

Final Report

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Task 8**

**A Project to Assess the Feasibility and Need for Support of Cervical Cancer Screening
in Public STD Control Clinics**

to

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- What challenges are associated with cervical cancer screening, follow-up, referral, diagnosis, surveillance, and education in STD clinics?
- When abnormal Pap results are reported, can the clinic assure that women receive appropriate diagnostic and treatment services?
- Would the addition of a comprehensive cervical cancer screening service in STD clinics have a negative impact upon the delivery of primary STD prevention, diagnosis, treatment, and epidemiologic services?
- What would be the overall economic cost of providing this additional service?

The objective of the first phase of this project was to gather data to support the design of the demonstration project. Together, information from all three phases will answer the research questions.

Methodology

As part of this first phase of a three-phase project, we visited nine STD clinics to explore the availability, adequacy, and usefulness of data elements in addressing the research questions.’ The nine sites included three STD clinics that presently conduct cervical cancer screening and six that do not. **Four** clinics are in large cities, four are in medium-sized cities, and one is in a small city. Sites are fairly evenly distributed geographically across the United States.

In order to facilitate site selection, a request for information was sent to DSTDP Project Officers (PO) to be shared with STD Program Managers in each of the PO’s project areas within the continental United States. The purpose of the request for information was to develop a list of candidate project sites and to learn more about the number of women seen in STD clinics that serve variously sized population centers. Site selection criteria included:

- The clinic is a stand-alone STD clinic (i.e., some portion of each week is devoted solely to seeing persons presenting for STD-related services).
- The clinic sees a high volume of female patients relative to the size of the city or county in which it is located.
- The clinic is willing to provide cervical cancer screening as part of a national demonstration project that is likely to include intensive follow-up of women with abnormal findings.
- The clinic can provide the information needed to conduct the project, including patient demographics and a record of service delivery.
- The clinic does not have a contract with the State’s Breast and Cervical Cancer Early Detection Program (BCCEDP) .

¹ **The nine STD clinics visited were located in Brooklyn, NY; Clark Co., NV; Detroit, MI; Kent Co., MI; Memphis/Shelby Co., TN; Norfolk, VA; Norwalk, CT; Orange Co., CA; and Wake Co., NC.**

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- The existing or needed relationships with a cytopathology laboratory
- The current practices and additional needs regarding patient education and counseling
- The current practices and additional needs regarding patient tracking, follow-up, and referral

The number of patients seen in each clinic ranged from about 70 per month to 1,929. Unfortunately, each clinic kept data concerning patient census in different ways, such that it was not possible to say for sure how many individual patients are seen or examined at each clinic during a **one-**month or one-year time period. We were able to reasonably calculate that women make up between 30 and 50 percent of STD clinic clientele and approximately 40 to 90 percent of those are first time patients. During demonstration project, we would need to assess whether women are receiving Pap testing in other locations, but during Phase 1 we were not able to obtain any reliable information on where and when women seen in STD clinics receive Pap testing.

There is wide variability in the methods of information collection and management among the Phase 1 STD clinic sites. The comprehensiveness of data/information systems does not necessarily correspond to whether or not the STD clinic does Pap smear screening (two of the clinics with the most advanced computerized information systems do not offer such screening). Among those clinics offering Pap smears, the information systems contain most of the data that would be needed for evaluation purposes, but certain aspects would need to be systematized differently. This does not necessarily mean that a clinic not currently using a computerized information system would have to develop one to participate in the demonstration project, but it would have to develop ways to take the important information out of patient charts and lab reports and manage it in a central database.

Staffing patterns in the STD clinics correspond to particular functions: intake; education and counseling; examination; and tracking, follow-up, and referral. In all the clinics we visited, initial patient intake is being conducted by clerical staff with additional intake being conducted by DIS (or persons with a similar role) and practitioners. In all clinics, staff who conduct the exams provide patient education and counseling on **STDs** prior, during, or after the exam, or use a combination of approaches;. For those clinics that provide Pap smears, some education is provided by the practitioner taking the smear. The staff members who conduct examinations in STD clinics vary from nurses, to nurse practitioners (NP) or physician assistants (PA), to physicians. In the three STD clinics we visited that conduct Pap smears, one uses nurses and the other two use physicians. In speculating about who would conduct the procedure where it is not in place, there was much divergence in opinion as to whether public health nurses (**PHNs**) are qualified to do the procedure, or if it should be reserved for **NPs** or **PAs**, or even limited to physicians. There is consensus that nurses need additional training to be able to learn proper clinical technique and to have the knowledge necessary for comprehensive patient education on cervical cancer. There is also consensus that interpretation of Pap smear cytopathology findings should be done by a physician (or NP or PA with physician consultation), as well as clinical follow-up decisions based on those findings.

For tracking, follow-up, and referral, there was general agreement across all sites that these functions should be done by **PHNs** alone or in combination with DIS. The impressions we got from DIS we interviewed are that DIS do not feel qualified enough to be the contact point for patients calling in about abnormal Pap smear results or to provide information on results in the field. The role for DIS in cervical cancer screening, if any, would be to locate patients with high-grade abnormal results who are not responding to other methods of contacting them. Some respondents, including nurses and DIS, said that

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The demonstration protocol requires a comprehensive system of tracking patients from the time of intake through the follow-up of all patients with abnormalities. In addition, the evaluation component of the protocol requires several data collection activities. Ideally, the clinic has a computerized information system (with protection of confidential information); however, manual systems of data management can be adapted for this protocol.

One of the most important decisions to be made is who should actually perform Pap testing. Our findings suggest that public health nurses (**PHNs**) who are experienced **RNs** with additional training can perform the Pap test if also **mentored** at the clinic. In jurisdictions that do not allow **RNs** to conduct this level of testing, a Nurse Practitioner (NP) or Physician Assistant (PA) may do the test. The one situation to be avoided is using more than one examiner for a patient (i.e., RN for STD testing followed by NP, PA, or MD for Pap testing). A nursing, medical, laboratory, or public health assistant may also be needed to assist in the collection, labeling, and sending of specimens. The clinic should use CDC clinical guidelines for cervical cancer screening in STD clinics, last updated in 1997, as a standard, although some clinics may wish to supplement these guidelines in a manner consistent with those followed in other clinics within the Health Department.

Follow-up is crucial to the success of this project. We suggest that the person who coordinates follow-up and functions as the case manager for all women with abnormal results be a PHN. Follow-up, case finding, and outreach are normal functions for public health staff, and the public health nurse has the advantage of clinical knowledge concerning the etiology, prevention, and care of cervical cancer or precancerous lesions. If a PHN is not available for this position, then the case manager should be someone who can perform follow-up, case finding, and outreach, as well as communicate clinical information to both patients and referral sources. The PHN or other follow-up case manager may be assisted by clerical and junior level public health staff (e.g., junior public health advisors). Another key person may be a DIS experienced in finding difficult-to-locate women who will have time specifically allotted to finding women with high-grade lesions.

The clinic needs to set up relationships with two kinds of external agencies: the cytopathology laboratory and the referral settings for women with abnormal Pap smear results. The PHN/case manager is the staff person who should be responsible for setting up these relationships. In addition, the STD clinic may need to identify outside sources of technical assistance for information systems and sources of training for staff who will be carrying out the protocol, as well as ongoing continuing education in all clinical areas,

For the implementation of cervical cancer screening we recommend that the following steps be integrated within the clinic flow:

- Intake which consists of (1) obtaining accurate demographic and locating information from each patient; (2) obtaining self-reported Pap smear history from each female patient (past 12 months, 1-3 years, over 3 years., or never); and (3) recording patient information into a data management system.
- **Medical History** which consists of (1) obtaining supplemental patient history in order to better determine if the woman has in fact had a Pap smear in the past one to three years; (2) having the patient sign a medical records release (for confirmation of Pap smear within past 12 months and/or for gathering information from referral sites); (3) delivering some counseling and education regarding cervical cancer screening; (4) following clinical guidelines for deciding whether a Pap smear should be done; and (5) having the patient

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- 2) *Establish policy and procedures concerning normal Pap smear results.* Not notifying **women** who have had a normal smear is a defensible option considering the special confidentiality concerns of the women, and the staff time involved in such communication, or the clinic may choose to notify the woman by mail of her normal result, using this mailing as an opportunity to reinforce patient education geared towards establishing the habit of obtaining an annual Pap smear. A third option is the clinic may have a policy of asking women to call the clinic for results, at which time she is told of her normal smear, and the need to receive a smear in one year is reinforced.
- 3) *Establish procedures for follow-up of abnormal Pap smear results.* While clinical decisions are to be made by a physician - or a PA or NP in consultation or under supervision of a physician - once the decision is made the PHN/case manager will expedite the process of finding the woman. The follow-up procedures become increasingly intense reflecting the increasing seriousness of the abnormality as defined by the Bethesda System. This protocol is based on the premise that the STD clinic considers it to be its responsibility to further educate and counsel women with abnormalities and to see that they receive any indicated **treatment**. This will certainly mean developing liaison relationships with staff at all settings in the STD clinics' referral network. The PHN/case manager should attempt to solve all problems within a 6-week period. For women with HSIL or above, this may mean involving DIS in assisting the PHN in locating the woman, or the PHN may do all home visits herself. If a woman is lost to follow-up, the reason will be noted after a combination of telephone calls, registered letters, and home visits have been used. If a woman refuses follow-up, she should sign a waiver that demonstrates that she has been counseled on the seriousness of this decision, and one more follow-up call should be made within 3 weeks after the patient has signed the waiver.

