [2] No [3] Unsure

**CONSENT FORM**  
**CDC SYPHILIS SURVEY**

---

The Centers for Disease Control (ODO) and the City of Long Beach, Department of Health and Human Services, is doing a study to see why people get sexually transmitted diseases. We are doing this because there has been a large increase in the number of people getting sexually transmitted diseases during the past year and we don't know why.

If it is okay with you, I will ask you some questions about sex and drugs to help us understand why sexually transmitted diseases are increasing. No one will know how you answered the questions because your name will not be written on the questionnaire so no one will be able to identify you.

Your participation is voluntary, and if you refuse to participate this will not affect your visit today or in the future. If you decide to help in this study, please remember that I am not here to judge your behavior. We need honest answers from you so that we can learn more about sexually transmitted diseases and keep people healthy.

Will you participate? It will take about 10 minutes of your time.

**ATTACHMENT F**  
**Procedures Manual**

**“EVALUATION OF THE REASONS FOR THE  
INCREASE IN REPORTED CASES OF SYPHILIS”**

**CONDUCTED BY  
THE CENTERS FOR DISEASE CONTROL**

**Procedural Manual for Data Collection  
Palm County Health Unit  
West Palm Beach, Florida  
1990**

**Prepared by:**

---

*James Bell Associates, Inc.*

*2200 Clarendon Blvd, Suite 1000*

*Arlington, Virginia 22201*

*(703) 528-3230*

## OBJE

Anecdotal reports from a number of areas in the United States have suggested a link between drugs or drug-related behaviors and the acquisition of sexually transmitted diseases, including syphilis, chancroid and PPNG. Investigators at the centers for Disease control (CDC) in Atlanta designed this case-control study of syphilis patients to 1) assess the roles of drug use and related behaviors (particularly drug-related prostitution) as risk factors for the acquisition of syphilis; 2) assess the importance of this association as a cause of the increases in syphilis occurring in the United States; 3) determine the effect of drug use on the outcome of STD partner referral activities; and 4) further investigate the possibility of IV needle-related transmission of syphilis.

James Bell Associates, Inc. (JBA) is a private consulting firm in Arlington, Virginia that has been contracted by CDC and the U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation to develop, implement and monitor the data collection procedures for the study. As prescribed by the study protocol, JBA will conduct data collection activities at 8 sites. Each site will interview approximately 120 cases and 240 controls. The length of the study period will vary with conditions at each site (e.g., the volume of patients and staff availability), but generally it is expected that data collection will take approximately five months at each site.

This document describes the information necessary to successfully execute the CDC case-control study of drug use and syphilis in West Palm Beach, Florida. Data collection will take place at the Palm County Health Unit located at 3701 Broadway. The STD clinic operates 12:30 p.m. to 3:00 p.m. on Monday, 8:00 a.m. to 10:30 a.m. on Tuesday, Thursday and Friday, and is closed on Wednesday.

## L~::~~TIONAL ORGANIZATION

The clinical and disease control operations of the Palm County Health Unit (i.e. the clinic) are organized under one line of authority: Dr. James Howell, Dept. of Health and Rehabilitative Services (HRS) Deputy District Administrator for Health. Jadis Porter-Robinson is the STD Program Manager who oversees the syphilis control activities performed by 17 Disease Intervention Specialists (DIS). Each week, five teams of DIS rotate their responsibilities to conduct partner referral interviews at the clinic and trace syphilis contacts in the community. Each day, approximately four DIS conduct interviews at the clinic.

All patients who believe they may have contracted an STD present at the clinic and complete a clinic registration form.

Clerk gives patient a letter of the alphabet if they were referred to the clinic by DIS, or are being seen for the second time. All other patients receive a number.

For every patient who registers, clerk searches the "Expected-In" box for pink copy of 2936 form which indicates that the patient has been referred to the clinic by DIS.

If the 2936 form is present, clerk attaches it to the medical record along with the appropriate lab slips. Medical chart is placed in box for clinician.

Patient pays at cashier then has blood drawn. At this time, DIS asks patient if they want to be tested for the HIV-Antibody. Patients who decline the test return to the waiting room. Patients who accept are counseled by DIS and then return to the waiting area.

Patient is called to the examining room. Doctor exams patient and places medical chart in "Pending Lab" box. When lab results become available, they are attached to the chart and placed in the Doctors review box.

Doctor determines diagnosis and course of treatment. Patient returns to waiting room until nurse is available. Nurse calls patient to exam room and treats patients.

For all patients diagnosed with syphilis, the nurse gives chart to the Clinic Coordinator (i.e., a DIS supervisor).

**Clinic Coordinator gives the medical chart to a DIS interviewer (DIS sit in interview rooms). Clinic Coordinator keeps a log of the patient's name, diagnosis and treatment and the DIS interviewer.**

DIS conduct the patient counseling/partner referral interviews. The 954 and 2936 forms are completed and submitted to supervisor within 24 hours.

After the interview, Clinic Coordinator returns the medical chart to the clerk.

Medical records clerk keeps a log of the patient's name, date of birth, diagnosis, lab results, treatment, physician. Clerk places lab slips in medical chart.

The following 17 DIS will participate in the study:

- |                             |                          |
|-----------------------------|--------------------------|
| 1. Hardnett, Carla          | 10. White, Thomas        |
| 2. Times, Rose              | 11. Jones, Yolanda       |
| 3. Carroll, Herbert         | 12. Mazzeo, Michele      |
| 4. Chatmon, Lena            | <b>13. St. Cyr, Jean</b> |
| 5. Do, Kim                  | 14. Gavin, Karen         |
| 6. Lay, John                | 15. Finney, Richard      |
| 7. Scott, Jan               | 16. Arrowsmith, Susan    |
| 8. <b>Spozarsky, George</b> | 17. Raupfer, Kris        |
| 9. Webb, Lisa               |                          |

The Clinic Coordinators (12-17) will be responsible for selection of cases and controls, assuring that the survey instrument is completed accurately and recording information in the study log book. The remaining DIS are responsible for the administration of the questionnaire.

Kris Raupfer will serve as the Study Coordinator. She will be responsible for recording patient diagnosis and lab results, assuring that the data flows to JBA in a manner indicated by this protocol and for relaying information between DIS staff and JBA.

How these responsibilities will be carried out is fully described in the following sections of this procedural manual.

**Method:**

Patients who possess a registration ticket having an even number as the last digit and meet the requirements under "Criteria" above will be selected as candidates for the controls. At the time patient is asked if they want to be tested for the HIV Antibody, DIS will ask patient if they'd be willing to participate in the study. If patient agrees, they will be interviewed by the next available DIS. Each DIS will complete two control interviews per day.

**Number:**

Given the estimated flow of patients that meet the criteria above, approximately 15-20 patients per day are potential candidates. The number of controls selected will be 8 per day (four DIS conducting two interviews each). In approximately two months, the required 240 controls will be selected and interviewed.

~

The informed consent form is a separate document from the questionnaire; patient's signature is required for participation. The questionnaire consists of diagnosis and lab results sections followed by the study questions to be asked by the interviewer. A unique study number is pre-printed on the top right corner of every page of each questionnaire.

Blank informed consent forms and questionnaires will be located in a box in the registration area.

**When to administer:**

Prior to administering the questionnaire to cases and controls, the interviewer must read the informed consent form to the patient.

Cases – Using the selection criteria, Clinic Coordinator will determine which syphilis patients are candidates for participation. For patients selected as candidates, Clinic Coordinator will give DIS an informed consent form and a questionnaire prior to the partner referral interview. DIS interviewers will administer the questionnaire to patients prior to the usual partner referral/counseling interview.

Controls – If a patient is to receive HIV pretest counseling, DIS interviewers will administer the questionnaire prior to counseling patients. If patient declines HIV test, but agrees to participate in the study, DIS will administer the

questionnaire before the patient returns to the waiting area.

**Diagnosis and Lab Results:**

Study Coordinator will complete the diagnosis and lab result information after the questionnaire has been administered.

**Tagging Participants:**

Cases and Controls — Clinic Coordinators will remove the yellow sticker with the study number written on it from the questionnaire and stick it on the bottom left corner of the clinical records of the cases and controls. This sticker indicates that the patient is a study participant and is not to be interviewed again as a case or control.

**Tracking Refusals:**

Interviewers will keep record of case and control candidates who 1) refuse to participate prior to hearing the informed consent information, or 2) refuse to sign the consent form after having it read to them. Interviewers will keep track of these refusals on the informed consent form (i.e., by completing the information in the box on the bottom of page 2 of the consent form).

Interviewers will give all consent forms and completed questionnaires to the Clinic Coordinator on duty.

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A log book located in the registration area will be used to record: (1) Clinic Coordinator on duty; (2) DIS interviewer; (3) patient's (a) name; (b) registration number; (c) lot number if the patient is a case; (d) study number; (e) date of birth; (f) date of visit; (4) lab tests ordered; (5) date lab results received; (5) comments; and, (6) date the survey instrument was sent to JBA (to be completed by the Study Coordinator).

After receiving the completed questionnaires from the interviewers, the Clinic Coordinator will review the questionnaire for completeness and accuracy, and then correctly record the case or control in the study logbook. Clinic Coordinators are responsible for each questionnaire that he/she logs.

Informed consent forms with patient signatures will kept in a folder called "Consent Given." (Signed consent forms are the property of the clinic and will not be returned to JBA.) Informed consent forms not signed by patients will be kept in a folder called "Consent Refused."

Clinic Coordinators will place completed questionnaires that

In the log book, the Study Coordinator will record the date the completed questionnaires are sent to JBA.

The Study Coordinator is responsible for regularly checking the log book to ensure that all questionnaires are returned JBA within 15 days after the date of the patient's visit. If more than 15 days elapses, the Coordinator will notify the Clinic Coordinator responsible for that questionnaire.

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JBA is responsible for orienting clinic and DIS staff who are involved in the execution of the data collection plan. The purpose of the orientation is to describe the objectives of the study; educate staff about their roles and responsibilities; and review all phases of the data collection process. These activities will be carried out by explaining all sections of this Procedural Manual. JBA staff will also discuss certain data collection issues (described below) and answer questions.

Staff orientation is scheduled for March 14, 1990.

Laura Aiuppa of JBA, and Jadis Porter-Robinson, STD Program Manager will guide the orientation of DIS staff, receptionists, clinicians, and medical records clerk.

DIS should note these additional data collection issues:

1. Definition of sex

One Disease Intervention Specialist commented that when some male patients are asked about their sexual encounters, they do not always consider oral sex from another man as "having sex". Probing this issue with case and control participants will help elicit more accurate information about all types of sexual encounters.

2. Interviewer's Impressions

When interviewers record their impressions of the validity of the patient's answers (questions 59 and 60), they should consider:

- a. rating the validity of a patient's drug use behavior based on observational evidence of drug use (track marks; red, glazed eyes; slurred speech, etc.)
- b. rating the validity of a patient's sex behavior based on their drug use — heavy drug users are more likely to exchange sex for drugs.

**“EVALUATION OF THE REASONS FOR THE  
INCREASE IN REPORTED CASES OF SYPHILIS”**

CONDUCTED BY

**THE CENTERS FOR DISEASE CONTROL**

**Procedural Manual for Data Collection**

**Dallas County STD Clinic**

**Dallas, Texas**

**1990**

Prepared by:

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*James Bell Associates, Inc.*

*2200 Clarendon Blvd., Suite 1005*

*Arlington, Virginia 22201*

*(703) 528-3230*

u clinical diagnosis of primary or secondary syphilis; and

- voluntarily presented at the clinic for treatment;

— This also includes patients who present voluntarily for the initial test at the clinic or at a private physicians office but who have to be referred in for treatment.

— DIS referrals and patients tested and treated elsewhere but seen at the clinic for STD interviews only will be excluded.

- When:

DIS supervisors will select candidates for the cases each day at the time of the counseling/partner referral interviews.

- Number:

Given the estimated flow of patients that meet the above criteria, 3–5 cases per day can be expected. In approximately 2–3 months, the required 120 cases will be selected and interviewed.

#### B. Selecting Controls

- Criteria:

Candidates for the controls will include those patients who meet the following two conditions as indicated on their registration form and clinical record (both conditions must bernet):

- clinical diagnosis of STDs other than syphilis, non-STDs (e.g. vaginal candidiasis, bacterial vaginosis) or no disease. Patients diagnosed with syphilis within the last 12 months will be excluded; and

- voluntarily presented at the clinic for treatment  
— patients seen only for HIV testing will be excluded.

- u Method:

Patients who possess a registration ticket having an even number as the last digit and meeting the requirements under “Criteria” above will be selected as candidates for the controls. The clinicians will refer these patients to the DIS for the study interview.

- Number:

Given the estimated flow of patients that meet the criteria above, approximately 70-75 patients per day are potential candidates. The number of controls selected will be 8–10 per

### III. OVERVIEW OF STAFF ROLES FOR THE STUDY

The following DIS will participate in the study:

Team One:

1. Bob Kelly
2. Robert Ray
3. Judy Wootton
4. Linda Mins
5. Ruth Abdullah

Team Two:

6. Ron Stinson
7. Danny Barnes
8. Ralph Villareal
9. Cindy Shelton
10. Debbie Collins

#### Supervisors:

Pam Beachum

Al Gonzales

The DIS supervisors are responsible for assuring that the questionnaires are completed accurately, recording pending lab results and documenting information in the study log book. The remaining DIS are responsible for administering the questionnaire.

John Mayfield, Assistant Program Manager, will serve as the Study Coordinator. He will be responsible for overseeing all study-related activities, assuring that the data flows to JBA in a manner indicated by this protocol and for relaying information between DIS staff and JBA.

How these responsibilities will be carried out is fully described in the following sections of this procedural manual.

### IV. SELECTION OF CASES AND CONTROLS

#### A. Selecting Cases

• Criteria:

Candidates will include all patients who meet the following two conditions as indicated on their registration form and clinical record (both conditions must be met):

- clinical diagnosis of primary or secondary syphilis; and
- voluntarily presented at the clinic for treatment;

— This also includes patients who present voluntarily for the initial test at the clinic or at a private physicians office but who have to be referred in for treatment.

— DIS referrals and patients tested and treated elsewhere but seen at the clinic for STD interviews only will be excluded.

- When:  
DIS interviewers will select candidates for the cases each day at the time of the counseling/partner referral interviews.
- Number:  
Given the estimated flow of patients that meet the above criteria, 2-3 cases per day can be expected. In approximately two to three months, the required 120 cases will be selected and interviewed.

#### B. Selecting Controls

- Criteria:  
Candidates for the controls will include those patients who meet the following two conditions as indicated on their registration form and clinical record (both conditions must be met):
  - clinical diagnosis of STDs other than syphilis, non-STDs (e.g. vaginal candidiasis, bacterial vaginosis) or no disease. Patients diagnosed with syphilis within the last 12 months will be excluded; and
  - voluntarily presented at the clinic for treatment  
— patients seen only for HIV testing will be excluded.
- Method:  
Patients who possess a registration ticket having an even number as the last digit and who meet the requirements under "Criteria" above will be selected as candidates for the controls. After the exam, clinicians will notify the DIS. DIS will ask these patients to participate in the study. Using the clinic logbook that records interviews, the supervisor is to ensure that each DIS conducts 2 control interviews per day.
- When:  
Each day, half of the controls will be selected in the morning and half in the afternoon to prevent selection bias.
- Number:  
Given the estimated flow of patients that meet the criteria above, approximately 80-120 patients per day are potential candidates. The number of controls selected will be 20 per day. In approximately two weeks, the required 240 controls will be selected and interviewed.

## V. ADMINISTERING THE QUESTIONNAIRE

The informed consent form is a separate document from the questionnaire and must be read to potential participants prior to administering the questionnaire. The questionnaire consists of diagnosis and results sections followed by the study questions to be asked by the interviewer. A unique study number is pre-printed on the top right corner of every page of each questionnaire.

Blank questionnaires will be located in a box next to the forms used for HIV pretest counseling. Supervisors will give a blank questionnaire to DIS prior to the interview.

- When to administer:

Cases — DIS interviewers will administer the questionnaire to patients prior to the usual partner referral/counseling interview and after obtaining informed consent.

Controls — DIS interviewers will administer the questionnaire to patients after they have seen a clinician, prior to other STD interviews and after obtaining informed consent.

- Lab Results:

- Lab results available at the time of the interview will be recorded on the lab results form (p.2).

— If some or all of the lab results are pending at the time of the interview, DIS will indicate the tests with pending results. The supervisors will record the results at a later time (refer to Section VII.)

- Tagging Participants:

Cases and Controls — Interviewers will remove the yellow sticker with the study number written on it from the lab form and stick it on the bottom left corner of the clinical records of the cases and controls. This sticker indicates that the patient is a study participant and is not to be interviewed again as a case or control.

- Tracking Refusals:

Interviewers will keep a record of case and control candidates who refuse to participate (all refusals should be recorded, i.e., those who refuse prior to, and after, hearing the informed consent information). Interviewers will record refusals on the informed consent form by completing the information in the box at the bottom of the form.

- Interviewers will give completed questionnaires to the

supervisor on duty.

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## VI. LOGGING CASES AND CONTROLS

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A log book, located on the supervisor's desk, will be used to record: 1) supervisor on duty; 2) DIS interviewer; 3) patient's (a) name; (b) clinic "patient number" if the patient is a case; (c) study number; (d) date of birth; (e) date of visit; 4) date all lab results received; 5) comments; and, 6) date the survey instrument was sent to JBA.

- After the interview, the DIS worker will give the completed questionnaire to the DIS supervisor on duty.
- The DIS supervisors will review the questionnaire for completeness and accuracy, and then correctly record the questionnaire in the logbook. Supervisors are responsible for each questionnaire that he/she logs.
- Supervisors will place informed consent forms used to record refusals in a folder called "Consent Refused."
- Each supervisor will keep completed questionnaires that have all test results recorded on the lab results form in a folder called "Closed Questionnaires." Questionnaires that have pending lab results will be kept in a folder called "Open Questionnaires," see further instructions in section VII below.

## VII. COLLECTING THE FINAL LAB RESULTS

- For questionnaires in the "Open Questionnaire" folder, the supervisors are responsible for collecting the final lab results.
- Every day, supervisors will 1) list study numbers for questionnaires in the "Open Questionnaire" folder; 2) refer to the log book to identify the patient's name corresponding to each study number; 3) retrieve lab results for these patients from the lab result list posted daily; and 4) record the results on the questionnaire.
- Supervisors will record the date the the lab form is completed in the logbook and place the questionnaire in the "Closed Questionnaire" folder.

- Every week, the Study Coordinator will check the logbook to ensure that all questionnaires have completed lab results forms within 10 days after the date of the patient's interview. If more than 10 days elapses, the Study Coordinator will notify the supervisor responsible for that questionnaire and request that the lab results be obtained and recorded.
- The Study Coordinator will review questionnaires placed in the "Closed Questionnaire" folder and then send to JBA according to the instructions below.

T~S~TING DATA TO JBA

- Once a week, the Study Coordinator will collect the completed questionnaires from the "Closed Questionnaire" folder and send them to JBA by certified mail in envelopes provided. The clinic will be reimbursed postage.
- In the log book, the Study Coordinator will record the date the completed questionnaires are sent to JBA.
- The Study Coordinator is responsible for regularly checking the log book to ensure that all questionnaires are returned JBA within 15 days after the date of the patient's visit. If more than 15 days elapses, the Coordinator will notify the supervisor responsible for that questionnaire.

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IX. ORIENTATING STAFF

JBA is responsible for orienting clinic and DIS staff who are involved in the execution of the data collection plan. The purpose of the orientation is to describe the objectives of the study; educate staff about their roles and responsibilities; and review all phases of the data collection process. These activities will be carried out by explaining all sections of this Procedural Manual. JBA staff will also discuss certain data collection issues (described below) and answer questions.

Staff orientation is scheduled for April 2, 1990.

Laura Aiuppa of JBA, and Don Hutcheson, STD Program Manager will guide the orientation of DIS staff, receptionists, clinicians, and medical records clerk.

DIS should note these additional data collection issues:

1. Definition of sex

One Disease Intervention Specialist commented that when some male patients are asked about their sexual encounters, they do not always consider oral sex from another man as "having sex". Probing this issue with case and control participants will help elicit more accurate information about all types of sexual encounters.

2. Interviewer's Impressions

When interviewers record their impressions of the validity of the patient's answers (questions 60 and 61), they should consider:

- a. rating the validity of a patient's drug use behavior based on observational evidence of drug use (track marks; red, glazed eyes; slurred speech, etc.)
- b. rating the validity of a patient's sex behavior based on their drug use — heavy drug users are more likely to exchange sex for drugs.

**“EVALUATION OF TILE REASONS FOR THE  
INCREASE IN REPORTED CASES OF SYPHILIS”**

CONDUCTED BY  
**TILE CENTERS FOR DISEASE CONTROL**

**Procedural Manual for Data Collection**

**Near South Specialty Clinic  
Chicago, Illinois  
1990**

Prepared by:

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*James Bell Associates, Inc.*

*2200 Clarendon BlvcL, Suite 1005*

*Arlington, Virginia 22201*

*(703) 528-3230*

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STUDY OBJECTIVES

K Anecdotal reports from a number of areas in the United States have suggested a link between drugs or drug-related behaviors and the acquisition of sexually transmitted diseases, including syphilis, chancroid and PPNG. Investigators at the Centers for Disease Control (CDC) in Atlanta designed this case-control study of syphilis patients to 1) assess the roles of drug use and related behaviors (particularly drug-related prostitution) as risk factors for the acquisition of syphilis; 2) assess the importance of this association as a cause of the increases in syphilis occurring in the United States; 3) determine the effect of drug use on the outcome of STD partner referral activities; and 4) further investigate the possibility of IV needle-related transmission of syphilis.

James Bell Associates, Inc. (JBA) is a private consulting firm in Arlington, Virginia that has been, contracted by CDC and the U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation to develop, implement and monitor the data collection procedures for the study. As prescribed by the study protocol, JBA will conduct data collection activities at 8 sites. Each site will interview approximately 120 cases and 240 controls. The length of the study period will vary with conditions at each site (e.g., the volume of patients and staff availability), but generally it is expected that data collection will take approximately five months at each site.

K~ This document describes the information necessary to successfully execute the CDC case-control study of drug use and syphilis in Chicago, Illinois. Data collection will take place at the Near South Specialty Clinic located at 1306 S. Michigan Ave. The STD clinic operates 8:30 a.m. to 4:30 p.m. every day (except Wednesday) and 11:30 a.m. to 7:00 p.m. on Wednesday.

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## I. OPERATIONAL ORGANIZATION

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The clinical and disease control operations of the Near South Specialty Clinic (i.e. the clinic) are organized under the authority of the Public Health Department. Louise Galaska is the STD Program Director. Mark Wilson, Deputy Director, oversees the operational activities the STD program. Each day, two teams of DIS rotate their responsibilities to conduct partner referral interviews at the clinic and trace syphilis contacts in the community. Each day, approximately five DIS conduct interviews at the clinic.

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## II. PATIENT FLOW

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- All patients who believe they may have contracted an STD present at the clinic and complete a clinic registration form.
- Clerk gives patient a letter of the alphabet if they were referred to the clinic by DIS, or are being seen for the second time. All other patients who volunteer or are referred by a private physician receive a number.
- For every patient who registers, clerk searches the "Expected-In" box for white copy of 2936 form which indicates that the patient has been referred to the clinic by DIS. If the 2936 form is present, clerk transfers the information to the medical record along with the appropriate lab slips.
- Clerical staff enter registration information into the computer.
- The optically scanned medical record is given to nurse. Patient waits in to be called by the nurse for examination.
- Clinician exams patient. Blood sample and GC smear taken to the lab for testing. Patient waits outside exam room to await stat lab results.
- Patient returns to exam room where clinician diagnosis and treats patient based on lab results.
- For all patients diagnosed with syphilis or gonorrhea the clinician gives chart to a DIS supervisor for patient counseling/partner referral interview.
- DIS supervisor gives the medical chart to a DIS interviewer. Supervisor keeps track of the number of interviews performed by each DIS.
- DIS conduct the patient counseling/partner referral

interviews. The STD IR and 2936 forms are completed and submitted to supervisor within 24 hours.

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III. OVERVIEW OF STAFF ROLES FOR THE STUDY

The following 13 DIS will participate in the study:

Team One:

1. Judy Kimberly
2. Gloria Andrews
3. Gus Conda
4. Steven Kowalewski
5. Yolanda Richardson
6. Susan Marcus
7. Heidi Beidinger

Team Two:

8. Kendra Gilbert
9. April Wilkerson
10. Michael Ford
11. )Romni Neiman
12. Lillian Clayton
13. Michelle Thomas

Supervisors:

Carol Sharp

Joe Betros

The DIS supervisors are responsible ensuring that questionnaires are completed accurately, recording pending lab results onto the questionnaire, and recording information in the study log book. The remaining DIS are responsible for the administration of the questionnaire.

Joe Betros will serve as the Study Coordinator. He/she will be responsible for assuring that the data flows to JBA in a manner indicated by this protocol and for relaying information between DIS staff and JBA.

How these responsibilities will be carried out is fully described in the following sections of this procedural manual.

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IV. SELECTION OF CASES AND CONTROLS

A. Selecting Cases

• **Criteria:**

Candidates will include all patients who meet the following two conditions as indicated on their registration form and clinical record (both conditions must be met):

## ORIENTATING STAFF

JBA is responsible for orienting clinic and DIS staff who are involved in the execution of the data collection plan. The purpose of the orientation is to describe the objectives of the study; educate staff about their roles and responsibilities; and review all phases of the data collection process. These activities will be carried out by explaining all sections of this Procedural Manual. JBA staff will also discuss certain data collection issues (described below) and answer questions.

Staff orientation is scheduled for July 2. Data collection will begin July 3.

Laura Aiuppa of JBA, and Tracy Luster, STD Program Manager will guide the orientation of clinic staff.

### DATA COLLECTION ISSUES:

DIS should note the following when interviewing:

#### 1. Definition of sex

One Disease Intervention Specialist commented that when some male patients are asked about their sexual encounters, they do not always consider oral sex from another man as "having sex". Probing this issue with case and control participants will help elicit more accurate information about all types of sexual encounters.

#### 2. Interviewer's Impressions

When interviewers record their impressions of the validity of the patient's answers (questions 54 and 55), they should consider:

- a. rating the validity of a patient's drug use behavior based on observational evidence of drug use (track marks; red, glazed eyes; slurred speech, etc.)
- b. rating the validity of a patient's sex behavior based on their drug use - heavy drug users are more likely to exchange sex for drugs.