Evaluation

Battelle's recommendations for data collection activities to be conducted for the Phase 2 demonstration project will support the evaluation analysis to be conducted as Phase 3 of this project. Phase 2 data collection activities will be the responsibility of each of the demonstration site clinics. **Many** of the forms already in use at the clinics may be modified to accommodate the project, but some new forms or worksheets may be needed to track the referral component of the program.

Below are the key data points that must be collected at each clinic in order to support **both** the tracking of patients and evaluation of the demonstration project. They may be gathered in each STD clinic through a computerized system, by hand, or through a combined electronic/manual system. They are:

- The number of *patients* who visit the STD clinic per month (separated by male/female)
- The number of *patients examined* in the STD clinic per month
- The number of *female* patients examined in the STD clinic per month
- The number of female patients examined who **are first-time visits** versus repeat visit?

² Although different STD clinics define "first-time visit" and "repeat" differently, for purposes of the demonstration project "first-time visit" will be anyone who has not been seen in the STD clinic in the past year.

EXECUTIVESUMMARY

TITLE: A Project to Assess the Feasibility and Need for Support of Cervical Cancer Screening in Public STD Clinics

CONTRACT NUMBER: 200-96-0599, Task 08

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Statement of the Problem

This report presents the results of the first phase of a three-phase project sponsored by the Centers for Disease Control and Prevention (CDC) to assess the feasibility and need for support of cervical cancer screening in publicly funded sexually transmitted disease (STD) control clinics. This project is a collaborative effort between the CDC Division of Cancer Prevention and Control (DCPC) and the Division of STD Prevention (DSTDP).

The first phase of the project had three purposes: (1) selection of the sites to be considered for the demonstration project and collection of baseline information on each; (2) development of a Demonstration Site Protocol for identifying, screening, tracking, and following-up on women at high risk for cervical cancer and precancerous lesions in STD clinics; and (3) development of a budget estimate for the Phase 2 demonstration project. During the first phase of this project, Battelle conducted site ~~visits to~~ nine STD clinics in order to gather data for the design of the protocol. The initiation of the second and third phases will depend upon the findings of the first phase.

It is anticipated that during the second phase, a set of STD clinics will be chosen from among the original nine sites to implement demonstration projects following the prescribed protocol design. The ~~third~~ phase will consist of validation, analysis, and interpretation of the findings of the demonstration projects. CDC will then integrate this information into the decision-making process to improve cervical cancer control among underserved populations at high risk of developing pre-cancerous and cancerous lesions of the cervix.

Evaluative Objectives

The entire three-phase project is guided by a series of questions which are:

- Are STD clinics an appropriate location for identifying women who have not been screened in the past one to three years for cervical cancer?

These key data points will provide the most basic measure of the project's ability to deliver cervical cancer screening to women who need the service and see that women who have abnormal results are served. Additional process and outcome measures or descriptors that correspond to the project's overall research questions can enhance the Phase 3 analysis. Some of these data would need to be collected through patient surveys and/or through in-depth interviews with staff. If CDC and clinics choose to go this route, time will need to be allotted to designing the data collection tools and obtaining necessary clearances.

Conclusion

Findings from Phase 1 project show that it is feasible to carry out cervical cancer screening in public STD clinics, but that information systems necessary for demonstrating the need for this activity are lacking. With the implementation of a demonstration project, further information can be developed concerning the use of STD clinics for reaching women who may not be receiving Pap testing, an important public health measure for the prevention of cervical cancer.

Battelle used this information to stratify the sites according to (1) the size of the metropolitan area in which each clinic is located, (2) the number of women seen in each clinic, (3) whether or not the clinic is conducting Pap tests, and (4) whether or not the clinic will be able to supply the information necessary to learn about demographic and cost issues.

For data collection, two sets of instruments were used, one set for sites that presently conduct cervical cancer screening in the STD clinic and one for those that do not. Battelle conducted in-depth interviews with several categories of STD clinic staff, including Clinic Director or Manager, Medical Director or Physician-in-Charge, providers of clinical services, Disease Intervention Specialists @IS), follow-up or outreach staff, and the laboratory manager.

We also visited and interviewed staff at a family planning clinic and/or a colposcopy clinic in each location. Visiting these clinics allowed us to better understand the full range of services available to women in the community. Clinic staff we interviewed included the clinic Program Director or Manager, a clinical provider, and follow-up/referral staff. Staff members explained the relationship between the local STD clinic and the family planning/colposcopy clinic and the procedures involved in tracking and referring patients. We learned how women enter the system, how the referral system works, and finally how and when services are rendered.

In analyzing the data collected from the respondents at each clinic, key issues were addressed both within and across all sites, in order to develop a logical basis for assessing whether replication of a finding has occurred (or failed to occur). The analysis process had three steps:

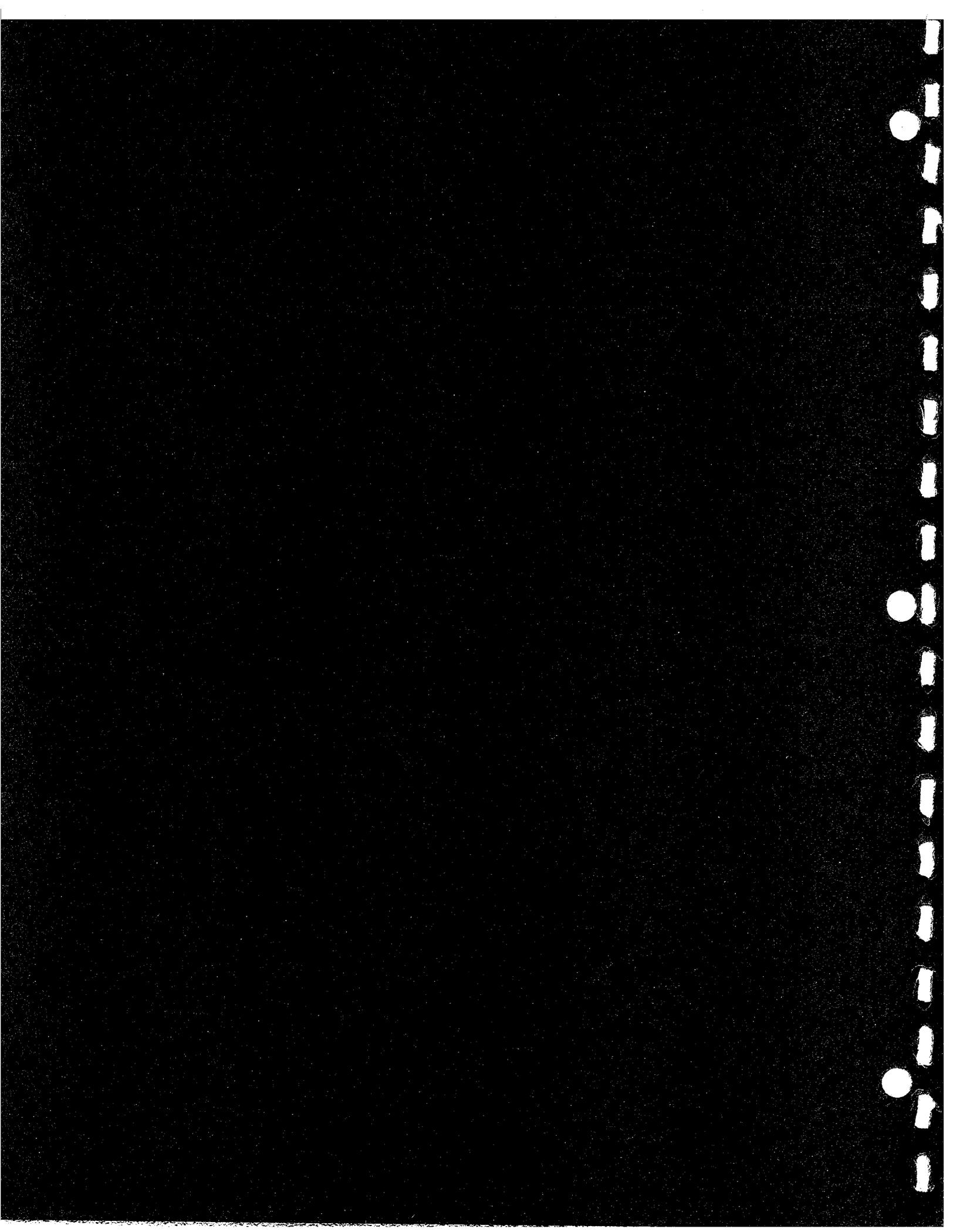
- Create an outline of key points to be addressed, based upon the project objectives,
- Write an individual summary of each site using the outline as a basis for organization, and
- Use the individual summaries to write the report and demonstration project protocol.

We wrote nine individual site summaries, presented in a separate document, based upon the outline of key points/findings. Each summary was organized by the same categories, facilitating comparison of findings across sites. We then were able to organize the data by topic across all sites, noting similarities and differences. The topical organization also allowed tests of pattern replication by comparing sets of topical reports. It was on the basis of this cross-site topical set of findings that we developed the Phase 1 project findings and recommendations for the demonstration project protocol.

Major Findings

The findings that were developed from data across all nine sites revolve around **the** following issues:

- The number of female patients seen in the STD clinics
- The information gathering and processing ability (and needs) of the STD clinics
- The staffing patterns, needs, and training requirements for cervical cancer screening in STD clinics



even the function of visiting patients at their homes should be the responsibility of **PHNs**, since they would be better able to explain the condition and need for follow-up.

Establishing connections between the STD clinics and a cytopathology laboratory for processing and evaluating Pap smear slides would not be difficult. In those sites where the STD clinic is not currently doing Pap smears, all but two have family planning programs on-site **that** offer Pap smears and already have a contract with a cytopathology lab. In all of these sites, respondents in the family planning clinics said that the external lab contract is not specific to the family planning clinic, but instead to the Health Department, and the STD clinic could piggyback onto the contract with very little difficulty. In the two sites where the Health Department does not operate Title X family planning services, other local sources provide those services and the STD clinic could either establish a contract with the same cytopathology lab as those providers or could go with a different lab. Either way, establishing these contracts was not seen by our respondents as an insurmountable obstacle. Costs for processing Pap smears averaged around \$8.00 per slide.