**“CASE CONTROL STUDY OF SYPHILIS AM)  
DRUG USE”**

CONDUCTED BY

**THE CENTERS FOR DISEASE CONTROL**

**Procedural Manual for Data Collection**

**Memphis and Shelby County STD Clinic**

**Memphis, Tennessee**

1990

Prepared by:

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*James Bell Associates, Inc.*

*2200 Clarendon Blvd., Suite 1005*

*Arlington, Viiginia 22201*

*(703) 528-3230*

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STUDY OBJECTIVES

Anecdotal reports from a number of areas in the United States have suggested a link between drugs or drug-related behaviors and the acquisition of sexually transmitted diseases, including syphilis, chancroid and PPNG. Investigators at the Centers for Disease Control (CDC) in Atlanta designed this case-control study of syphilis patients to 1) assess the roles of drug use and related behaviors (particularly drug-related prostitution) as risk factors for the acquisition of syphilis; 2) assess the importance of this association as a cause of the increases in syphilis occurring in the United States; 3) determine the effect of drug use on the outcome of STD partner referral activities; and 4) further investigate the possibility of IV needle-related transmission of syphilis.

James Bell Associates, Inc. (JBA) is a private consulting firm in Arlington, Virginia that has been contracted by the Centers for Disease Control to develop, implement and monitor the data collection procedures for the study. As prescribed by the study protocol, JBA will conduct data collection activities at 8 sites. Each site will interview approximately 120 cases and 240 controls. The length of the study period will vary with conditions at each site (e.g., the volume of patients and staff availability), but generally it is expected that data collection will take approximately five months at each site.

K~

This document describes the information necessary to successfully execute the CDC case-control study of drug use and syphilis in Memphis, Tennessee. Data collection will take place at the Memphis and Shelby County STD clinic located at 814 Jefferson Ave. The clinic operates 7:30 a.m. to 8:00 p.m. on Monday, and 7:30 a.m. to 4:30 p.m. Tuesday through Friday.

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## I. OPERATIONAL ORGANIZATION

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The clinical and disease control operations of the Memphis and Shelby County STD Clinic (i.e., the clinic) are organized under the authority of the Shelby County Health Department. Tracy Luster is the STD Program Manager. Each day, three teams of DIS rotate their responsibilities to conduct partner referral interviews at the clinic and trace syphilis contacts in the community. Approximately seven DIS conduct interviews at the clinic each day.

- Contacts, patients with positive tests for STDs and volunteer patients phone the STD clinic appointment number for next day appointments. Patients without an appointment are worked into available openings.
- All patients who present at the clinic and complete a clinic registration form receive a number to identify them during the visit.
- For every patient who registers, clerk searches the "Expected-In" box for the pink copy of the 2936 form which indicates the patient was referred by DIS. If the 2936 form is present, clerk transfers the information to the medical record along with the appropriate lab slips. If patient is new to the clinic, a medical record is made.
- Medical record is given to the nurse. Patient waits for nurse to call them into the examination area.
- Clinician examines patient. Blood sample and GC smear sent to lab for testing. Patients who are contacts or have signs or symptoms of syphilis requiring stat lab results wait in designated waiting area..
- For all patients diagnosed with syphilis or gonorrhea the clinician gives chart to a DIS supervisor for patient counseling/partner referral interviews.
- DIS supervisor gives the medical chart to a DIS interviewer. **Supervisor keeps** track of the number of interviews performed by each DIS.
- DIS conduct the patient counseling/partner referral interview. **STD interview** record and the 2936 forms are completed and **submitted to the supervisor within 24 hours.**

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### III. OVERVIEW OF STAFF ROLES FOR THE STUDY

The following DIS will participate in the study:

Yolanda Richardson, TDY Federal Assignee  
Neomia Spencer, Shelby County STD Program

Supervisors:

**Regina Hardy**  
**Paulette Jackson**  
**Kenneth Robinson**

The DIS supervisors are responsible for ensuring that candidates for the study are routed to Yolanda Richardson, the study interviewer responsible for administering the questionnaire. Neomia Spencer will be responsible for ensuring that questionnaires are completed accurately, recording pending lab results onto questionnaires and recording information in the study log book.

Tracy Luster, STD Control Program Manager, will serve as the Study Coordinator. She will be responsible for assuring that the data flows to JBA in a manner indicated by this protocol and for relaying information between DIS staff and JBA.

How these responsibilities will be carried out is fully described in the following sections of this procedural manual.

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#### A. Selecting Cases

• **Criteria:**

Candidates will include all patients who meet the following two conditions as indicated on their registration form and clinical record (both conditions must be met):

- clinical diagnosis of primary or secondary syphilis; and
- voluntarily presented at the clinic for medical evaluation;

Includes patients who present voluntarily for an initial syphilis test at the clinic or at a private physicians

office but who have to be referred in by DIS for evaluation.

\* Patients excluded: (1) contacts to syphilis patients who are referred by DIS; (2) patients tested and treated elsewhere but seen at the clinic for STD interviews only.

- Method:

Using the selection criteria, Supervisors will determine which syphilis patients are candidates for participation. For patients selected, supervisors will give the study interviewer the medical record.

- When:

Each day, cases will be selected in the morning and afternoon to prevent selection bias.

## B. Selecting Controls

- Criteria:

Candidates for the controls will include those patients who meet the following two conditions as indicated on their registration form and clinical record (both conditions must be met):

- clinical diagnosis of STOs other than syphilis, non-STDs, or no disease; and
- voluntarily presented at the clinic for medical evaluation.

\* Patients excluded: (1) patients diagnosed with syphilis within the last 12 months; (2) patients seen only for HIV testing.

- Method:

Patients who possess a medical record number with a 0 or a 5 as the last digit and who meet the requirements under "Criteria" above will be selected as candidates for the controls. After the exam, clinicians will notify the DIS of these candidates. DIS will ask these patients to participate in the study.

- When:

Each day, half of the controls will be selected in the morning and afternoon to prevent selection bias.

these refusals by completing the information in the box on the back of the consent form.

#### AND CONTROLS

The designated clinic DIS will maintain a log book to record: 1) supervisor on duty; 2) patient's (a) name; (b) medical record number; (c) lot number if the patient is a case; (d) study number; (e) date of birth; (f) date of visit; 3) lab tests ordered; 4) date lab results are received; 5) comments; and 6) date the questionnaire was sent to JBA.

- Each day after the interviews are completed, the study interviewer will correctly record the case or control in the study logbook.
- Informed consent forms used to track refusals will be kept in a folder called "Consent Refused."
- **Questionnaires that have pending lab results will be placed in a folder called "Open Questionnaires," see further instructions in section VII below. Completed questionnaires that have all test results recorded on the lab results section will be placed in a folder called "Closed Questionnaires."**
- At the end of each day, the interviewer will **put all consent forms and completed questionnaires** in a designated "locked" file in the Study Coordinator's office.

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- For questionnaires in the "Open Questionnaire" folder, the **designated clinic DIS is responsible** for collecting the final lab results as described below.
- Every day, the designated clinic DIS will 1) list study numbers for questionnaires in the "Open Questionnaire" folder; 2) refer to the log book to identify the patient's name (or **medical record number**) **corresponding** to each study number; 3) retrieve lab results for **these patients from the medical record**; and 4) record the results on the questionnaire.
- Clinic DIS will record the date the lab form is completed in the logbook and place the questionnaire in the "Closed Questionnaire" folder.

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vii. COLLECTING THE FINAL LAB **RESJ~jj**

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- As stated, interviewers will enter the name and study number of patients who have pending lab results into the computer program designed for this study.
- Referring to the computer program once a week, supervisor will (1) generate the listing of study participants that have pending lab results; (2) give the list to DIS who will retrieve the medical record and enter the results into the computer.
- Supervisors will (1) retrieve final lab results from the computer; (2) record the lab results on the questionnaires; (3) in the logbook, record the date the lab form is completed; and (4) place the questionnaire in the "Closed Questionnaire" folder.
- Every week, the Study Coordinator will check the logbook to ensure that all questionnaires have completed lab results forms within 14 days after the date of the patient's interview. If more than 14 days elapses, the Study Coordinator will notify the Supervisor responsible for that questionnaire and request that the lab results be obtained and recorded.

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~3ZT~ITTING\_DATA TO JBA]

- Once a week, the Study Coordinator will mail 1) the completed questionnaires from the "Closed Questionnaire" folder, and 2) the unsigned informed consent forms from the "Consent Refused" folder to JBA by certified mail in the envelopes provided.
- JBA will provide the clinic with money for postage. Postage receipts must be given to JBA.
- In the log book, the Study Coordinator will record the date the completed questionnaires are sent to JBA.
- The Study Coordinator is responsible for regularly checking the log book to ensure that all questionnaires are returned JBA within 20 days after the date of the patient's visit. If more than 20 days elapses, the Coordinator will notify the Supervisor responsible for that questionnaire.

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## IX. ORIENTATING STAFF

JBA is responsible for **orienting** clinic and DIS staff who are **involved in the execution** of the data collection plan. The purpose **of the orientation is to describe the objectives of the study**; educate staff about their roles and responsibilities; and review all phases of the data collection process. These activities will be carried out by explaining all sections of this Procedural Manual. JBA staff will also **discuss certain data collection issues** (described below) and answer questions.

Staff orientation is scheduled for April 10, 1990.

Laura Aiuppa of JBA, and Mark Wilson, STD Program Deputy Director, will guide the orientation of DIS staff, receptionists, clinicians, and medical records clerk.

DIS should note these additional data collection issues:

### 1. Definition of sex

**One Disease Intervention Specialist** commented that when some male patients are asked about their sexual encounters, they do not always consider oral sex from another man as "having sex". Probing this issue with case and control participants will help elicit more accurate information about all types of sexual encounters.

### 2. Interviewer's Impressions

When interviewers record their impressions of the validity of the patient's answers (questions 59 and 60), they should consider:

a. rating the validity of a patient's drug use behavior based on observational evidence of drug use (track marks; red, glazed eyes; slurred speech, etc.)

b. rating the validity of a patient's sex behavior based on their drug use — heavy drug users are more likely to exchange sex for drugs.

## B3I~IENTATING STAFF

JBA is responsible for orienting clinic and DIS staff who are involved in the execution of the data collection plan. The purpose of the orientation is to describe the objectives of the study; educate staff about their roles and responsibilities; and review all phases of the data collection process. These activities will be carried out by explaining all sections of this Procedural Manual. JBA staff will also discuss certain data collection issues (described below) and answer questions.

Staff orientation is scheduled for July 2. Data collection will begin July 3.

Laura Aiuppa of JBA, and Tracy Luster, STD Program Manager will guide the orientation of clinic staff.

### DATA COLLECTION ISSUES:

DIS should note the following when interviewing:

#### 1. Definition of sex

One Disease Intervention Specialist commented that when some male patients are asked about their sexual encounters, they do not always consider oral sex from another man as "having sex". Probing this issue with case and control participants will help elicit more **accurate information about** all types of sexual encounters.

#### 2. Interviewer's Impressions

When interviewers record their impressions of the validity of the patient's answers (questions 54 and 55), they should consider:

- a. rating the validity of a patient's drug use behavior based on observational evidence of drug use (track marks; red, glazed eyes; slurred speech, etc.)
- b. rating the validity of a patient's sex behavior based on their drug use — heavy drug users are more likely to exchange sex for drugs.

## STUDY OBJECTIVES

Anecdotal reports from a number of areas in the United States have suggested a link between drugs or drug-related behaviors and the acquisition of sexually transmitted diseases, including syphilis, chancroid and PPNG. Investigators at the Centers for Disease Control (CDC) in Atlanta designed this case-control study of syphilis patients to achieve the following objectives:

- 1) assess the roles of drug use and related behaviors (particularly drug-related prostitution) as risk factors for the acquisition of syphilis;
- 2) assess the importance of this association as a cause of the increases in syphilis occurring in the United States;
- 3) determine the effect of drug use on the outcome of STD partner referral activities; and
- 4) further investigate the possibility of IV needle-related transmission of syphilis.

K.- James Bell Associates, Inc. (JBA) is a private consulting firm in Arlington, Virginia that has been contracted by the Centers for Disease Control to develop, implement and monitor the data collection procedures for the study. As prescribed by the study protocol, JBA will conduct data collection activities at 7 sites, with most sites interviewing approximately 120 cases and 240 controls. The length of the study period will vary with conditions at each site (e.g., the volume of patients and staff availability), but generally it is expected that data collection will take approximately six months at each site. Long Beach has agreed to participate for a six month period collecting as many cases and controls as possible during this period.

This document describes the information necessary to successfully execute the CDC case-control study of drug use and syphilis in Long Beach, California. Data collection will take place at the City of Long Beach, Department of Health and Human Services located at 2655 Pine Avenue. The clinic operates 8:00 a.m. to 4:00 p.m. Monday, Thursday and Friday; 11:00 a.m. to 7:00 p.m. Tuesday; and 9:00 a.m. to 4:00 p.m. Wednesday.

## STUDY OBJECTIVES

Anecdotal reports from a number of areas in the United States have suggested a link between drugs or drug-related behaviors and the acquisition of sexually transmitted diseases, including syphilis, chancroid and PPNG. Investigators at the Centers for Disease Control (CDC) in Atlanta designed this case-control study of syphilis patients to achieve the following objectives:

- 1) assess the roles of drug use and related behaviors (particularly drug-related prostitution) as risk factors for the acquisition of syphilis;
- 2) assess the importance of this association as a cause of the increases in syphilis occurring in the United States;
- 3) determine the effect of drug use on the outcome of STD partner referral activities; and
- 4) further investigate the possibility of IV needle-related transmission of syphilis.

James Bell Associates, Inc. (JBA) is a private consulting firm in Arlington, Virginia that has been contracted by the Centers for Disease Control to develop, implement and monitor the data collection procedures for the study. As prescribed by the study protocol, JBA will conduct data collection activities at 7 sites. Each site will interview approximately 120 cases and 240 controls. The length of the study period will vary with conditions at each site (e.g., the volume of patients and staff availability), but generally it is expected that data collection will take approximately six months at each site.

This document describes the information necessary to successfully execute the CDC case-control study of drug use and syphilis in New Orleans, Louisiana. Data collection will take place at the Delgado City Clinic located at 320 Claiborne Ave. The clinic operates 7:30 a.m. to 4:00 p.m. Monday through Friday.

## I. OPERATIONAL ORGANIZATION

The clinical and disease control operations of the Delgado City Clinic (i.e., the clinic) are organized under the authority of the City of New Orleans, Department of Health. Gail Thorton-Collins is the Clinic Administrator. The study will be conducted under the supervision of:

Van D. Jenkins, Senior Public Health Advisor of the State of Louisiana for HIV/AIDS Services, and

Frank R. Meyers, Senior Public Health Advisor for STD control and HIV prevention at the Delgado Clinic.

Each day, two teams of DIS rotate their responsibilities to conduct counseling/partner referral interviews at the clinic and trace syphilis contacts in the community. Five DIS conduct interviews at the clinic each day.

## II. PATIENT FLOW

- All patients who present at the clinic and complete a clinic registration form and receive a number to identify them during the visit.
- Clerk calls the patients by number to get information/reason for the visit. This information is recorded on clinic registration form.
- Some patients come with epidemiological referral cards (yellow for gonorrhea and white for all other STDs) given by DIS.
- For every patient who registers, clerk searches the ~Expected-1b6x for the yellow copy of the 2936 form which indicates the patient was referred by DIS. If the 2936 form is present, clerk transfers the information to the medical record along with the appropriate lab slips.
- If patient is new to the clinic, a medical record is made. For patients who have visited the clinic before the clerk searches his/her STO case record.
- Clerk calls the patients by number again. He obtains information from the patient and records it on a new STO case record sheet.
- Male patients go directly to the laboratory with their medical chart and wait until lab technician calls them for a smear test. The phlebotomist then calls the patients to draw blood sample.
- Female patients place their medical record in the box marked "Nurse" and wait for the phlebotomist to call them. They are then called back to see a clinician.

- Clinician examines patient. Blood sample and GC smear sent to lab for testing. Patients who are contacts or have signs or symptoms of syphilis requiring stat lab results wait in designated waiting area.
- For all patients whether or not (diagnosed with any sexually transmitted disease, the nurse gives chart to a 015 supervisor for patient's pretest counseling. Partner referral interviews are conducted for HIV and syphilis patients only.
- DIS supervisor gives the medical chart to a DIS interviewer. Supervisor keeps track of the number of interviews performed by each DIS.
- DIS conduct the patient counseling/partner referral interview. STD interview record and the 2936 forms are completed and submitted to the supervisor within 48 hours.
- 015 give referral cards to patients and in turn patients give the cards to their contacts for evaluation and treatment at the clinic.
- Patients must come to the clinic to receive lab results. Patients with positive results are given new appointments for treatment and counseling as required.
- Patients are seen on a first come, first serve basis.

### **III. OVERVIEW OF STAFF ROLES FOR THE STUDY**

The following DIS will participate in the study:

Joseph James, Communicable Disease Prevention Supervisor  
 Edmond Morris, Front Une Supervisor  
 Victoria Rayle, Front Une Supervisor  
 Abid Mehmood, M.D., M.P.H. (Study Coordinator)

The supervisors and DIS are responsible for ensuring that candidates for the study are routed to Abid Mehmood, the study interviewer responsible for administering the questionnaire and for ensuring that questionnaires are completed accurately, recording pending lab results onto questionnaires and recording information in the study log book.

Van Jenkins and Frank Meyers will supervise the study to ensure that the data flows to JBA in a manner indicated by this protocol and for relaying information between 015 staff and JBA.

How these responsibilities will be carried out is fully described in the following sections of this procedural manual.

## IV. SELECTION OF CASES AND CONTROLS

### A. Selecting Cases

#### Criteria:

Candidates will include all patients who meet the following two conditions as indicated on their registration form and clinical record (both conditions must be met):

1. clinical diagnosis of primary or secondary syphilis; and
2. voluntarily presented at the clinic for medical evaluation;

Includes patients who present voluntarily for an initial syphilis test at the clinic or at a private physician's office but who have to be referred in by 015 for evaluation.

\* **Patients excluded:** (1) contacts to syphilis patients who are referred by 015; (2) patients tested and treated elsewhere but seen at the clinic for STO interviews only.

#### Method:

Using the selection criteria, Supervisors will determine which syphilis patients are candidates for participation. For patients selected, supervisors will give the DIS the medical record. After the 015 conducts the pre-test HIV counseling/partner referral interview, he will notify the study coordinator of these candidates. The coordinator will ask the patients to participate in the study.

#### When:

Each day, cases will be selected in the morning and afternoon to prevent selection bias.

### B. Selecting Controls

#### Criteria:

Candidates for the controls will include those patients who meet the following two conditions as indicated on their registration form and clinical record (both conditions must be met):

1. clinical diagnosis of STOs other than syphilis, non-STOs, or no disease; and
2. voluntarily presented at the clinic for medical evaluation.

\* **Patients excluded:** (1) patients diagnosed with syphilis within the last 12 months; (2) patients seen only for HIV testing.

**Method:**

Patients who possess a medical record number with a 0 or a 5 as the last digit and who meet the requirements under “Criteria” above will be selected as candidates for the controls. After the 015 conduct the pre-test counseling, he will notify the study coordinator of these candidates. The coordinator will ask these patients to participate in the study.

**When:**

Each day, half of the controls will be selected in the morning and afternoon to prevent selection bias.

## V. ADMINISTERING THE QUESTIONNAIRE

The questionnaire consists of diagnosis and lab results sections followed by the study questions. A unique study number is pre-printed on the top right corner of every page of each questionnaire.

Prior to administering the questionnaire to cases and controls, the study coordinator must read informed consent form to the patient.

Blank informed consent forms and questionnaires will be located in the interview room assigned for use specifically for study participants.

**When to administer:**

Cases – Study coordinator will administer questionnaire after the 015 has conducted the usual partner referral/counseling interview.

Controls – Study coordinator will administer the questionnaire after the DIS has conducted the usual partner referral/counseling interview.

**Lab Results:**

- Lab results available at the time of the interview will be recorded on the lab results form (p.2 of the questionnaire).
- If some or all of the lab results are pending at the time of the interview, study coordinator will indicate the tests with pending results. The coordinator will record the results at a later time (refer to Section VII.)

**Tagging Participants:**

Cases and Controls – On the lab-section of the questionnaire will be a yellow peel-off sticker with the study number written on it. The interviewer will pull off this sticker and stick it on the outside folder of the medical record of cases and controls. This sticker indicates that the patient is a study participant and is not to be interviewed again as a case or control.

### Tracking Refusals:

The interviewer will keep track of case and control candidates who (1) refuse prior to hearing the informed consent information, or (2) refuse to sign the consent form after having it read to them. The interviewer will keep track of these refusals by completing the information in the box on the back of the consent form.

## VI. LOGGING CASES AND CONTROLS

The study coordinator will maintain a log book to record: 1) supervisor on duty; 2) patient's (a) name; (b) medical record number; (c) lot number if the patient is a case; (d) study number; (e) date of birth; ~ date of visit; **3**) lab tests ordered; 4) date lab results are received; 5) comments; and 6) date the questionnaire was sent to JBA.

- Each day after the interviews are completed, the study interviewer will correctly record the case or control in the study logbook.
- Informed consent forms used <sup>110</sup> track refusals will be kept in a folder called "Consent Refused."
- Questionnaires that have pending lab results will be placed in a folder called "Open Questionnaires," see further instructions in section VII below. Completed questionnaires that have all test results recorded on the lab results section will be placed in a folder called "Closed Questionnaires."
- At the end of each day, the coordinator will put all consent forms and completed questionnaires in a designated "locked" file in his office.

## VII. COLLECTING THE FINAL LAB RESULTS

For questionnaires in the "Open Questionnaire" folder, the study coordinator is responsible for collecting the final lab results as described below.

- Every day, the coordinator will: 1) list study numbers for questionnaires in the "Open Questionnaire" folder; 2) refer to the log book to identify the patient's name (or medical record number) corresponding to each study number; 3) retrieve lab results for these patients from the medical record; and 4) record the results on the questionnaire.
- The coordinator will record the date the lab form is completed in the logbook and place the questionnaire in the "Closed Questionnaire" folder.

- Every week, the coordinator will check the logbook to ensure that all questionnaires have completed lab results forms within 10 days after the date of the patient's interview. If more than 10 days elapses, the coordinator will obtain and record the results.

## VIII. TRANSMITTING DATA TO JBA

- Once every two to three weeks, the coordinator will mail 1) the completed questionnaires from the "Closed Questionnaire" folder, and 2) the informed consent forms from the "Consent Refused" folder to JBA by certified mail in the envelopes provided.
- JBA will provide the clinic with money for postage. Postage receipts must be given to JBA.
- In the log book, the coordinator will record the date the completed questionnaires are sent to JBA.
- The Study Coordinator is responsible for regularly checking the log book to ensure that all questionnaires are returned JBA within 15 days after the date of the patient's visit.

## IX. DATA COLLECTION ISSUES

When administering the questionnaire, interviewers should note:

### 1. Definition of sex

One Disease Intervention Specialist commented that when some male patients are asked about their sexual encounters, they do not always consider oral sex from another man as "having sex". Probing this issue with case and control participants will help elicit more accurate information about all types of sexual encounters.

### 2. Interviewer's Impressions

When interviewers record their impressions of the validity of the patient's answers (questions 54 and 55), they should consider:

- a. rating the validity of a patient's drug use behavior based on observational evidence of drug use (track marks; red, glazed eyes; slurred speech, etc.)
- b. rating the validity of a patient's sex behavior based on their drug use -- heavy drug users are more likely to exchange sex for drugs.

## X. ORIENTATING STAFF

Laura Aluppa of JBA is responsible for orienting clinic and DIS staff who are involved in the execution of the data collection plan. The purpose of the orientation is to describe the objectives of the study; educate staff about their roles and responsibilities; and review all phases of the data collection process. These activities will be carried out by explaining all sections of this Procedural Manual. JBA staff will also discuss certain data collection issues (described below) and answer questions.

Staff orientation is scheduled for January 28, 1991. Data collection will begin the same day.

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STUDY OBJECTIVES

Anecdotal reports from a number of areas in the United States have suggested a link between drugs or drug-related behaviors and the acquisition of sexually transmitted diseases, including syphilis, chancroid and PPNG. Investigators at the Centers for Disease Control (CDC) in Atlanta designed this case-control study of syphilis patients to 1) assess the roles of drug use and related behaviors (particularly drug-related prostitution) as risk factors for the acquisition of syphilis; 2) assess the importance of this association as a cause of the increases in syphilis occurring in the United States; 3) determine the effect of drug use on the outcome of STD partner referral activities; and 4) further investigate the possibility of IV needle-related transmission of syphilis.

James Bell Associates, Inc. (JBA) is a private consulting firm in Arlington, Virginia that has been contracted by CDC and the U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation to develop, implement and monitor the data collection procedures for the study. As prescribed by the study protocol, JBA will conduct data collection activities at 8 sites. Each site will interview approximately 120 cases and 240 controls. The length of the study period will vary with conditions at each site (e.g., the volume of patients and staff availability), but generally it is expected that data collection will take approximately five months at each site.

This document describes the information necessary to successfully execute the CDC case-control study of drug use and syphilis in Philadelphia. Data collection will take place at Health Center Number One, Philadelphia's main STD clinic located at 500 Broad Street. The clinic operates 8:00 a.m. to 5:00 p.m. on Tuesday, Thursday and Friday, and 8:00 a.m. to 9:00 p.m. on Monday and Wednesday.

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iii. OVERVIEW OF STAFF ROLES FOR THE STUDY

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Two DIS will share the responsibility of executing study activities at Health Center Number One. One will be involved for the first half of the study's duration, **and the other** during the second half. These DIS will select study cases and controls, administer the questionnaire, log information and ensure data flows to JBA in a manner indicated by this protocol. DIS supervisors will provide **oversight of all study activities.**

How these responsibilities will be carried out is fully described in the following sections of this procedural manual.

~

#### A. Selecting Cases

##### Criteria:

Candidates will include all patients who meet the following two conditions as indicated on their registration form and clinical record (both conditions must be met):

clinical diagnosis of primary or secondary syphilis; and  
voluntarily presented at the clinic for medical evaluation;

Includes patients who present voluntarily for an initial syphilis test at the clinic or at a private physicians office but who have to be referred in by DIS for evaluation.

\* Patients excluded: (1) contacts to syphilis patients who are referred by DIS; (2) patients tested and treated elsewhere but seen at the clinic for STD interviews only.