In the literature and among the people we interviewed, there is agreement that patient education is important in a cervical cancer screening program. This may be especially true when it is done in an STD clinic, since there is a lack of continuity of care in this setting. Therefore, follow-up and having patients return to the clinic for referral to further diagnosis can be difficult in an STD clinic. The most critical aspect is convincing **the** patient of the importance and value of consistent Pap smears, that follow-up of abnormal Pap smear results can prevent cancer, and to alleviate confusion that the patient may have as to the meaning of the various procedures she may require.

In most STD clinics that are not offering cervical cancer screening, tracking, follow-up, and referral are handled mainly by the DIS. Most follow-up activities in STD clinics involve contact tracing and partner notification for syphilis, gonorrhea, and possibly chlamydia and/or HIV. Most of our respondents felt that nurses should be responsible for Pap screening follow-up activities. Some respondents said that the actual clinical referral should be written by a physician, but the physician would not necessarily have to be employed full-time by the STD clinic. Among the clinics that offer Pap testing, one has a PHN who allocates half to three-quarters of her time to handle tracking, follow-up, and referral for patients with abnormal Pap smear results. In another, the NP in charge of the Pap screening program in the STD clinic handles all aspects of tracking, follow-up, and referral. However, in one site, no nurses are employed in the clinic and a Public Health Advisor, an epi-clerk, and DIS handle follow-up activities.

Recommendations

Demonstration Site Protocol

The findings of the Phase 1 project supported the development of a protocol for implementing a demonstration project concerning the feasibility of, and need for, cervical cancer screening in public STD clinics. This protocol may be implemented either in clinics that currently provide Pap testing or in those that do not offer this service. In the former situation, the clinic would simply enhance procedures already in place. However, the protocol is written so that it could be used as a guide for STD clinics initiating Pap smear testing and follow-up of women with abnormal findings. In either situation, the end-point is confirmation that a patient with an abnormal Pap smear result has been seen by an appropriate provider for treatment, or that a decision was made by a qualified follow-up provider that no treatment is indicated.

been estimated that over 80 percent of cervical cancer cases result from this infection. The Committee encourages the Division of Cancer Prevention and Control, Breast and Cervical Cancer Program, in collaboration with the Centers for Disease Control and Prevention (CDC) STD program, to develop a demonstration project on the link between HPV infection and cervical cancer. This project would examine how to identify and screen women at high risk of HPV infection and what surveillance strategies should be employed to assure early detection of cervical cancer in HPV- infected women.

In 1996, the American Cancer Society estimated there were 15,700 new cases of cervical cancer in the US (McMeekin et al. 1997). Several epidemiologic factors have been associated with cervical cancer and its precursor lesions including, but not limited to, early age at first sexual intercourse, a history of multiple partners, cigarette smoking, and low socioeconomic status (Cox 1995). Other research suggests that cervical dysplasia may be associated with several **STDs**, such as herpes simplex, chlamydia, and trichomonas (Campbell et al. 1994; **Kamb** 1995).

Cervical cancer has a slow onset in most women, beginning with low-grade abnormalities and proceeding to more severe abnormalities. According to The Bethesda System (TBS),¹ the former is classified as low-grade squamous intra-epithelial lesions (LSIL) and the latter as high-grade squamous intra-epithelial lesions (HSIL) (Campbell 1994; Schiffman and Brinton 1995). If abnormalities are not detected and treated, carcinoma *in situ* may develop, usually after age 35, followed by invasive cervical cancer usually seen in women after age 55 (**Schiffman** and Brinton 1995; McMeekin et al. 1997). **One-**third of all grades of SIL will regress, whereas 41 percent persist and 25 percent progress. Of lesions that progress, 10 percent progress to carcinoma *in situ* and 1 percent to invasive cancer (NIH 1996). The course of the disease is more rapid in HIV-positive women, for whom invasive cervical cancer is an AIDS-defining condition (Braun 1994; Stratton and Ciacco 1994).

Genital HPV infection is the most common sexually transmitted virus in the US. It is estimated that 40 million Americans are currently infected and that an additional three million are infected annually (**Kenney** and Reuss 1994). There is a demonstrated association between specific strains of HPV transmitted through sexual contact and the development of cervical abnormalities that culminate in invasive cervical cancer. However, it is unknown what percentage of women infected with HPV will develop

¹ **The 1988 Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnoses introduced the new term low-grade squamous intra-epithelial lesion (SIL) and high-grade SIL. Low-grade SIL encompasses cellular changes associated with HPV and mild dysplasia/cervical intra-epithelial neoplasia 1 (CIN1). High-grade SIL includes moderate dysplasia/CIN2, severe dysplasia/CIN3, and carcinoma in situ (CIS/CIN3) (CDC 1993).**

- The number of first-time female patients who *have not received a Pap smear elsewhere* in the past year, one to three years, more than three years, or never
- The number of female patients who *receive a Pap smear in the STD clinic*
- Whether or not the patient *changed contact information* after receiving education and counseling on cervical cancer
- *The length of time* it took to receive Pap smear results from reference lab (for each patient)
- The number of female patients with *normal Pap smear results*
- The number of female patients with *abnormal Pap smear results* (broken down by the Bethesda system)¹
- By result, the number of female patients *to get repeat smears* and the number of female patients to get *colposcopy*
- The number of *contact attempts per patient, the timeframe* of each contact attempt, and the *method of actual contact*²
- *The date when contacted* the patient with the result
- The number of female patients with abnormal results who were *referred by the STD clinic to further diagnostic services* (e.g., colposcopy)
- Whether these female patients went *to the first colposcopy appointment* or had to be *rescheduled*
- *when* the patient got the colposcopy (to compare with the date when contacted with result)
- The number of female patients referred for further diagnosis who have *conditions serious enough for further treatment*
- Whether these patients *got to the appointment* for treatment
- The *result* of the further treatment

¹ **Data on unsatisfactory slides should be broken down further in order determine, for evaluation purposes, whether it was due to infection or improper preparation of slide. Improper preparation of slide is a training issue, whereby the presence of infection is a feasibility issue of conducting cervical cancer screening in STD clinics.**

² **Include data on refusals and inability to locate patients.**

As alluded to earlier, STD clinics see a population of young, sexually active women who are at high risk of recurrent HPV infection, a group for which regular Pap screening could have a high return in early detection and prevention of cervical cancer. It is the early detection and treatment of precancerous lesions that will make the difference in preventing cervical cancer. Research suggests that screening in STD clinic settings reaches women who are unlikely to have been screened appropriately elsewhere in the health care system (Lyttle et al. 1985; Marcus et al. 1990; Schwebke and Zajackowski 1997). Women tested in STD clinics have a high proportion of abnormal Pap test results compared to those screened in family planning clinics (Lyttle et al. 1985). Prevalence studies have found that precursor lesions for cervical cancer occur approximately five times more often among women attending STD clinics than among women attending family planning clinics (CDC 1993).

Despite this compelling evidence, many STD clinics do not include Pap smears as a part of their routine service. For example, as part of site selection for this project, CDC conducted a survey of State Health Departments asking about the primary STD clinic in a large, medium, and small city in each state (see Section 2.1). Data were received on 47 STD clinics from 22 states and the District of Columbia. Of these, 22 reported that they offer Pap testing and 26 that they do not.

Opposition to implementing the service in such clinics often includes that (1) Pap smears obtained from women with lower genital infection are difficult to evaluate and often yield unreliable results, (2) there is a lack of resources for additional services in STD clinics, and (3) it is difficult to conduct **follow-up** of STD patients (Schwebke and Zajackowski 1997). These are important considerations because limited follow-up and treatment may curtail the effectiveness of early detection efforts for those women with severe dysplasia (Briggs et al. 1980; Campbell et al. 1994; Kamb et al. 1995).

Therefore, a key issue in conducting such screening programs is the need to perform follow-up with women who have abnormal tests. In one study, only 7.6 percent of women screened contacted the clinic as instructed for results (Tavelli et al. 1985). Through follow-up procedures the clinic was able to reach only 49 of 102 women with abnormal smears, in spite of a protocol that asked each woman to sign an agreement form stating that her address and telephone number were correct (Tavelli et al. 1985). Since an inability to successfully follow women with abnormal smears reduces the yield of cervical cancer screening programs in terms of cancers prevented, any program developed to address the screening of women in STD clinics must address the issue of tracking and follow-up.

In considering the cost effectiveness of screening women for cervical cancer, researchers noted that a key issue is whether more money should be spent on “enhancing the accuracy of Pap **smears**” or whether these resources should be used to “include a greater number of women in primary screening.” On

110-1000-1000

tracking, and following-up on women at high risk for cervical cancer and precancerous lesions in STD clinics; and (3) development of a budget estimate for the Phase 2 demonstration project.

1.3 First Phase Project Design

The design of the Phase 1 project was derived from a series of questions which the entire **three-**phase project seeks to answer. The research questions for the three-phase project are:

- Are STD clinics an appropriate location for identifying women who have not been screened in the past one to three years for cervical cancer?
- What challenges are associated with cervical cancer screening, follow-up, referral, diagnosis, surveillance, and education in STD clinics?
- When abnormal Pap results are reported, can the clinic assure that women receive appropriate diagnostic and treatment services?
- Would the addition of a comprehensive cervical cancer screening service in STD clinics have a negative impact upon the delivery of primary STD prevention, diagnosis, treatment, and epidemiologic services?
- What would be the overall economic cost of providing this additional service?