##### Method:

The study interviewer will select candidates for the cases after the patient is diagnosed with syphilis. Patients meeting study criteria for cases will be asked to participate.

##### When:

Each day, cases will be selected in the morning and afternoon to prevent selection bias.

## B. Selecting Controls

### Criteria:

Candidates for the controls will include those patients who meet the following two conditions as indicated on their registration form and clinical record (both conditions must be met):

clinical diagnosis of STDs other than syphilis, non-STDs, or no disease; and

voluntarily presented at the clinic for medical evaluation.

\* Patients excluded: (1) patients diagnosed with syphilis within the last 12 months; (2) patients seen only for HIV testing.

### Method:

The DIS study interviewer will go to the clinic to select the next patient who exits an examination room and possesses a registration ticket having an even number as the last digit. Patients meeting study criteria for controls will be asked to participate.

### When:

Each day, half of the controls will be selected in the morning and afternoon to prevent selection bias.

The questionnaire consists of diagnosis and lab results sections followed by the study questions. A unique study number is pre-printed on the top right corner of every page of each questionnaire.

Prior to administering the questionnaire to cases and controls, the interviewer must read informed consent form to the patient.

### When to administer:

Cases — the interviewer will administer the questionnaire prior to the usual partner referral/counseling interview but after HIV pretest counseling.

Controls — the interviewer will administer the questionnaire after patients have seen a clinician and after HIV pretest

counseling.

Lab Results:

-- Stat lab results available at the time of the interview will be recorded on the top half of the lab results section of the questionnaire (p.2).

-- For lab results which are pending at the time of the interview, the interviewer will (a) indicate the pending lab results on the bottom half of the lab results section; and (b) at the perforation, tear the bottom half of the lab form from the rest of the questionnaire and clip it to the patient's medical record for posting of results at a later time (refer to Section VII.)

Tagging Participants:

Cases and Controls — On the lab section of the questionnaire will be a red peel-off sticker with the study number written on it. The interviewer will pull off this sticker and place it onto a designated spot of the clinical record of cases and controls. This sticker indicates that the patient is a study participant and is not to be interviewed again as a case or control.

Tracking Refusals:

The interviewer will keep track of case and control candidates who (1) refuse prior to hearing the informed consent information, or (2) refuse to sign the consent form after having it read to them. The interviewer will keep track of these refusals by completing the information in the box on the back of the consent form.

ES

The interviewer will maintain a log book to record: 1) supervisor on duty; 2) the interviewer; 3) patient's (a) name; (b) registration number; (c) lot number if the patient is a case; (d) study number; (e) date of birth; (e) date of visit; 4) lab tests ordered; 5) date lab results received; 5) comments or explanations; and, 6) date the questionnaire was sent to JBA.

Each day after the interviews are completed, the interviewer will correctly record the case or control in the study logbook.

Informed consent forms used to track refusals will be kept in a folder called "Consent Refused."

In the log book, the interviewer will record the date the completed questionnaires are sent to JBA.

A DIS supervisor is responsible for regularly checking the log book to ensure that all questionnaires are returned JBA within 15 days after the date of the patient's visit. If more than 15 days elapses, the supervisor will notify the interviewer.

“CASE CONTROL STUDY OF SYPHILIS AND DRUG USE”

Conducted by  
The Centers for Disease Control

Procedural Manual for Data Collection  
City of Long Beach  
Department of Health and Human Services  
Long Beach, California

1991

Prepared by:

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James Bell Associates, Inc.  
2200 Clarendon Blvd., Suite 1005  
Arlington, Virginia 22201  
(703) 528-3230

## STUDY OBJECTIVES

Anecdotal reports from a number of areas in the United States have suggested a link between drugs or drug-related behaviors and the acquisition of sexually transmitted diseases, including syphilis, chancroid and PPNG. Investigators at the Centers for Disease Control (CDC) in Atlanta designed this case-control study of syphilis patients to achieve the following objectives:

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- 2) assess the importance of this association as a cause of the increases in syphilis occurring in the United States;
- 3) determine the effect of drug use on the outcome of STD partner referral activities; and
- 4) further investigate the possibility of IV needle-related transmission of syphilis.

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This document describes the information necessary to successfully execute the CDC case-control study of drug use and syphilis in Long Beach, California. Data collection will take place at the City of Long Beach, Department of Health and Human Services located at 2655 Pine Avenue. The clinic operates 8:00 a.m. to 4:00 p.m. Monday, Thursday and Friday; 11:00 a.m. to 7:00 p.m. Tuesday; and 9:00 a.m. to 4:00 p.m. Wednesday.

ATTACHMENT G

Sample Page From Clinic Log

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C

CENTER FOR DISEASE CONTROL LOG BOOK - SYPHILIS AND DRUG USE STUDY

STUDY NUMBER	DATE OF INTERVIEW (MM/DD/YY)		PATIENT'S NAME (LAST, FIRST NAME, MI)	PATIENT'S LOT # (IF APPLICABLE)	DATE OF BIRTH (MM/DD/YY)		ANY LAB TESTS PENDING? (CIRCLE)		DATE ALL LAB TESTS RECEIVED		015 SUPERVISOR ON DUTY (LAST, FIRST NAME)	INTERVIEWER (LAST, FIRST NAME)	
	MM	DD			YY	MM	DD	YY	YES	NO			MM
1-	1	/	/	_____	_____	/	/	YES	NO	/	/	_____	_____
1-	2	/	/	_____	_____	/	/	YES	NO	/	/	_____	_____
1-	3	/	/	_____	_____	/	/	YES	NO	/	/	_____	_____
1-	4	/	/	_____	_____	/	/	YES	NO	/	/	_____	_____
1-	5	/	/	_____	_____	/	/	YES	NO	/	/	_____	_____
1-	6	/	/	_____	_____	/	/	YES	NO	/	/	_____	_____
1-	7	/	/	_____	_____	/	/	YES	NO	/	/	_____	_____
1-	8	/	/	_____	_____	/	/	YES	NO	/	/	_____	_____
1-	9	/	/	_____	_____	/	/	YES	NO	/	/	_____	_____
1-	10	/	/	_____	_____	/	/	YES	NO	/	/	_____	_____

## ATTACHMENT H

Partner Refeirral Data Collection Form

SITE I - FLORIDA

Disposition codes

- A = Epidemiologic treatment (preventively treated).
- B = Refused preventive treatment (tested not infected).
- C = Infected, brought to treatment.
- D = Infected, not treated.
- E = Previously treated this infection.
- F = Not infected.
- O = Insufficient information to begin investigation.
- H = Unabl, to locate.
- J = Located and refused examination.
- K = Moved from jurisdiction.
- L = Other.

Syphilis Stage

- 10 = Primary
- 20 = Secondary
- 30 = Early latent
- 40 = Late latent
- 8 = Unknown
- 9 = Other

<u>STUDY ID #</u>	<b>Total Number of Contacts, Suspects and Associates <u>ReDorted By Patient</u> <i>or none, enter 0</i></b>	<b>For each contact, suspect and associate, specif~</b>	
		<u>DisDosition</u>	<u>Svtihilis Sta2e</u>
	<b>Contacts:</b> _____	1. _____ 6. _____	1. _____ 6. _____
		2. _____ 7. _____	2. _____ 7. _____
		3. _____ 8. _____	3. _____ <b>8</b> _____
		4. _____ 9. _____	4. _____ 9. _____
		<b>5</b> _____ <b>10</b> _____	<b>5</b> _____ <b>10</b> _____
	<b>Suspects:</b> _____	1. _____ 6. _____	1. _____ 6. _____
		2. _____ 7. _____	2. _____ <b>7</b> _____
		3. _____ <b>8</b> _____	<b>3</b> _____ <b>8</b> _____
		4. _____ 9. _____	4. _____ 9. _____
		<b>5</b> _____ <b>10</b> _____	<b>5</b> _____ <b>10</b> _____
	<b>Associates:</b> _____	1. _____ 6. _____	1. _____ 6. _____
		2. _____ 7. _____	2. _____ 7. _____
		3. _____ 8. _____	3. _____ 8. _____
		4. _____ 9. _____	4. _____ 9. _____
		<b>5</b> _____ 10. _____	<b>5</b> _____ <b>10</b> _____

**WAS ORIGINAL PATIENT (STUDY PATIENT) REINTERVIEWED?**

- Yes** 1
- No 2
- Unsure 3

SITES 2- 7

Disposition Codes

- 0 = Not infected.
- 1 = Infected, brought to treatment.
- 2 = Infected, return to treatment this infection.
- 3 = Previously treated this infection.
- 5 = Infected, not treated.
- 6 = Unable to locate.
- 7 = Located and refused examination.
- 8 = Insufficient information to begin investigation.
- 9 = Moved from jurisdiction.
- X = Epidemiologic treatment (preventively treated).
- V = Other.

Syphilis Stage

- 10 = Primary
- 20 = Secondary
- 30 = Early latent
- 40 = Late latent
- 8 = Unknown
- 9 = Other

<u>STUDY ID #</u>	<b>Total Number of Contacts, Suspects and Associates ReDorted By Patient</b> <i>or none, enter 0</i>	<b>For each contact, suspect and associate, specif-.</b>			
		<u>DisDisposition</u>		<u>Sy~hilis Stafe</u>	
	<b>Contacts:</b>	1. _____	6.	1.	6.
		2. _____	7. _____	2.	7.
		3. _____	8.	3.	8.
		4. _____	9.	4.	9.
		<b>5.</b> _____	<b>10.</b> _____	<b>5.</b>	10.
	<b>Suspects:</b> _____	1. _____	6. _____	1.	6.
		2. _____	7. _____	2.	7.
		3. _____	8. _____	3.	8.
		4. _____	9. _____	4.	9.
		<b>5.</b> _____	<b>10.</b> _____	<b>5.</b>	10.
	<b>Associates:</b> _____	1. _____	6.	1.	6. _____
		2. _____	7.	2.	7. _____
		3. _____	8. _____	3.	8. _____
		4. _____	9. _____	4. _____	9. _____
		<b>5.</b> _____	10.	<b>5.</b>	10.

**WAS ORIGINAL PATIENT (STUDY PATIENT REINTERVIEWED?)**

- Yes 1
- No 2
- Unsure 3

## ATTACHMENT I

### Distribution of Study Cases Among Census Tracts

C

Memory allocated a total of 10153 Values, accumulated across all Variables.  
There also may be up to 1269 Value Labels for each Variable.

CENSUS

Value Label	Value	Frequency	Percent	Valid Percent	Valid Percent
	32	4	3.7	3.7	3.7
	14	3	2.8	2.8	6.5
	31	3	2.8	2.8	9.3
	82	3	2.8	2.8	12.1
	83	3	2.8	2.8	15.0
	85	3	2.8	2.8	17.8
	173	3	2.8	2.8	20.6
	264	3	2.8	2.8	23.4
	284	3	2.8	2.8	26.2
	15	2	1.9	1.9	28.0
	18	2	1.9	1.9	29.9
	27	2	1.9	1.9	31.8
	41	2	1.9	1.9	33.6
	102	2	1.9	1.9	35.5
	112	2	1.9	1.9	37.4
	147	2	1.9	1.9	39.3
	149	2	1.9	1.9	41.1
	152	2	1.9	1.9	43.0
	153	2	1.9	1.9	44.9
	167	2	1.9	1.9	46.7
	169	2	1.9	1.9	48.6
	267	2	1.9	1.9	50.5
	277	2	1.9	1.9	52.3
	1	1	.9	.9	53.3
	5	1	.9	.9	54.2
	13	1	.9	.9	55.1
	22	1	.9	.9	56.1
	23	1	.9	.9	57.0
	37	1	.9	.9	57.9
	50	1	.9	.9	58.9
	63	1	.9	.9	59.8
	65	1	.9	.9	60.7
	73	1	.9	.9	61.7

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## ATTACHMENT J

### Field Rules

## “Case Control Study of Syphilis and Drug Use”

### Data Collection ]Procedures for Interviewers

#### Block Areas:

1. Go to the block areas that have preselected for this study. No other blocks will be included.
2. Before going out into the field, meet with the supervisor and receive your block assignments.

#### Households:

3. Use rules below to select households in each block area. Randomly pick a new rule everytime you go out into the field. Use the rule for the entire shift.

#### Rules

- a. Go to NW corner, move clockwise and select the first (corner) house on the right.
  - b. Go to NW corner, move clockwise and select the fourth house on the right.
  - c. Go to NE corner, move clockwise and select the first (corner) house on the right.
  - d. Go to NE corner, move clockwise and select the fourth house on the right.
  - e. Go to SE corner, move clockwise and select the first (corner) house on the right.
  - f. Go to SE corner, move clockwise and select the fourth house on the right.
  - g. Go to SW corner, move clockwise and select the first (corner) house on the right.
  - h. Go to SW corner, move clockwise and select the fourth house on the right.
4. If the resident(s) is not at home, return to the house again on a different day. After making a total of two unsuccessful attempts to contact the resident, go to the next house.

5. If selected household is vacant or if no one was eligible, go to the next household.
6. Multiple-Unit Housing: To select a household in buildings with more than one household, use a the table of random numbers.

Individuals:

7. If more than one eligible individual lives in a selected household, select study participant using the table of random numbers.
8. Number individuals from youngest to oldest.

ATTACHMENT K

Community Control Enrollment

COMMUNITY CONTROL ENROLLMENT BASED ON CASE MATCH

The following table compares the demographics of the Philadelphia clinic cases with the community controls interviewed. As indicated by the study protocol, at least two controls were to be selected for each case, matched on census tract, sex, age, and race. In a few census tracts, the intended match was not met on all demographic variables, particularly in the age ranges over 45 since controls were collected using the age range of 45-65 for the match, but the match should have been made using five year intervals. In other tracts, the match was met, but additional controls were interviewed that do not match the case; we have defined these additional controls as "extra." These exceptions to the matching are indicated in the table, using the codes in the Community Control Key below.

Community Control Key

- 1 = Sex does not match case.
- 1x = Sex does not match case; extra.
- 2 = Age not in case age-range.
- 2x = Age not in case age-range; extra.
- 3 = Race does not match case.
- 3x = Race does not match case; extra.

CLINIC CASES					COMMUNITY CONTROLS				
CENSUS TRACT	SEX	RACE	AGE	STUDY NUMBER	SEX	AGE	RACE	STUDY NUMBER	
1	M	BLK	30-34	6150	M	31	BLK	1230	
					M	33	BLK	1210	
5	F	BLK	25-29	6365	M <sup>1</sup>	26	BLK	1215	
						29	BLK	1102	
13	M	BLK	35-39	6200	M	35	BLK	1173	
					M	35	BLK	1174	
14	M	BLK	20-24	6022	M	21	BLK	1017	
					M	21	BLK	1112	
					M	21	BLK	1062	
	M	BLK	25-29	6009	M	26	BLK	1169	
					M	25	BLK	1088	
	M	BLK	45-49	6007	M	642	BLK	1016	
					M	572	BLK	1124	
					M	~	BLK	1021	
15	F	BLK	15-19	6197	F	19	BLK	1080	
					F	15	BLK	1131	
					F	17	BLK	1130	

CLINIC CASES					COMMUNITY CONTROLS			
CENSUS TRACT	SEX	RACE	AGE	STUDY NUMBER	SEX	AGE	RACE	STUDY NUMBER
15 (cont.)	M	BLK	20-24	6156	M	21	BLK	1081
					M	22	BLK	1132
18	M	BLK	25-29	6186	M	27	BLK	1216
					M	27	BLK	1008
	M	BLK	40-44	6130	M	44	BLK	1012
					M	40	BLK	1108
22	M	BLK	40-44	6173	M	43	BLK	1172
					M	40	BLK	1175
23	M	BLK	55-59	6109	M	452	BLK	1144
					M	432	BLK	1147
27	M	BLK	30-34	6118	M	30	BLK	1254
	M	BLK	30-34	6300	M	30	BLK	1214
					M	31	BLK	1120
					M	33	BLK	1212
					M	32	BLK	1110
					M	34	BLK	1109
					M	31	BLK	1111
					M	30	BLK	1213
31	M	BLK	30-34	6355	M	33	BLK	1039
					M	34	BLK	1037
					M	30	BLK	1030
	F	BLK	15-19	6120	F	16	BLK	1038
					F	17	BLK	1044
					F	19	BLK	1013
	F	BLK	25-29	6065	F	25	BLK	1043
					F	25	BLK	1045
					F	28	BLK	1014

CLINIC CASES					COMMUNITY CONTROLS1			
CENSUS TRACT	SEX	RACE	AGE	STUDY NUMBER	SEX	AGE	RACE	STUDY NUMBER
32	M	BLK	15-19	6272	M	15	BLK	1114
	F	BLK	15-19	6100	M	15	BLK	1090
					F	18	BLK	1086
	F	BLK	15-19	6372	F	17	BLK	1041
					F	17	BLK	1002
					F	18	BLK	1048
	M	BLK	20-24	6326	F	19	BLK	1053
					M	22	BLK	1020
M					23	BLK	1089	
M	BLK	20-24	6326	M	22	BLK	1047	
				M	22	BLK	1047	
37	M	BLK	40-44	6056	M	40	BLK	1091
					M	43	BLK	1092
41	M	BLK	30-34	6270	M	32	BLK	1057
					M	32	BLK	1073
	M	BLK	60-64	6070	M	472	BLK	1200
					M	582	BLK	1201
50	M	BLK	25-29	6037	M	28	BLK	1271
					M	26	BLK	1272
63	M	BLK	40-44	6202	M	41	BLK	1186
					M	44	BLK	1258
					M	452	BLK	1248
65	M	BLK	30-34	6370	M	30	BLK	1059
					M	32	BLK	1060
73	F	BLK	20-24	6082	F	24	BLK	1138
					F	22	BLK	1166
					Mix	20	BLK	1160
79	M	BLK	25-29	6284	M	25	BLK	1190
					M	29	BLK	1191

CLINIC CASES					COMMUNITY CONTROLS			
CENSUS TRACT	SEX	RACE	AGE	STUDY NUMBER	SEX	AGE	RACE	STUDY NUMBER
81	F	BLK	15-19	6013	F	16	WHT <sup>3</sup>	1183
					F	17	BLK	1149
82	M	BLK	25-29	6027	M	29	BLK	1122
					M	25	BLK	1029
					M	31	BLK	1125
	M	BLK	30-34	6292	M	33	BLK	1113
					M	42	BLK	1079
					M	44	BLK	1085
	M	BLK	40-44	6261	M	212x	BLK	1035
					M	212x	BLK	1018
					M	242x	BLK	1078
					Fix	15	BLK	1076
Fix	16	BLK	1074					
83	M	BLK	25-29	6103	M	26	BLK	1260
					M	25	BLK	1019
					M	29	BLK	1075
	M	BLK	30-34	6090	M	30	BLK	1104
					M	30	BLK	1127
	M	BLK	30-34	6354	M	31	8LK	1024
					M	30	BLK	1023
84	F	BLK	25-29	6012	F	29	BLK	1171
					F	29	BLK	1077
85	M	BLK	20-24	6164	M	21	BLK	1116
					M	20	BLK	1009
					M	22	BLK	1051
					M	24	BLK	1251
	M	BLK	35-39	6245	M	38	BLK	1072
					M	35	BLK	1117
					M	38	BLK	1253
					M	38	BLK	1253

CLINIC CASES					COMMUNITY CONTROLS			
CENSUS TRACT	SEX	RACE	AGE	STUDY NUMBER	SEX	AGE	RACE	STUDY NUMBER
85 (cont.)	F	BLK	15-19	6035	F	16	BLK	1034
					F	19	BLK	1252
					F	15	BLK	1115
91	M	BLK	40-44	6369	M	44	BLK	1246
					M	40	BLK	1247
93	M	BLK	30-34	6030	M	30	BLK	1224
					M	30	BLK	1054
					M	34	BLK	1141
					M	30	BLK	1223
101	M	WHT	30-34	6148	M	30	WHT	1239
					M	33	WHT	1240
102	M	BLK	35-39	6050	M	39	BLK	1155
					M	36	BLK	1154
	M	BLK	40-44	6298	M	40	BLK	1156
					M	43	BLK	1123
					M	41	BLK	1152
104	F	BLK	20-24	6076	F	21	BLK	1267
					F	24	BLK	1177
					F	21	BLK	1146
					F	20	BLK	1266
105	M	BLK	15-19	6327	M	16	BLK	1181
					M	16	BLK	1137
106	M	BLK	35-39	6357	M	34	BLK	1184
					M	37	BLK	1180
107	M	BLK	30-34	6222	M	33	BLK	1139
					M	31	BLK	1159
					M	33	BLK	1263
					M	292x	BLK	1098

CLINIC CASES					COMMUNITY CONTROLS			
CENSUS TRACT	SEX	RACE	AGE	STUDY NUMBER	SEX	AGE	RACE	STUDY NUMBER
108	M	BLK	25-29	6144	M	27	BLK	1264
					M	27	BLK	1197
					M	28	BLK	1099
					M	28	BLK	1100
					M	26	BLK	1278
					M	25	BLK	1265
109	M	BLK	40-44	6019	M	42	BLK	1153
					M	40	BLK	1249
					M	41	BLK	1128
					M	332x	BLK	1262
111	M	BLK	40-44	6371	M	40	BLK	1194
					M	42	BLK	1193
					Fix	42	BLK	1270
					Fix	44	BLK	1277
112	M	BLK	20-24	6094	M	24	BLK	1199
					M	20	BLK	1133
	F	BLK	30-34	6185	F	34	BLK	1134
					F	32	BLK	1176
114	F	BLK	40-44	6089	F	40	BLK	1192
					F	43	BLK	1094
					Mix	40	BLK	1093
120	F	BLK	15-19	6362	F	17	BLK	1259
					F	19	BLK	1261
134	M	HSP	35-39	6172	M	38	HSP	1071
					M	37	HSP	1046
139	M	BLK	35-39	6125	M	38	BLK	1031
					M	35	BLK	1036
					M	36	BLK	1083

CLINIC CASES					COMMUNITY CONTROLS			
CENSUS TRACT	SEX	RACE	AGE	STUDY NUMBER	SEX	AGE	RACE	STUDY NUMBER
147	M	BLK	30-34	6323	M	33	BLK	1187
					M	34	BLK	1157
					M	34	BLK	1188
	F	BLK	30-34	6029	F	30	BLK	1158
					F	33	BLK	1226
					F	33	BLK	1161
149	M	BLK	40-44	6216	M	43	BLK	1275
					M	44	BLK	1274
	M	BLK	40-44	6243	M	44	BLK	1280
					M	41	BLK	1276
					M	41	BLK	1279
					M	43	BLK	1281
151	M	BLK	50-54	6066	M	652	BLK	1033
					M	472	BLK	1126
152	M	BLK	15-19	6246	M	15	BLK	1042
					M	15	BLK	1063
	M	BLK	40-44	6104	M	41	BLK	1170
					M	44	BLK	1064
					M	44	BLK	1027
153	M	BLK	25-29	6271	M	29	BLK	1167
					M	28	BLK	1151
	M	BLK	45-65	6011	M	55	BLK	1168
					M	63	BLK	1150
155	M	BLK	30-34	6108	M	34	BLK	1195
					M	30	BLK	1011
161	M	BLK	30-34	6254	M	33	BLK	1219
					M	31	BLK	1143
164	F	BLK	20-24	6026	F	23	BLK	1198
					F	24	BLK	1006

CLINIC CASES					COMMUNITY CONTROLS			
CENSUS TRACT	SEX	RACE	AGE	STUDY NUMBER	SEX	AGE	RACE	STUDY NUMBER
164 (cont.)					F	24	UNK <sup>3X</sup>	1136
					F	21	BLK	1142
167	F	BLK	20-24	6041	F	21	BLK	1058
					F	24	BLK	1055
	F	BLK	20-24	6345	F	22	BLK	1040
					F	22	BLK	1032
					F	20	BLK	1056
169	M	BLK	40-44	6163	M	40	BLK	1101
					M	40	BLK	1119
	F	BLK	15-19	6132	F	15	BLK	1121
					F	17	BLK	1118
					M	<b>242x</b>	<b>BLK</b>	<b>1204</b>
172	M	BLK	35-39	6329	M	35	BLK	1105
					M	36	BLK	1106
173	M	BLK	20-24	6075	M	20	BLK	1015
					M	22	BLK	1068
	M	BLK	20-24	6283	M	21	BLK	1067
					M	21	BLK	1065
	M	BLK	40-44	6189	M	44	BLK	1066
					M	40	BLK	1052
179	F	BLK	50-54	6091	M <sup>1</sup>	452	BLK	1255
196	M	BLK	25-29	6318	M	29	BLK	1286
					M	26	BLK	1285
198	M	BLK	20-24	6361	M	24	BLK	1135
					M	24	BLK	1237
					M	23	BLK	1232
					M	21	BLK	1203

CLINIC CASES					COMMUNITY CONTROLS			
CENSUS TRACT	SEX	RACE	AGE	STUDY NUMBER	SEX	AGE	RACE	STUDY NUMBER
200	F	BLK	20-24	6139	F	24	BLK	1244
					F	23	BLK	1269
					F	23	BLK	1268
					F	20	BLK	1234
					F	21	BLK	1145
201	M	BLK	30-34	6315	M	30	BLK	1202
					M	34	BLK	1222
					M	30	BLK	1220
					M	34	BLK	1205
202	M	BLK	25-29	6374	M	28	BLK	1238
					M	28	BLK	1140
					M	28	BLK	1221
244	F	BLK	15-19	6047	F	15	BLK	1007
					F	18	BLK	1189
245	M	BLK	40-44	6010	M	40	BLK	1256
					M	43	BLK	1250
246	M	BLK	30-34	6206	M	34	BLK	1103
					M	34	BLK	1107
251	M	BLK	35-39	6337	M	35	BLK	1231
					M	35	BLK	1233
254	M	BLK	35-39	6360	M	35	BLK	1284
					M	36	BLK	1227
					M	39	BLK	1095
					M	37	BLK	1283
261	F	BLK	20-24	6356	F	24	BLK	1185
					F	21	BLK	1148
263	M	BLK	55-59	6068	M	602	BLK	1096
					M	652	BLK	1235