As part of the first phase, we visited nine STD clinics to explore the availability, adequacy, and usefulness of data elements in addressing these research questions. The information developed in the site visits forms the basis for the demonstration project protocol and budget estimate that will guide subsequent phases of the research.

The first phase of the project also included identifying likely sites for the demonstration project. Battelle defined criteria for choosing the nine STD clinics that were visited to obtain information for the design of the protocol. Of these nine clinics, a subset will be selected.¹ Battelle has included criteria in this report for choosing the clinics, but CDC will be responsible for selecting the sites and inviting them to participate in the second and third phases of the project.

¹ One option discussed was that the demonstration project would consist of four sites, two that are currently offering cervical cancer screening in the STD clinic and two that are not.

either LSIL or HSIL. There are several types of papillomavirus that vary in clinical presentation as well as level of oncogenicity. For example, HPV type 16 accounts for 50 percent of cervical cancer cases in the US. HPV type 16 together with types 18, 31, and 45 account for 80 percent of cervical cancer cases in the US. (Cox 1995; NIH 1996).

Papillomaviruses with little or no oncogenicity typically cause external genital warts, which are often diagnosed and treated (Holly 1996). Exophytic genital and anal warts are benign growths most commonly caused by HPV types 6 or 11. Other types present in the anogenital area (e.g. types 31 and 35) have been strongly associated with genital dysplasia and cervical cancer. These types are usually associated with subclinical infection, but occasionally are found in exophytic warts (Kenney and Reuss 1994).

By contrast, papillomaviruses associated with moderate-to-severe cervical dysplasia are not easily detected. However, if women are screened with a Pap test, the early stages of cervical intra-epithelial neoplasia can be picked up and treated. In this way, cervical cancer can be prevented by early detection and treatment of precancerous lesions. Since nearly 50 percent of cervical cancers in the US occur in women who have never been screened, and 60 percent of cases develop in women who have not been screened in the last five years, it seems clear that widespread or even periodic screening of all women could dramatically reduce the incidence of cervical cancer (McMeekin et al. 1997). Improvements in population-based coverage of Pap screening and effective follow-up of abnormal findings have invariably been associated with marked reductions in cervical cancer mortality. CDC has noted that, “although no clinical trials have studied the efficacy of the Papanicolaou (Pap) test in reducing cervical cancer mortality, experts agree that it is an effective technology. Since the introduction of the Pap test in the 1940s, cervical cancer mortality rates have decreased by 75 percent” (Henson, Wyatt, and Lee 1996).

Although Pap smears have been shown to significantly reduce the incidence of invasive cervical cancer and are relatively inexpensive to perform, false negatives and false positives are frequent (McMeekin et al. 1997). Even so, expanding screening programs to unscreened populations or screening selected, at-risk populations may be an appropriate measure to reduce the incidence of invasive cervical cancer. Yet, if this is to be done in a cost-effective manner, “it may be most practical to identify where these people go for medical care” (Greenwald et al. 1985). In the 1980s, Greenwald and co-authors found that many of the women at high risk of cervical cancer in New York State were attending emergency rooms. One purpose of the project reported here is to look at the feasibility of identifying women at high risk of cervical cancer who are not receiving screening at publicly funded STD clinics.

- Training of staff to use clinical guidelines and, for clinics that do Pap testing, training of various levels of staff to conduct this procedure
- Length of time of physical exam for women - without Pap smear, with Pap smear
- Location of reference lab and method for transporting slides
- Length of time for receiving results from the lab
- Method of contacting patients for all types of abnormal results, and specifically for abnormal Pap results
- Number of repeat smears conducted per year
- Protocols established for differential results
- Methods in place for getting patients to return due to unsatisfactory slides or need for repeat smears
- Clinical providers that women favor for reproductive health care
- Presence or absence of evidence that some women prefer, or are resistant to, cervical cancer screening in STD clinic
- Challenges and facilitating factors to carrying out these tasks

Research Question 3: When abnormal Pap results are reported, can the clinic assure that women receive appropriate diagnostic and treatment services?

- Procedures for follow-up of **STDs**, including staff involved and level of effort expended to find patients
- Procedures for referral of women with abnormal Pap test results
- Evidence of sensitivity to possible need to adapt procedures for different age groups or ethnic **groups**
- Evidence of a referral network (list of referral sources)
- Effect of patient's insurance status on referral source
- Presence of incentives to motivate women to follow up on referrals
- Protocol in place to protect clinic against liability or to encourage clients to follow up on screening results
- Record keeping or tracking system of referrals (e.g., database)

1.4 Research Questions and Data Elements

Five research questions were developed by CDC to be answered throughout the course of the three-phase project. An important goal of Phase 1 was to identify data elements to address these questions and to build indicators to be used in assessment of the demonstration project. Each research question presented in this section is followed by a list of data elements proposed to address it. This list was refined based on information obtained during the Phase 1 research.

Research Question 1: Are STD clinics an appropriate location for identifying women who have not been screened in the past one to three years for cervical cancer?

- Ability to obtain a medical history for sexual risk factors
- Type of record keeping and data included - such as number of women examined, whether patients have been screened in the past, ages of female patients, history of pregnancy
- Where women currently go (if they go) for cervical cancer screening
- Verification of patient's identity
- Factors that may affect the ability of a woman to get to the clinic - e.g., public transportation, hours of operation, need to pay, appointment, or walk-in
- Factors that may affect a woman's willingness to keep appointments or wait to be examined - e.g., ambience of waiting room and length of average wait, availability of child care
- Presence or absence of materials that **may** assist women in self-identification, such as attractive educational materials in the waiting room
- Training needed by staff to identify women who should receive cervical cancer screening
- Presence or absence of counseling with regard to cervical cancer risk
- Perceived challenges and facilitating factors to identifying women for screening

Research Question 2: What challenges are associated with cervical cancer screening, follow-up, referral, diagnosis, surveillance, and education in STD clinics?

- Type of staffing mix, including clinical supervision
- Type of clinical guidelines in use - STD, cervical cancer screening

- Costs associated with tracking women with abnormal findings
- Costs associated with follow-up
- Costs associated with referral

1.5 Organization of the Report

This report is organized to address the research questions presented in Section 1.4. Methodology of Phase 1 research is discussed in Chapter 2. Findings from the nine site visits, with cross-site summary tables, are presented in Chapter 3. Chapter 4 presents the issues to be considered and steps to be taken in implementing the demonstration project protocol, as well as step-by-step decision points for clinics to follow in planning, start-up, and implementation. Chapter 5 presents a framework for the demonstration project evaluation plan. The document also contains four appendices. These are the budget matrix (Appendix A), a glossary of terms (Appendix B), examples of forms and letters (Appendix C), and sample size estimates (Appendix D). A separate document contains the nine site visit reports.

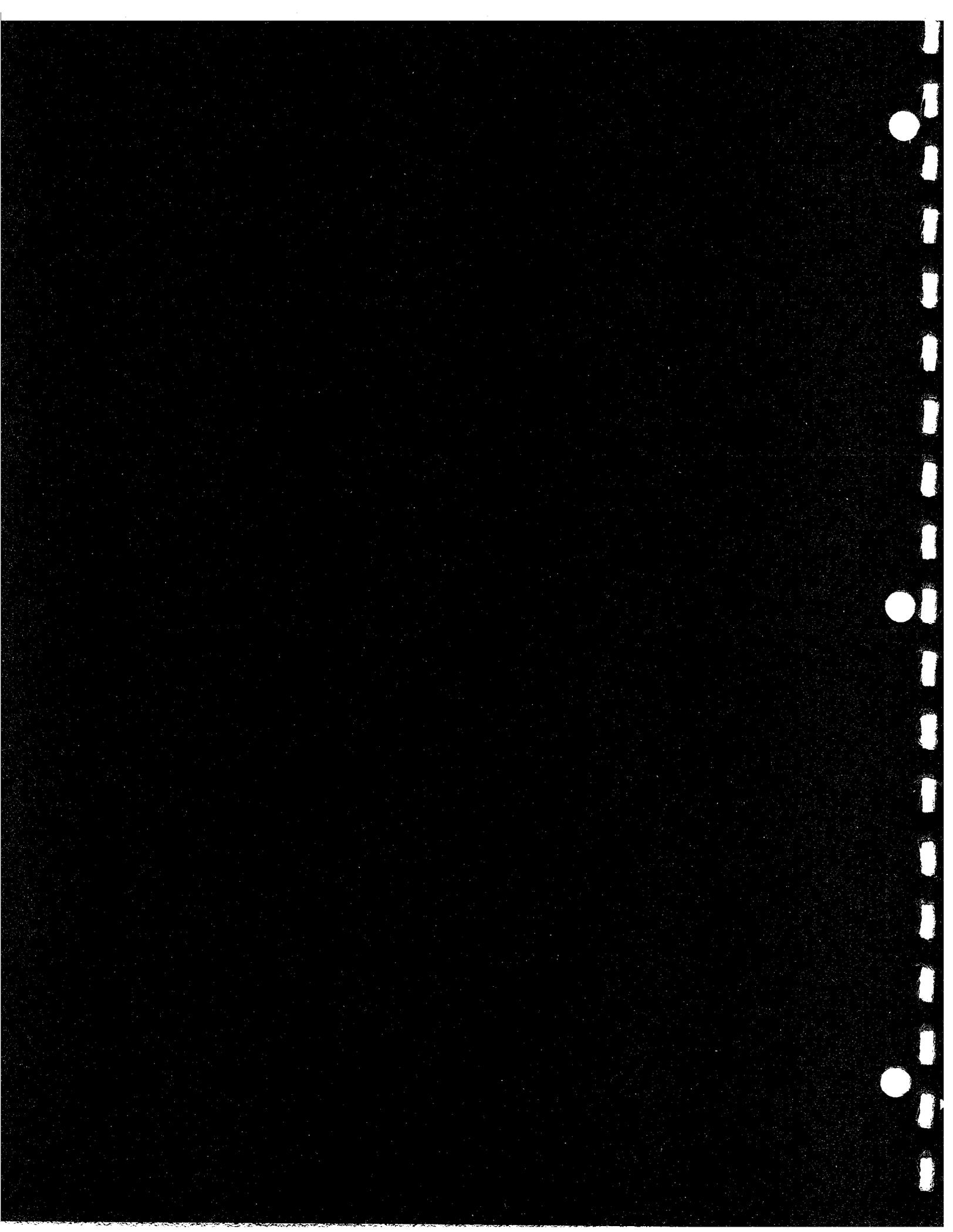
- Types of collaborations and relationships with other publicly funded or non-profit health care agencies
- Proximity of diagnostic and treatment services to STD clinic
- Presence or absence of in-service training for staff
- Challenges and facilitating factors with regard to making appropriate referrals and following up on results of referral

Research Question 4: Would the addition of a comprehensive cervical cancer screening service in STD clinics have a negative impact upon the delivery of primary STD prevention, diagnosis, treatment, and epidemiologic services?