CLINIC CASES					COMMUNITY CONTROLSI			
CENSUS TRACT	SEX	RACE	AGE	STUDY NUMBER	SEX	AGE	RACE	STUDY NUMBER
264	M	ELK	20-24	6126	M	20	BLK	1082
					M	22	BLK	1070
	M	BLK	30-34	6363	M	32	ELK	1207
					M	33	BLK	1182
	M	ELK	45-49	6014	M	502	BLK	1069
				M	47	BLK	1061	
266	F	BLK	15-19	6168	F	15	BLK	1129
					F	19	BLK	1196
267	M	BLK	20-24	6297	M	21	BLK	1084
					M	21	BLK	1163
	M	BLK	40-44	6005	M	43	BLK	1164
					M	41	BLK	1165
277	M	BLK	20-24	6358	M	24	BLK	1208
					M	24	BLK	1241
	F	BLK	25-29	6191	F	25	ELK	1245
					F	28	BLK	1282
					F	28	BLK	1243
278	M	BLK	35-39	6373	M	36	ELK	1217
					M	38	BLK	1218
280	M	BLK	40-44	6141	M	44	ELK	1228
					M	43	ELK	1229
281	M	ELK	50-54	6364	M	452	BLK	1097
					M	452	BLK	1209
282	F	BLK	25-29	6293	F	29	BLK	1206
					F	29	BLK	1178
283	M	BLK	25-29	6375	M	26	BLK	1179
					M	25	ELK	1162

CLINIC CASES					if	COMMUNITY CONTROLSI			
CENSUS TRACT	SEX	RACE	AGE	STUDY NUMBER		SEX	AGE	RACE	STUDY NUMBER
284	M	BLK	35-39	6314		M	35	BLK	1049
						M	36	BLK	1025
						M	38	BLK	1010
	M	BLK	40-44	6351		M	43	BLK	1028
						M	42	BLK	1050
						F	25	BLK	1022
	F	BLK	25-29	6205		F	25	BLK	1022
						F	28	BLK	1257

## FIELDS

## Coding Instructions:

A STAGE4	Enter number as written on line next to number 4. of "Syphilis Stage" section of Associates. or 99 if blank.
64 A ~AGE5	Enter number as written on line next to number 5. of "Syphilis Stage" section of Associates, or 99 if blank.
65 A STAGE6	Enter number as written on line next to number 6. of "Syphilis Stage" section of Associates, or 99 if blank.
66 A STAGE7	Enter number as written on line next to number 7. of "Syphilis Stage" section of Associates, or 99 if blank.
67 A STAGE8	Enter number as written on line next to number 8. of "Syphilis Stage" section of Associates, or 99 if blank.
58 A_STAGE9	Enter number as written on line next to number 9. of "Syphilis Stage" section of Associates, or 99 if blank.
69 A_STAGE10	Enter number as written on line next to number 10. of "Syphilis Stage" section of Associates, or 99 if blank.
70 RE iwr vw	Corresponds to last question ("was original patient reinterviewed"). Enter 1 if Yes, 2 if No, 3 if Unsure, 9 if No response.
71 BLANKY N	If all items were blank (i.e., entered as 99), enter Y (this does not include the Study ID and "Reinterviewed" question). If any item in those sections (not including the Study ID and "Reinterviewed" question) was answered, enter N.

# CODING AND DATA ENTRY GUIDELINES

## REIFUSED.DBF

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This is to document the coding and data entry guidelines for the demographic data collected on individuals who refused to participate in the study, "Evaluation of the Reasons for the Increase in Reported Cases of Syphilis."

These data have been coded and entered in the data base file called **REFUSED.DBF**. In the list that follows, the field names of the data base are listed, and are matched with the corresponding question on the data collection instrument.

### GENERAL RULES

The following general rules applied in the coding and data entry of these questions:

- No fields were left blank. All non-responses were entered as 9. If the field has more than one digit or character length, a 9 was entered as many times as needed to "fill up" the field. For example, field name AGE (corresponding to question 3) is a two-digit field. The data entry was either the number as written by the interviewer, or 99 to indicate no response.
- All data entry codes were consistent with the choice numbers as indicated by each question. For example, for the field name RACE (corresponding to question 2), the data in that field will only be 1 (White), 2 (Black), 3 (American/Alaskan native), 4 (Asian/Pacific Islander), 8 (Other), or 9 (no response). Any data entry in fields corresponding to questions on the data collection form that are not consistent with the codes next to each question are the result of data entry error, and the hard copy of the survey should be pulled and re-entered properly.

### NUMBER FIELDS AND CHARACTER FIELDS

Fields SITE\_NUM, STUDY\_NUM, AGE, and SYP\_DIAG are numeric fields. Fields SEX and RACE are character fields.

CODING INSTRUCTIONS  
REFUSED.dbf

Question  
Number:

Coding Instructions:

FIELDS

1 SITE~M

N/A

Handwritten at top of front page

2 STUDY\_NUM

N/A

Handwritten at top of front page. (Often identified as "ID" or "Consent ID.")

3 SEX

1

1 = Male, 2 = Female, 9 = No response.

4 RACE

2

1 = White, 2 = Black, 3 = American/Alaskan Native, 4 = Asian/Pacific Isf., 8 = Other, 9 = No response.

5 AGE

3

Enter number as written or 99 = No response.

6 SYPDIAG

4

1 = Yes, 2 = No, 3 = Unsure, 9 = No response.

## CODING AND DATA ENTRY GUIDELINES

### SYPHA.DBF

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This is to document coding and data entry guidelines for the responses to the questionnaire administered to Philadelphia community residents for the study “Evaluation of the Reasons for the Increase in Reported Cases of Syphilis.

The responses to this questionnaire have been coded and entered in the data base file called **SYPHA.DBF**. In the list that follows this section, the field names of the data base are listed, and are matched with the corresponding question in the survey.

#### GENERAL RULES

The following general rules applied in the coding and data entry of the questionnaire:

- No number fields were left blank. The only blank fields in the data base are fields corresponding to ~explanation or “other” questions in the questionnaire, for which either the respondent or interviewer was asked to comment, or was asked to write in another choice not given in a multiple choice listing.
- **All non-responses to number fields were entered as 9. Any question without a response of any kind was entered as 9.** If the field has more than one digit or character length, a 9 was entered as many times as needed to “fill up” the field. For example, field name MENSXMO\_18 (corresponding to question 18 in the questionnaire, which asks the respondent to list the number of men s/he had sex with in the last 3 months) is a three-digit field. The data entry was either the number as written by the interviewer, or 999 to indicate no response.
- All non-responses to character-only fields were left blank. Character-only fields are of two types: a) fields corresponding to questions where the interviewer or respondent is asked to comment or explain a response; and b) fields corresponding to questions where the interviewer or respondent chooses “other” on a multiple choice listing, and is asked to specify.

## DATE FIELDS

Throughout SYPHA.DBF, date responses were coded and entered as three separate 2-digit fields. For example, question 15b of the questionnaire asked for the date of the most recent episode of gonorrhea. The response was coded and entered into three fields in SYPHA.DBF: HAD\_GONMTH, HAD\_GONDAY, and HAD\_GONYR. Each field is two-digits long and corresponds to the appropriate part of the date entered. This allowed the data entry personnel to enter partial dates. For example, if the response to the question 15b was 2/83 (i.e., February 1983, with no day listing), the data entry personnel was instructed to enter the following:

HAD\_GONMTH: 02  
HAD\_GONDAY: 99  
HAD\_GONYR: 83

99 was entered in the HAD\_GONDAY field in keeping with the general rule that no responses in number fields were to be entered as 9.

## SPECIFIC RESPONSES LIST

In the table that follows, where specific lists of number responses are given as coding instructions for a field, data analysis personnel can assume that only those responses are in that field for all records. For example, the coding instructions for field name HISPAN\_9 (corresponding to question 9 on the questionnaire) is "1 = Yes, 2 = No, 3 = Unsure, 9 = No response." In all records for that field, the responses will only be 1, 2, 3, or 9: no other numbers should be in this field, and in no records should this field be blank. Any deviation from this indicates a data entry error, and the hard copy of the survey should be pulled and re-entered properly.

CODING INSTRUCTIONS

:SYPHA.dbr

FIELDS	Question Number:	Coding Instructions:
1 REC NUMBER	N/A	Entered at end of data entry (lists Dbase record number).
2 SITE NUM	N/A	Found on label, first pg. Always coded as "A."
3 STUDY NUM	N/A	On label, first pg. Enter entire number following hyphen.
4 INTERVWER	1	Enter number as written.
5 INT_DATE	2	Enter date as written.
6 CENSUS	3	Enter census tract number as written, 999 = No response.
7 BLOCK	3	If block number listed by writer, enter that number; 999 = No response.
8 SEX4	4	1 = Male, 2 = Female, 9 = No response.
9 ZIPS	5	Enter zip code as written, 99999 = No response.
t0 AGE6	6	Enter age as written (one to two digits), 99 = No response.
11 MARITAL 7	7	1 = Married, 2 = Never Married, 3 = Divorced, 4 = Separated, 5 = Widowed, 9 = No response.
12 RACE 8	8	1 = White, 2 = Blank, 3 = American/Alaskan Native, 4 = Asian/ Pacific, 8 = Other, 9 = No response.
13 HISPAN 9	9	1 = Yes, 2 = No, 3 = Unsure, 9 = No response.
14 EMPLOY_10	10	1 = Yes, 2 = No, 3 = Unsure, 9 = No response.
15 SCHOOL_11	11	1 = Yes, 2 = No, 3 = Unsure, 9 = No response.
16 GRADE 12	12	Enter number as written, 99 = No response.
17 PHONE 13	13	1 = Yes, 2 = No, 3 = Unsure, 9 = No response.
18 HAD_SYP14A	14a	1 = Yes, 2 = No, 3 = Unsure, 9 = No response.
19 HAD_SYPMTH	14b	Enter numbers in day part of date; 99 if blank.
20 HAD_SYPDAY	14b	Enter numbers in month part of date; 99 if blank.
HAD_SYPYR	14b	Enter numbers in year part of date; 99 if blank.
HAD_GONI5A	i5a	1 = Yes, 2 = No, 3 = Unsure, 9 = No response.
23 HAD_GONMTH	15b	Enter numbers in day part of date; 99 if blank.
24 HAD_GONDAY	15b	Enter numbers in month part of date; 99 if blank.
25 HAD_GONYR	i5b	Enter numbers in year part of date; 99 if blank.
26 ULCER 16A	16a	1 = Yes, 2 = No, 3 = Unsure, 9 = No response.
27 ULC_MED16B	16b	1 = Yes, 2 = No, 3 = Unsure, 9 = No response.
28 ULC_CAR16C	16c	Enter number corresponding to response in survey; 9 if no response.
29 OTHCAREEXP	16c	Character field; enter any written comments.
30 NO_CARE16D	16d	Enter first number corresponding to response to question; 9 if no response.
31 NOCARE2	16d	Enter second number corresponding to response to question; 9 if no response.
32 NOCARE3	16d	Enter third number corresponding to response to question; 9 if no response.
33 OTHNOCARE	16d	Character field; enter any written comments.
34 MENSXYR17	17	Enter number written or 9999 if no response.
35 MENSXMO18	18	Enter number written or 999 if no response.
36 WOMSXYR 19	19	Enter number written or 9999 if no response.
37 WOMSXMO 20	20	Enter number written or 999 if no response.
38 USECONi) 21	21	1 = Never, 2 = Sometimes, 3 = Usually, 4 = Every Time, 9 = No response.
39 M CRAC 22B	22b	1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
40 MCOKE22C	22c	1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
41 MMARI 22D	22d	1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
42 M HERO 22E	22e	1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
43 MALCO 22F	22f	1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
~44 MOTH 22G	22g	1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
45 MOTHDRUG	22g	Character field; enter any written comments.
&-1 W_CRAC 23B	23b	Enter number as written, or 99 if no response.
WCOKE23C	23c	Enter number as written, or 99 if no response.
48 WMARI23D	23d	Enter number as written, or 99 if no response.
49 W HERO 23E	23e	Enter number as written, or 99 if no response.
50 WALCO 23F	23f	Enter number as written, or 99 if no response.
51 WOTH_23G	23g	Enter number as written, or 99 if no response.
52 WOTHORUG	23g	Character field; enter any written comments.

	Question Number :	Coding Instructions:
	FIELDS	
53	NEEDLE 24A	24a 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
54	N COKE_24B	24b 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
55	NHERO24C	24c 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
56	N AMPH24D	244 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
57	<b>NOTH 24E</b>	24c 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
58	<b>NOTHDRUG</b>	24e Character field; enter any written comments.
59	SHARE 25	25 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
60	<b>GIVESX 26A</b>	26a 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
61	<b>GIVMON 26B</b>	26b 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
62	<b>GIVDRG26C</b>	26c 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
63	GMONEY26D	26d Enter number as written, or 99 if no response.
64	<b>GDRUG26E</b>	26e Enter number as written, or 99 if no response.
65	<b>GCRAC 26F</b>	26f 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
66	<b>G COKE 26G</b>	26g 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
67	<b>GHERO 26H</b>	26h 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
68	<b>GMARI 26I</b>	26i 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
69	<b>GALCO 26J</b>	26j 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
70	<b>G OTHDR26K</b>	26k 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
71	GOTHEXP	26k Character field; enter any written comments.
72	<b>GCOND 26L</b>	26l 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
73	<b>REC SX 27</b>	27a 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
74	RECMON27B	27b 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
75	RECDRG27C	27c 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
	R MONEY27D	27d Enter number as written, or 999 if no response.
	RDRUG 27E	27e Enter number as written, or 99 if no response.
78	<b>RCRAC 27F</b>	27f 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
79	RCOKE27G	27g 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
80	RHERO 27H	27h 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
81	<b>R MARI 27I</b>	27i 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
82	R ALCO 27J	27j 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
83	<b>ROTH 27K</b>	27k 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
84	ROTHEXP	27k Character field; enter any written comments.
85	ORAL_27L	27l 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
86	VAGIN 27M	27m 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
87	ANAL 27N	27n 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
88	<b>R COND 27O</b>	27o 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
89	PRTNER28	28 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
90	CRACKHSE29	29 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
91	SAMEDAY 30	30 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
92	PRT24HR 31	31 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
93	SHRPRESX32	32a 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
94	S CRAC 32B	32b 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
95	SCOKE32C	32c 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
96	S_HERO 32D	32d 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
97	S MAR1 32E	32e 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
98	SALCO32F	32f 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
99	5 OTH 32G	32g 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
100	S_OTHEXP	32g Character field; enter any written comments.
101	SX1TIME33A	33a 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
	BAR_33B	33b 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
103	STREET 33C	33c 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
104	CRAKHSE33D	33d 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
105	WORK 33E	33e 1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.

106	SCHOOL	33F	1 = Yes, 2 = <b>No</b> , 3 = Unsure, 4 = Refused, 9 = No response.
~17	NOREM3	33g	1 = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
)8	MET OTH	33h	I = Yes, 2 = No, 3 = Unsure, 4 = Refused, 9 = No response.
..	MEET_EXP	33h	Character field; enter any written comments.
	VALID	34	1 = Yes, 2 = No, 9 = No response.
1	VALIDNO_35	35	Enter first number corresponding to response to question; 9 if no response.
2	VALIDNO_B	35	Enter second number corresponding to response to question; 9 if no response.
113	VALIDNO C	35	Enter third number corresponding to response to question; 9 if no response.
4	<b>VALID OTH</b>	35	Character field; enter any written comments.
s	<b>COMMENTS</b>	36	Character field; enter any written comments.

## **ATTACHMENT I**

### **Coding and Data Entry Instructions**

## CODING AND DATA ENTRY GUIDELINES

### SYPHi .DBF AND SYPH2.DBF

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This paper documents the coding and data entry of the responses to the questionnaire administered to clinic patients enrolled in the study, *Evaluation of the Reasons for the Increase in Reported Cases of Syphilis*.TM

The responses to this questionnaire have been coded and entered in two data bases:

**SYPHi .DBF:** contains all responses for the first half of the questionnaire (questions 1 through 46 in the version of the questionnaire used in Florida, and questions 1 through 47 in the version used at all other sites).

**SYPH2.DBF:** contains all responses for the second half of the questionnaire (questions 47 through 61 in the version of the questionnaire used in Florida, and questions 48 through 62 in the version used at all other sites).

### THE FLORIDA QUESTIONNAIRE

Please note that there are two versions of the study questionnaire being coded. ~~The original version of the questionnaire, only used at the Florida site, did not contain two questions relating to previous diagnosis of syphilis. However, these questions were subsequently added and appear in the questionnaire being used at other sites as questions 17a and 17b. Interviewers at the Florida site were instructed to write this information in at the bottom of page one of the questionnaire. As a result, in the Florida version only, the number in the field name for all questions after 17 does not match the number of the question in the questionnaire. For example, RPRVDRL 18 corresponds~~ question number 17 in the Florida version and question number 18 in the other version. This will not affect the analysis of the data since each field contains the appropriate data from both questionnaires: this is only a numbering discrepancy

In the table that follows, "Coding Instructions," the field names of the data base are listed and are matched with the corresponding question in both versions of the questionnaire. In the FLA column, "handwritten" means that the information was provided

by the interviewer in the margin of the questionnaire.

## GENERAL RULES

The following general rules apply in the coding and data entry of the these questionnaires:

- **No number** fields will be left blank. The only blank fields that will occur will be “explanation” or “other” fields, where the respondent or interviewer was asked to comment, or write another choice not given in a multiple choice listing.
- **All non-responses to** number fields are entered as 9. Any question without a response of any kind will be entered as 9. If the field has more than one digit or character length, a 9 will be entered as many times as needed to “fill up” the field. For example, field name MENSXMO\_44 in SYPHi.DBF (which corresponds with question 44 in the questionnaire .. and question 43 in the Florida questionnaire – and asks the respondent to give a number for the number of men the respondent had sex with in the last 3 months) is a three-digit field. The data entry will either be a number as written by the interviewer, or 999 to indicate no response.

NOTE: For field name SYP\_Y\_3B (which corresponds to question 3b in both versions of the questionnaire), 9 is a valid response, as it corresponds to the multiple-choice answer “Unknown”. In this case, the non-response coding is 99. This is the only question in the survey that has 9 as a valid response.

- All non-responses to character-only **fields are left blank. Character-only** fields are of two types: a) fields corresponding to questions where the interviewer or respondent is asked to comment or explain a response; and b) fields corresponding to questions where the interviewer or respondent chooses “other” on a multiple choice listing, and is asked to specify it.

## DATE FIELDS

Throughout both SYPH1.DBF and SYPH2.DBF, date responses have been converted to three separate 2-digit fields. For example, question 39b of the questionnaire (question 38b of the Florida questionnaire) asks for the date of most recent episode of gonorrhea. The response is broken down into three fields in SYPH1.DBF: HAD\_GONDAY, HAD\_GONMTH, and HAD\_GONYR. Each field is two-digits long and correspond to the appropriate part of the date entered. This allows the data entry personnel to enter partial dates. For example, if the response to the above-mentioned

## I. OPERATIONAL ORGANIZATION

The clinical and disease control operations of the City of Long Beach, Department of Health and Human Services (i.e., the clinic) are organized under the authority of Diana M. Bonta, R.N., M.P.H, Administrator of the City of Long Beach Department of Health and Human Services. Marion Johnson, M.I. is Health Officer. Ruth Bundy is the Bureau Chief, Preventive Health Officer for the STD clinic. Tony Bustamante is the Communicable Disease Manager who oversees the syphilis control activities performed by eight DIS.

DIS rotate their responsibilities to conduct counseling/partner referral interviews at the clinic and trace syphilis contacts in the community. Each day, at least two DIS are scheduled to conduct interviews at the clinic.

## II. PATIENT FLOW

- Patients who believe they need an STD exam present at the registration window. Registration forms are given to patients who have clear symptom descriptions or are at clear risk or are there for premarital bloods. If symptoms or risk are not clear, the potential patient is sent to DIS for clarification and are either given registration forms or counseled and released.
- Patients turn in registration forms and are issued a number if they are a new patient or issued a letter if repeat or follow-up procedures are needed or if they are premarital patients. Patients presenting as DIS referrals are sent to DIS where the "expected-in" box is checked for a pink copy of a 2936, or the reason for the visit is ascertained. They may then receive registration forms. All non-DIS referred patients are sent to the cashier with registration forms and return with a cashier's slip.
- If there is a medical question on the registration form, such as ascertaining a problem connected with pregnancy or prior private clinic visit, the patient is sent to DIS who calls the appropriate facility to verify diagnosis or treatment or to verify history. If there is a problem from the patient's listing of risk or history, the patient is sent either to DIS or to the STO clinic manager to clarify and triage. Any pertinent information is added to the "comments section" of the chart and is signed using the DIS number.
- Patients hand in registration form to the registration clerk who fills out clinic charts. Patients are sent to the waiting area until the clinician calls them by their number or letter.
- At the waiting area, HIV counselors offer HIV testing and pretest counsel those consenting and then records those letters/numbers.
- Clinicians call patients by their number/letter. A physical exam, proper cultures and blood tests are administered. A stat lab microbiologist performs initial RPRs and

gonorrhea smears. Proper medications are administered based on symptoms, history and stat lab results. Diagnoses, medications, etc. are notated on chart. The chart and any non-injection is attached to the chart with instructions. All patients who have positive diagnoses are returned to the waiting area.

- HIV counselors call all those who have consented to be tested by number.
- Clinicians flick a switch in the lab room which turns on a light in the DIS room to alert DIS that there is a patient with a positive diagnosis of syphilis to investigate and counsel. **DIS, upon** seeing the light, go to the door of the stat lab room and obtain the chart and attached medication and information. DIS call patients by number/letter to investigate, inform and counsel.

### **iii. OVERVIEW OF STAFF ROLES FOR THE STUDY**

The following clinic staff will participate in the study:

Tony Bustamante, Communicable Disease Manager  
Darlene Turner Harper, DIS Supervisor  
Suvanne Lebovit, DIS (Study Coordinator)

~ Suvanne Lebovit, Study Coordinator, is responsible for administering the questionnaire to cases and controls and for ensuring that questionnaires are completed accurately, recording pending lab results onto questionnaires and recording information in the study log book.

Darlene Turner Harper, DIS Supervisor, will ensure DIS route patients to the Study Coordinator as required.

Tony Bustamante will supervise the study to ensure that the data flows to JBA in a manner indicated by this protocol and for relaying information between DIS staff and JBA.

How these responsibilities will be carried out is fully described in the following sections of this procedural manual.

## IV. SELECTION OF CASES AND CONTROLS

### A. Selecting Cases

#### Criteria:

Candidates will include all patients who meet the following two conditions as indicated on their registration form and clinical record (both conditions must be met):

1. clinical diagnosis of primary or secondary syphilis; and
2. voluntarily presented at the clinic for medical evaluation;

Includes patients who present voluntarily for an initial syphilis test at the clinic or at a private physicians office but who have to be referred in by DIS for evaluation.

\* **Patients excluded: (1) contacts to syphilis patients who are referred by DIS; (2) patients tested and treated elsewhere but seen at the clinic for STD interviews only.**

#### Method:

After DIS conduct the counseling/partner referral interview, the patient will be referred to the Study Coordinator. Using the selection criteria, the Study Coordinator will determine which syphilis patients are candidates for participation and will ask these patients to participate in the study.

#### When:

Each day, cases will be selected as they present themselves.

### B. Selecting Controls

#### Criteria:

Candidates for the controls will include those patients who meet the following two conditions as indicated on their registration form and clinical record (both conditions must be met):

1. clinical diagnosis of STDs other than syphilis, non-STOs, or no disease; and
2. voluntarily presented at the clinic for medical evaluation.

\* **Patients excluded: (1) patients diagnosed with syphilis within the last 12 months; (2) patients seen only for HIV testing.**

**Method:**

Using patient registration numbers, the Study Coordinator will select every third patient who meets the study criteria above as a candidate for the controls.

**When:**

Depending on room availability, controls will be selected in the morning and afternoon to prevent selection bias.

## **V. ADMINISTERING THE QUESTIONNAIRE**

The questionnaire consists of diagnosis and lab results sections followed by the study questions. A unique study number is pre-printed on the top right corner of every page of each questionnaire.

Prior to administering the questionnaire to cases and controls, the study coordinator must read informed consent form to the patient.

Blank informed consent forms and questionnaires will be located in the interview room assigned for use specifically for study participants.

**When to administer:**

Cases – Study coordinator will administer the questionnaire after the DIS has conducted the usual partner referral/counseling interview.

Controls – Study coordinator will administer the questionnaire before the patient sees the clinician.

**Lab Results:**

- Lab results available at the time of the interview will be recorded on the lab results form (p.2 of the questionnaire).
- If some or all of the lab results are pending at the time of the interview, study coordinator will indicate the tests with pending results. The coordinator will record the results at a later time (refer to Section VII.)

**Tagging Participants:**

Cases and Controls – On the lab section of the questionnaire will be a yellow peel-off sticker with the study number written on it. The Study Coordinator will pull off this sticker and stick it on the outside folder of the medical record of cases and controls. This sticker indicates that the patient is a study participant and is not to be interviewed again as a case or control.

**Tracking Refusals:**

The interviewer will keep track of case and control candidates who (1) refuse prior to hearing the informed consent information, or (2) refuse to sign the consent form

## VIII. TRANSMITTING DATA TO JBA

- Once every two to three weeks, the coordinator will mail 1) the completed questionnaires from the "Closed Questionnaire" folder, and 2) the informed consent forms from the "Consent Refused" folder to JBA by certified mail in the envelopes provided.
- JBA will provide the clinic with money for postage. Postage receipts must be given to JBA.
- In the log book, the coordinator will record the date the completed questionnaires are sent to JBA.
- The Study Coordinator is responsible for regularly checking the log book to ensure that all questionnaires are returned JBA within 15 days after the date of the patient's visit.

## IX. DATA COLLECTION ISSUES

When administering the questionnaire, interviewers should note:

### 1. Definition of sex

One Disease Intervention Specialist commented that when some male patients are asked about their sexual encounters, they do not always consider oral sex from another man as "having sex". Probing this issue with case and control participants will help elicit more accurate information about all types of sexual encounters.

### 2. Interviewer's Impressions

When interviewers record their impressions of the validity of the patient's answers (questions 54 and 55), they should consider:

- a. rating the validity of a patient's drug use behavior based on ~ evidence of drug use (track marks; red, glazed eyes; slurred speech, etc.)
- b. rating the validity of a patient's sex behavior based on their drug use .. heavy drug users are more likely to exchange sex for drugs.

## **X. ORIENTATING STAFF**

Laura Aiuppa of JBA is responsible for orientating clinic and DIS staff who are involved in the execution of the data collection plan. The purpose of the orientation is to describe the objectives of the study; educate staff about their roles and responsibilities; and review all phases of the data collection process. These activities will be carried out by explaining all sections of this Procedural Manual. JBA staff will also discuss certain data collection issues (described below) and answer questions.

Staff orientation is scheduled for March 4, 1991. Data collection will begin the same day.