- Overall view of the existing environment, especially clinic flow with and without Pap smears
- Services presently in place
- Prior experience with adding new services
- Perceptions of advantages and disadvantages of implementing new services (factors that make this easier and/or more difficult)
- Number of DIS (federal, state, local) assigned to the clinic and permanence of the assignment
- Presence or absence of other staff to do follow-up and counseling
- For clinics where cervical cancer screening is performed, factors associated with the decision to implement it
- Factors associated with the decision not to implement cervical cancer screening in clinics where it was considered but not implemented (or factors associated with the decision to *stop* conducting cervical cancer screening in clinics which once offered this service but no longer do so)
- Recommendations by clinics that do cervical cancer screening to clinics that are considering implementing this service

Research Question 5: What would be the overall economic cost of providing this additional service?

- Costs associated **with** screening in the clinic setting
- Costs associated with processing and evaluating the Pap smear slides



10 Minutes

- The clinic is a stand-alone STD clinic. This means that some portion of each week is devoted solely to seeing persons presenting for STD-related services. This does not mean that the clinic must be a full-time STD clinic, nor does it need to be located physically apart from other public health services.
- The clinic sees a high volume of female patients¹. We are interested in the number of individual patients examined at the STD clinic. The clinics were stratified by volume of patients in descending order within each city-size category. This was necessary to obtain an adequate number of female patients for Pap screening to be a worthwhile part of clinic services.
- The clinic is willing to provide cervical cancer screening as part of a national demonstration project that is likely to include intensive follow-up of women with abnormal findings.
- The clinic can provide the information needed to conduct the project, including patient demographics and a record of service delivery. It is easier to track services from clinics that use computer-based information systems. Clinics without computerized systems will be considered, but they must be able to collect this information in a systematic way. If clinics do not have this information, it must be possible to obtain the information from a local health department or other alternative source.
- The clinic does not have a contract with the State's Breast and Cervical Cancer Early Detection Program (BCCEDP) .

Table 2.1: Final Selected Site Locations by City Size and Current Pap Smear Screening Status

city Size	Pap Smear Screening Status	
	Yes	NO
Large (pop. 1,000,000+)	Brooklyn, NY (Fort Greene Clinic)	Memphis/Shelby County, TN
	Orange County, CA	Detroit, MI
Medium (pop. 200,000-999,999)	Wake County, NC	Norfolk, VA
		Clark County, NV
		Kent County, MI
Small (POP. < 200,000)		Norwalk, CT

¹ We did not assign a number of individual patients to be seen *a priori*. Rather, we asked CDC for information about the STD clinics in large, medium, and small cities reporting the greatest number of female patients in each state. These candidate clinics were ranked relative to each other and screened according to the other site selection criteria listed.

Once CDC and Battelle specified a set of eligible sites, the clinics were contacted to confirm their participation and to schedule a site visit. Again, Battelle contacted DSTDP and the Area Program Manager to apprise them of our choices and to ensure a good working relationship between the staff on site and our research team.

After all site visits were arranged, we sent each clinic a package of materials which included a letter confirming the dates and times of the site visit, relevant scheduling information, and a summary description of the goals of the project and site visit in a form appropriate for distribution to clinic staff. Clinic Directors and their staff were invited to call Battelle staff and/or the CDC Technical Monitor or DSTDP Project Officer with questions or concerns that arose before, during, or after the site visit.

2.2 Sample Selection

Battelle interviewed the following STD clinic staff:

- Clinic Director or Manager¹
- Medical Director or Physician-in-Charge
- Providers of clinical services
- DIS
- Follow-up or outreach staff
- Laboratory Manager

All of these people provided us with information that was specific to their roles in the clinic. At all sites, clinic staff gave us a walking tour of the facility, which allowed us to see the **lay-out** of the clinic and get a sense of the flow of operations. In addition to the clinic staff, we met with the STD Program Manager for the project area in which each clinic is located and/or the director of the local Health Department. These meetings provided us with general information about services offered at the Health Department. We learned how clinics operate as part of the Health Department, how decisions affecting the clinic are made, and administrative factors that affect the decision to offer cervical cancer screening in the STD clinic.

We also visited a family planning clinic and/or a colposcopy clinic at each location. Visiting these clinics allowed us to better understand the full range of services available to women in the community. Clinic staff with whom we met included the clinic Program Director or Manager, a clinical provider, and

¹ Some sites had a Program Director or Manager whose role was very similar to that of the Clinic Director/Manager. In those instances, we used the Clinic Director/Manager interview guide.

follow-up/referral staff. Staff members explained the relationship between the local STD clinic and the family **planning/colposcopy** clinic and the procedures involved in tracking and referring patients. We learned how women enter the system, how the referral system works, and finally how and when services are rendered.

2.3 Pilot Site Visits

A draft Research Plan was submitted to the CDC Technical Monitor and other identified CDC representatives on October 17, 1997. At the same time, Battelle submitted the instruments and the draft confidentiality agreement form to **Battelle's** Institutional Review Board (IRB) for human subjects approval. We received comments and incorporated all CDC feedback prior to the first pilot site visit, which was scheduled for November 1997.

Two of the sites were chosen as pilot sites', one where the STD clinic currently performs cervical cancer screening (Brooklyn, NY) and one where the STD clinic does not (Norfolk, VA). As a result of the pilot site visits, the research team incorporated the following changes:

- Interview guides were modified. The original instruments were too long to be useful in the clinic setting, especially while touring the facility. The length of the instruments was reduced, by focusing them specifically on each respondent's expertise and by reorganizing the order of the questions within the instrument to more accurately follow clinic flow.
- The registration clerk instrument was deleted. The interview guide for the clinic intake worker/registration clerk was not practical. We found that asking these respondents about their individual role in daily clinic operations during the tour of the STD facility was sufficient. Also, the clinic worksheet was replaced with a list of documentary data needed for each site.
- Additional interview guides were designed to use with new categories of respondents. The research team recognized the need to add additional respondent categories, such as Health Department laboratory director. By adding this respondent category, we alleviated the redundancy of asking all respondents about laboratory issues. In addition, we developed an interview guide to use in the event that we were able to talk to either a provider, a follow-up coordinator, or the clinic manager at a clinic to which women with abnormal Pap smear results are referred.

¹ **A pilot test is necessary for (1) assessing the ability of the project instruments to obtain the needed data, and (2) assessing whether the logistics for carrying out on-site project tasks need to be modified in any way.**

- Interviewing individual DIS or nurses was found to be quite time-consuming. As a result, DIS and/or nurse group interviews were scheduled when appropriate.
- A tour of the STD clinic flow was scheduled. The research team found this exercise very valuable. Through this process we were able to see how the STD clinic operations flow both with and without the addition of cervical cancer screening. We found that STD Clinic Managers and staff were more than happy to give us a tour of their facility.
- A courtesy visit with the local Health Department was scheduled at each site. Speaking informally with the Director of the Health Department and/or the Coordinator of **STDs** for the local health department was invaluable. These discussions provided the research team with critical information about the political, socioeconomic, and environmental factors that affect activities within the Health Department as a whole and within the STD clinic specifically. In addition, the Directors and STD Coordinators appreciated being briefed about the purpose of the project and given the opportunity to ask questions.

Findings from the pilot site visits regarding logistics and instrumentation were incorporated into a revised Research Plan along with comments received from CDC. The revised Research Plan was submitted to CDC on Wednesday, December 23. Given the substantive changes resulting from the pilot tests, Battelle re-submitted the Research Plan, instruments, and confidentiality agreement forms to Battelle's IRB for approval.'

2.4 Site Visits

As discussed in Section 2.3, two pilot site visits were completed in November and December of 1997. Seven site visits were conducted in the following locations in January 1998:

- Detroit, Michigan
- Grand Rapids, Michigan
- Memphis, Tennessee
- Las Vegas, Nevada
- Orange County, California
- Norwalk, Connecticut
- Wake  North Carolina

A project team of two Battelle researchers conducted data-collection activities. The two-day visit to each site consisted mainly of interviews, but it also included limited observations of clinic activities

¹ **In the Draft Research Plan, Battelle proposed to resubmit this package should significant modification be necessary after the pilot tests.**

conducted in public areas in order to get a sense of the general level of burden in the clinic. The schedule was generally the same at each site. Each visit began with a meeting with either the Health Department director or the program manager for the project area. This allowed us to become familiar with the health department as a whole and provided a context for the rest of the interviews. Next, we described our data collection activities to the clinic management and any available staff (considering their patient care **commitments**) in the STD clinic. We then spoke with the Clinic Manager about management of the clinic, services, staffing, funding, and record-keeping. After this interview, we usually received a tour of the clinic, including the reception and waiting area and examining rooms. We subsequently spoke with the Medical Director or Physician-in-Charge, followed by other providers such as physicians and nurses. Next, we met with a group of DIS staff, and we ended the day speaking with the Laboratory Manager.

The second day, we visited the family planning clinic, local Planned Parenthood, and/or the colposcopy clinic where patients from the STD clinic are referred or which has a clientele similar to that of the STD clinic. Contacts with such clinics were made before entering the field, although we left open the possibility of exploring a promising lead when in the field or by telephone after returning from the field. At these clinics we spoke with the Clinic Manager, clinical provider, and the person responsible for referrals and follow-up. We also received a brief tour of these clinics.

Table 2.2 presents the list of instruments used in this study.

2.5 Data Collection

Battelle conducted two-day site visits to each of the nine STD clinics selected according to the method described in Section 2.1. Some time was also spent (1) reviewing relevant program documents **on-site**, (2) visiting one or more family **planning** clinics or other settings serving women similar to those of interest to this project, and (3) visiting local diagnostic referral sites. Logistics for initiating these visits were discussed with STD Area Program Managers and STD Clinic Managers.

We conducted semi-structured, open-ended interviews, either with individuals or in group settings. During interviews, one researcher asked the questions while the other took notes and probed when necessary. Some interviews were audio tape recorded, but only after the respondent consented to this procedure. These recordings were not transcribed but were used as back-up, so that the interviewer could listen to them in case any responses were unclear. All respondents were informed of the confidentiality of their responses and were asked to give consent to be interviewed.

Table 2.2 Instruments/Respondents

Interview Instrument	Respondent Category	Purpose of Interview/Observations	Number Interviewed
Instrument Ia, Ib	STD Clinic Program Manager	-Clinic operations and flow -Impact of Pap testing on clinic flow -Impact of other new services	9
Instrument IIa, IIb	STD Clinic Medical Director	• Clinic operations - Clinical considerations - Impact of Pap testing on clinical services • Impact of other new services	8
Instrument IIIa, IIIb	STD Clinical Provider	• Clinical considerations - Impact of Pap testing or past experience with new services	9
Instrument IVa, IVb	DIS/PHA, Cervical Cancer Screening	- How follow-up is done - Impact of adding Pap testing - Experience with adding other new service	11
Instrument Va, Vb	STD Follow-up Person/ Health Educator	• Specifics about follow-up of women or abnormal Pap tests	7
Instrument VIa	Family Planning Clinic Program Manager	- Follow-up issues for women who need Pap smears or who have had abnormal Pap smears	7
Instrument VIb	Family Planning Clinical Provider	- Clinic issues - Follow-up issues	7
Instrument VIc	Family Planning Clinic Follow-up person/ Health Educator	• Follow-up issues • Knowledge of women's KAB	3
Instrument VII	Laboratory Manager- Cervical Cancer Screening	- Impact on workload of doing additional Paps - System for getting results to STD clinic	9
Instrument VIII	Dysplasia/ Colposcopy Clinic	- System for getting referrals from STD clinic	3
Instrument IX	STD Clinic Observation Guide	- Available transportation - How clinic is set-up (e.g. more than one waiting room, on-site lab, educational materials)	9
Instrument X	Documents to Request	- Forms, protocols/guidelines, education materials	9
Total Number Interviewed			73

In order to minimize the burden of on-site data collection, we compiled some information from existing records or data bases maintained at STD clinics. These included (1) clinic daily censuses, (2) numbers of women seen on a weekly, monthly or annual basis, (3) demographic information on the patient

population, and (4) data on services offered and to whom. From clinics that currently offer cervical cancer screening, we tried to obtain information from clinic records on (1) the number of women who receive Pap smears and (2) number of abnormal Pap smears.

2.6 Data Management

Site visit and documentary data were used to support the completion of the feasibility assessment and guided the development of the demonstration project protocol and cost-estimation model. While on site, each researcher reviewed the data collected each day and made marginal notes concerning the context and details of the interview. For interview data, each researcher was responsible for seeing that written interview responses were entered into word-processed files. Any sections that were incomplete or unclear were clarified by review of the audio tapes. The completed field notes were used by one member of the field team to write a summary report on each site. The summary reports were then passed to the other member of the field team for clarification and comprehensiveness. The nine site summaries guided the project findings and development of the demonstration project protocol.

2.7 Data Analysis

It is important that key issues be addressed across all informants in each site and across all sites, in order to develop a logical basis for assessing whether replication of a finding has occurred (or failed to occur). The comparability of observation is preserved by carefully adhering to a tested research plan during data collection, so that analysis can be conducted with reasonable confidence that investigators have looked at comparable things in all sites. The analysis process had three steps:

- Create an outline of key points to be addressed, based upon the project objectives,
- Write an individual summary of each site using the outline as a basis for organization, and
- Use the individual summaries to write the report and demonstration project protocol.

We wrote nine individual site summaries based upon the outline of key points/findings. Each summary was organized by the same categories, facilitating comparison of findings across sites. For example, one section contained the findings on the follow-up procedures of women with abnormal Pap test results; another contained the findings on laboratory procedures. We then were able to organize the data by topic across all sites, noting similarities and differences. The topical organization also allowed tests of

pattern replication by comparing sets of topical reports. It was on the basis of this cross-site topical set of findings that we developed the protocol contained in this report.

2.8 Data Quality Control

Data quality control considerations in a project like this one include reliability (**reproducibility** of the results), construct validity (correct operational definition of observations), and external validity (generalizability). The most serious threats to reliability come from uneven administration of the research plan. This is a question of quality control of the data collection. For this project, we have done our best to minimize deviations from the research plan in the field, using a core team of researchers, each of whom visited six of the nine sites. We are reasonably certain that data collection in all of the sites, including pilot sites, was similar enough that it does not bring the findings into question.

Accurate operational definition of the project (external validity) relates to whether we looked at the right things to answer the research questions. Did we talk to the right people, and did we ask them the right questions? What proportion of the “right people” did we interview? Would the results have been appreciably different if we had talked to different people at these sites or if we had collected different data from the same people?

We are confident that we collected the correct information to address the research questions and that we were thorough in data collection from all sources. We sought input from CDC and from knowledgeable researchers in other institutions in conceptualizing our project and in accessing existing sources of data on the project topic.

Generalizability of this study to other settings depends on the bias introduced by site selection and is linked to the clarity of the site selection design and the rigor with which it was carried out. It was to protect generalizability that we were careful to specify criteria for site selection prior to identifying any specific sites for data collection. The site selection criteria were outlined in Section 2.1.

2.9 Development of a Demonstration Project Protocol

Battelle developed a protocol for a demonstration project to be carried out in publicly funded STD clinics. The demonstration project protocol outlines how STD clinics will implement cervical cancer

screening following accepted guidelines. It also sets up data requirements for analyzing the results of the demonstration project. Factors to be assessed during the demonstration project include:

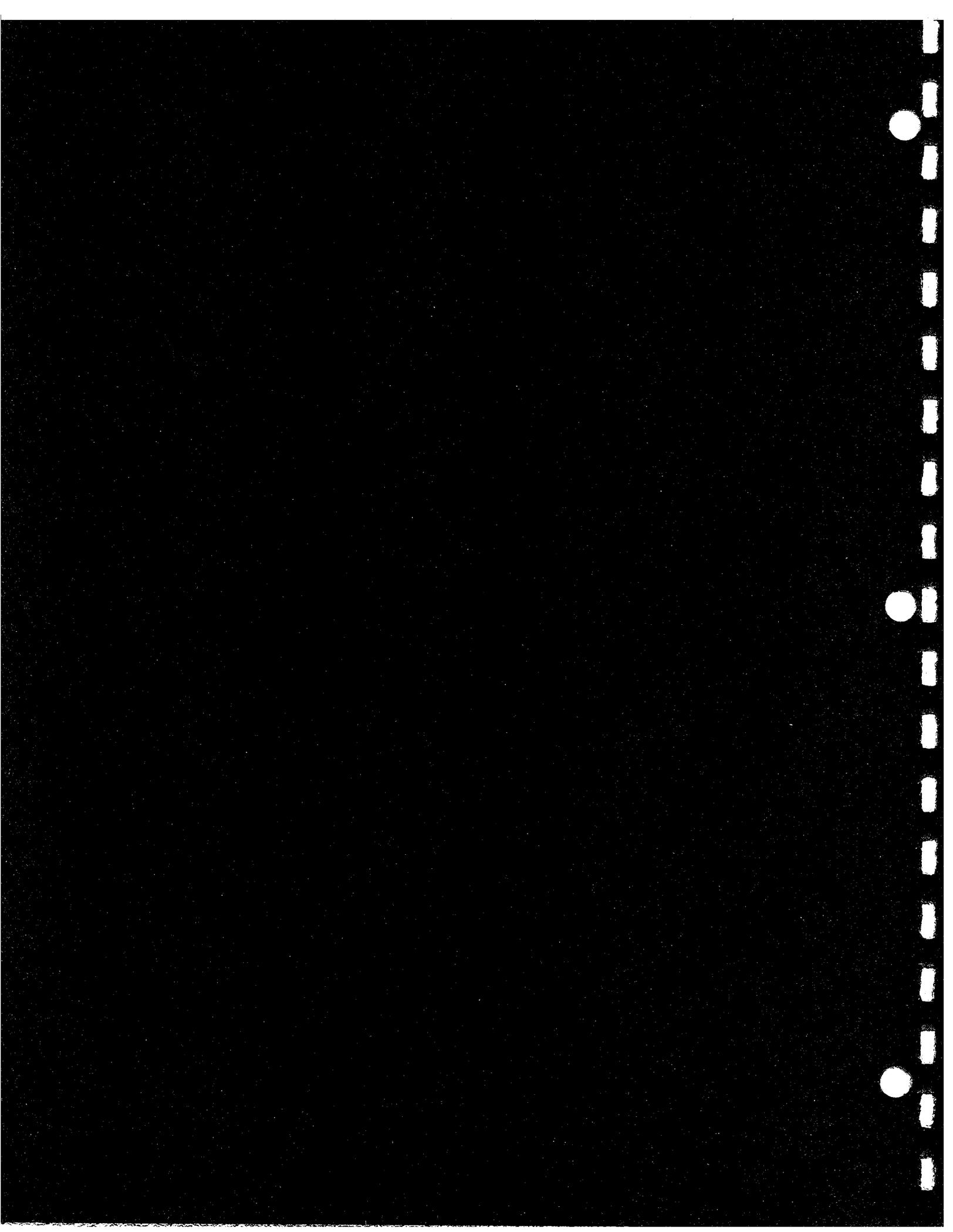
- The proportion of women who qualify for Pap testing in the STD clinic,
- What other sources of care women access (if at all) for Pap testing,
- The impact of cervical cancer screening services on STD clinic flow,
- The proportion of women with abnormal results (broken down by results category, age, and **race/ethnicity**),
- The ability of the STD clinic to refer women with abnormal findings, and
- The ability of the STD clinic to assess whether women who are referred actually get to the referral site, need further treatment, and receive treatment.

The protocol begins with planning for initiation of cervical cancer screening, but STD clinics that currently do Pap testing should assess their level of service and use the protocol as a basis for enhancing present services, particularly follow-up and referral of women with abnormal findings. For those clinics that do not currently provide cervical cancer screening services, the demonstration project takes steps needed to establish the services as well as to monitor follow-up and referral. The protocol design allows for flexibility needed to address specific needs of participating clinics. However, the design guarantees a core of standard practices and data management to support analysis and assessment across sites.

As part of Phase 1, Battelle developed a cost calculation procedure to produce a cost-estimation model for implementing the demonstration project. The estimation procedure is adaptable-to individual STD clinic volume, the clinic's stage in the process of establishing cervical cancer screening services, and the overall staffing mix within the facility. Battelle obtained estimates of the volume of patients screened for cervical cancer at the STD clinic and an estimate of the unit cost required to conduct those activities.

Following submission of the draft demonstration project protocol and cost-estimation model, Battelle met with the Project Officer, Project Staff, and the Technical Monitor at CDC to discuss findings and recommendations. CDC representatives reviewed the draft document and provided comments. Battelle incorporated comments of CDC staff into the Final Report and Demonstration Project Protocol.

30 Pages



3.0 Findings

In this chapter, we will present selected findings from the nine sites we visited and discuss the relevance of these findings to the project as a whole. A full description of the sites is contained in a separate document, “A Project to Assess the Feasibility and Need for Support of Cervical Cancer Screening in Public STD Control Clinic, Site Reports.”

3.1 Cross-Site Analysis

A cross-site presentation of selected findings can be found in three tables in this chapter. Table 3.1 contains the three sites in which the public STD clinic currently conducts cervical cancer screening. Tables 3.2 and 3.3 contain three sites respectively, in which the STD clinics do not currently conduct cervical cancer screening. This chapter moves beyond presentation of data to a discussion of the importance of the findings to the development of the demonstration project protocol and subsequent evaluation.

The issues discussed in this section include:

- the number of female patients visiting the STD clinics
- the information gathering and processing ability (and needs) of the STD clinics
- the staffing patterns, needs, and training requirements for cervical cancer screening in STD clinics
- the existing or needed relationships with a cytopathology laboratory
- the current practices and additional needs regarding patient education and counseling
- the current practices and additional needs regarding patient tracking, follow-up, and referral

3.1.1 Number of Female Patients Seen in STD Clinic

The site reports (see separate document) and the cross-site tables (3.1, 3.2, and 3.3) contain the data we were able to collect on the number of female patient visits in each of the nine public STD clinics. In the STD clinics located in large metropolitan areas (Brooklyn, Memphis, Detroit, and Orange County), the average number of patient visits per month ranges from 945 to 1,929. Even in the clinic that saw

1,929 patients in a month, approximately 30 percent either wanted only HIV tests and were not examined or wanted only education, information, or prescriptions. This demonstrates that not all patients counted in a clinic's census are actually examined.

In the STD clinics located in medium-sized cities (Norfolk, Kent County, Las Vegas, and Wake County), the average number of patient visits per month ranged from 210 to 625. In the STD clinic located in a small city (Norwalk), the clinic sees about 70 STD patients per month, almost all of whom are examined,

The gender distribution of patients in all clinics except Clark County is 60-65 percent male and 35-40 percent female. In Clark County, the split is around **50/50** male and female. The higher relative percentage of females to males in Clark County is most likely explained by the large number of legal prostitutes that come to the STD clinic for mandatory weekly and monthly **STD/HIV** testing.

The important factor is the number of *female* clients who are *examined* in each STD clinic per month. It is the female clients coming into the STD clinic for a full STD examination who will be most likely to receive cervical cancer screening. However, female clients coming into the clinic for other reasons, such as HIV testing, should also be offered a Pap smear and given information on its importance.

One more variable must be considered in this regard: the percentage of female clients who are first-time visits relative to those who are repeat visits. The STD clinic will, over the long run, perform Pap smears only for first-time clients, since after an introductory period repeat clients will have already been screened. The only STD clinics where we obtained data on the percentage of clients who are **first-time** visits rather than repeats are those currently conducting cervical cancer screening. There is some site-specific variability in this indicator also. In Brooklyn, for example, the percentage of-repeat visits is around 11 percent, while in Orange County and Wake County the percentage of repeat visits is around 60 percent. However, different clinics define the terms "first time" and "repeat" differently. For purposes of the demonstration project, first time visit will be defined as the first visit the patient has made to the STD clinic in the past 12 months.

In summary, approximately 40 to 90 percent of patients are first-time visits. We do not know the distribution of this between men and women, but we will assume that they are equally distributed. Also, women make up 30-50 percent of STD clinic clientele. Other issues will have to be addressed in this regard, including whether first-time female patients also see either private providers, Planned **Parenthood**, or are family planning clients, and are therefore likely to be already receiving cervical cancer screening services in those places. These questions can be answered during the evaluation of the proposed demonstration project.

3.1.2 Information Gathering and Processing Ability

There is wide variability in the methods of information collection and management among the STD clinic sites. The comprehensiveness of data/information systems does not necessarily correspond to whether or not the STD clinic does Pap smear screening. For example, the clinics with the most advanced computerized information systems are Detroit and Norwalk, neither of which does Pap smear screening. Among the clinics offering Pap smears, the information systems contain most of the data that would be needed for evaluation purposes, but certain aspects could be improved or better systematized. **In addition,** some clinics keep most patient information in handwritten charts and use the intake forms to either find the patient's existing chart or create a new one. While these clinics most likely would not need to adjust their systems appreciably in order to implement cervical cancer screening, for purposes of evaluation of a demonstration project they would need **to** gather and manage patient data in a more systematic manner.

A site such as Detroit, where a computerized information management and follow-up system is in place, would need only slight modification to incorporate cervical cancer screening. In a site such as Orange County, where comprehensive information on cervical cancer screening is collected, the need would be for methods to organize and manage those data. Some other sites that have no comprehensive data collection would need to develop alternatives for data management. One option to consider is based on the fact that all private reference labs that handle cytopathology processing and evaluation have advanced computerized information systems. Relationships could possibly be developed to utilize their systems in conjunction with the STD clinic information system. Also, in some sites where the STD clinic keeps patient information in handwritten charts, their central laboratories have computerized systems containing all test results (even those from outside labs).

Sites that do not have computerized information systems should not have to develop them in order to be able to gather and manage the appropriate data for a demonstration project and evaluation. These data can be gathered by hand. However, some clinics would have to develop ways to take the important information out of patient charts and lab reports and manage them in a central database **so** that they can be used for evaluation purposes.

3.1.3 Staffing Patterns, Needs, and Training

Staffing patterns in the STD clinics correspond to certain functions: intake; education and counseling; examination; and tracking, follow-up, and referral. Education and counseling and tracking, follow-up, and referral will also be discussed in later sections of this chapter. The discussion of these functions in this section relates specifically to staffing.

Staffing for Intake

In all the clinics we visited, patient intake is conducted by clerical staff. In Orange County, additional intake before examination is done by the communicable disease investigators (**CDIs**). Also, in most clinics the nurses, nurse practitioners, or physicians responsible for examinations do some level of intake relating to patients' medical histories. For a cervical cancer screening demonstration project and evaluation, intake is a very important step in the clinical process. It is important to obtain accurate information from the patient regarding whether or not she has had a Pap smear taken in the last year, one to three years, or over three years, and to obtain accurate contact information to facilitate follow-up. One idea is to ask the patient to confirm her contact information after she has received education on the importance of follow-up in preventing cervical cancer. At this point, if the patient has provided inaccurate information at intake, she can correct it. Therefore, the staff member providing post-exam education would have to coordinate with the intake person to make sure patient records are accurate.

Staffing for Education and Counseling

In all clinics, staff who conduct the exams provide patient education and counseling during or after the exam. In Detroit, disease intervention specialists (**DIS**) provide additional education and counseling for all patients after the exam. In Orange County, as mentioned above, **CDIs** provide education and counseling prior to the exam. (The **CDI** is the position equivalent to **DIS**.) In many of the other clinics, **DIS** provide additional education and counseling for patients who test positive for syphilis, gonorrhea, and sometimes HIV. Because Pap smears are part of a screening program, comprehensive patient education regarding cervical cancer, Pap smears, colposcopy, and other related issues is critical for convincing the patient of the importance of complying with follow-up recommendations.

Staffing for Examinations

The staff who conduct examinations in STD clinics include **RNs**, Nurse Practitioners (**NPs**) or Advanced Practice Nurses (**APNs**), physicians, and Physician Assistants (**PAs**). Our respondents varied in their opinions of which staff members would be qualified to conduct Pap smears. For example, in Brooklyn and Orange County, exams (including Pap smears) are conducted by physicians, while in Wake County exams and Pap smears are done by **RNs**. Some of our respondents expressed the opinion that **RNs** should not do Pap smears and that it should be the responsibility of **NPs** or physicians. In Clark County we were told that the State of Nevada Board of Nursing does not allow **RNs** to do Pap smears, but the STD clinic there is switching from **RNs** doing exams to having a PA and an NP. In summary, there is not agreement among our respondents as to whether it is appropriate for **RNs** to do Pap smears, but among those who believe that it is acceptable, there is consensus that **RNs** need additional training to learn proper clinical technique and to have the knowledge necessary for comprehensive patient education on cervical cancer. There is consensus that interpretation of Pap smear cytopathology findings should be done by an NP or physician, not by an RN, and that clinical follow-up decisions based on those findings should be made by someone with more advanced training than an RN.

Staffing for Tracking, Follow-up, and Referral

There was general agreement across all sites that tracking, follow-up, and referral should be done by public health nurses or a combination of **PHNs** and DIS. The DIS we interviewed do not appear to feel qualified to be the contact point for patients calling about abnormal Pap smear results or to provide detailed information on results in the field. The role of DIS in cervical cancer screening, if any, would be to locate patients with high-grade abnormal results who do not respond to letters and phone calls. For example, a nurse would be responsible for making telephone calls and sending letters to patients with abnormal results, and DIS would be called upon only after the initial attempts have failed. However, DIS told us that they would need additional training on cervical cancer, Pap smear screening, and colposcopy, and they still would not want to do much more than find patients and bring them into the clinic so that a nurse or physician could talk to them. Some respondents, including some nurses and DIS, said that even the function of visiting patients at their homes should be the responsibility of nurses, since they would be better able to explain the condition and need for follow-up.

3.1.4 Cytopathology Laboratory

From our site visits, we gained the impression that it would not be difficult to establish connections between the STD clinics and a cytopathology laboratory for processing and evaluating Pap smear slides. In sites where the STD clinic is not currently doing Pap smears, all but two have family planning programs on-site that offer Pap smears and already have a contract with a cytopathology lab. In all of these sites, respondents in the family planning clinics said that the external lab contract is not specific to the family planning clinic, but instead to the Health Department, and the STD clinic could piggyback onto the contract with little difficulty. In the two sites where the Health Department does not operate Title X family planning services, other local sources provide those services. We did not gather data on the presence of BCCEDP services in the sites, other than to confirm that the STD clinics were not receiving any funding from BCCEDP, but these programs would also have established relationships with cytopathology laboratories. In any of these cases, the STD clinic could establish a contract with the same cytopathology lab as those providers or could go with a different lab. Either way, establishing these contracts was not seen by our respondents as an insurmountable obstacle.

In the majority of sites where the Health Department has a contract with a cytopathology lab, the contracted lab provides Pap smear supplies (e.g., cytobrushes, spatulas, slides, fixative, etc.) as part of the overall cost. In all of these sites, the labs charge clinics per slide processed, Costs for this service ranged from ~~\$5-~~\$11 per slide, but averaged around \$8.

3.1.5 Education and Counseling

As mentioned in the section on staffing, some level of patient education and counseling is provided by staff who conduct the examinations. In certain clinics, additional education and counseling are offered by **DIS/CDIs** either before or after exams. DIS often give additional education and counseling to patients who test positive for syphilis and/or gonorrhea.

There is not much difference in the methods used to deliver education to patients between the STD clinics that provide cervical cancer screening and those that do not, except the additional coverage of cervical cancer screening issues. In two of the three STD clinics that provide Pap smears, physicians conduct the exams, and they also provide the education. In Wake County, however, the exams and Pap smears are done by **RNs** and an NP. According to our respondents at this site, the **RNs** and the NP provide somewhat different levels of education to patients. We were told that the NP gives full,

comprehensive education about cervical cancer and the screening process, but the RN with whom we spoke said that she does not provide as much education because she is not comfortable with her level of knowledge on the subject. This speaks to the issue of staffing and the need for training.

In the literature and among the people we interviewed, there is agreement that patient education is important in a cervical cancer screening program. This may be especially true in an STD clinic, which lacks continuity of care. Many respondents told us that patients in STD clinics seek care because of a pain or open lesion, or because of contact with an infected person, just want to get the infection treated, and do not want much contact with the clinic after the problem is alleviated. Therefore, it is difficult to convince patients to come back for referral to further diagnosis. These findings suggest that education and counseling of patients in the clinic at the time a Pap smear is taken is very important. The clinic staff must convince the patient of the importance and value of consistent Pap smears and that follow-up of abnormal Pap smear results can prevent cancer, and they must alleviate any patient confusion about the meaning of the various procedures she may have to endure. A sufficient level of education could increase compliance among STD clinic patients who have abnormal Pap smear results.

Numerous respondents suggested that, in addition to any education and counseling provided by clinicians during the exam, an STD clinic that implements a cervical cancer screening program may want to hire an additional staff member for a case management role. Most respondents felt that a public health nurse (RN with specific training and public health experience) could fill the case manager position. A case manager could combine the responsibilities of education and counseling about cervical cancer screening with responsibilities for tracking, follow-up, and referral. In this way, patients would interact with one staff member throughout the process, and the resulting rapport might facilitate patient compliance.

3.1.6 Tracking, Follow-up, and Referral

In most STD clinics that do not offer cervical cancer screening, DIS (or CDI or PHA) handle most of the tracking, follow-up, and referral. Most follow-up activities in STD clinics involve contact tracing and partner notification for syphilis, gonorrhea, and possibly chlamydia and/or HIV. The potential role for DIS in tracking, follow-up, and referral within a cervical cancer screening program was discussed in the section on staffing.

As mentioned in the previous section on education and counseling, most of our respondents felt that nurses should be responsible for follow-up activities. Some respondents said that the actual clinical referral should be written by a physician, but the physician would not necessarily have to be employed full-

time by the STD clinic. For example, a physician from a family planning or other program within the Health Department could consult a certain number of hours per week to check the charts of patients with abnormal Pap smear results and write the referrals for further diagnosis or treatment.

Also mentioned earlier is the idea that a clinic nurse could take on the role of case manager. In Orange County, a public health nurse (PHN) allocates half to three-quarters of her time to tracking, follow-up, and referral for patients with abnormal Pap smear results. Also in Orange County, the Health Department's colposcopy clinic has a full-time case manager who handles further scheduling, follow-up, education, and referral. In this site, the PHN works with the case manager in the colposcopy clinic to make the patient's colposcopy appointment. The case manager in the colposcopy clinic is then responsible for making sure the patient gets to her appointment and to further services if needed.

In Wake County, the NP in charge of the Pap screening program in the STD clinic handles all aspects of tracking, follow-up, and referral. In this site, most referrals for colposcopy are made to the Women's Clinic within the Human Services building, while high-grade cases are referred to Wake Medical Center next door. It takes several weeks to be seen at the Women's Clinic, but high-grade cases can be seen at Wake Medical Center within two or three days. Once the referral has been made, it is up to the case managers in the colposcopy clinics to make sure the patient gets to her appointment. Information on these appointments is sent back to the STD clinic to be included in the patients' charts, but we are unsure of the level of detail of this information.

In Brooklyn, responsibility for tracking, follow-up, and referral is shared among a Public Health Advisor, an epi clerk, and DIS. Patients with abnormal results are asked to return to the STD clinic to receive a referral. Clinic staff provide that patient with a list of referral sites and it is up to the patient to make the appointment. Whether or not a confirmation that the patient kept her follow-up appointment is sent to the STD clinic depends on which referral site the patient chooses, although the STD clinic gives each patient a self-addressed stamped envelope for the referral clinic to use to send results back to the STD clinic.

3.2 Linking Indicators to Research Questions

The goal of Phase 1 of this project has been to gather information about the nine sites to facilitate the demonstration project site selection and to facilitate development of the demonstration project protocol. The research questions and data elements (see Section 1.4) were used in Phase 1 to develop the data

collection instruments and analysis plan. Full answers to the research questions and data elements will be developed by the demonstration project. In this section, we will present some of the issues raised in the site visits regarding these research questions and data elements and relate them to the demonstration project.

3.2.1 Ability of STD Clinics to Identify Women Who Have Not Had a Pap Smear in the Last Year

Gathering correct patient information at intake in the STD clinic is important for two reasons. First, accurate information will be needed for informing patients of their Pap test results and for the referral process for patients who have abnormal results. Second, it is needed for evaluation of the demonstration projects.

Currently, all the STD clinics we visited have intake procedures for gathering the information needed to report STD test results to the patient and to find the patient if necessary. These STD clinics usually collect such information as the patient's name, address, telephone number, Social Security number, place of employment, and emergency contact person/number. The only clinic we visited that requires patients to produce identification is Detroit. In Las Vegas, the STD clinic requires identification only from patients who return for HIV test results and have forgotten to bring the appointment card given to them after the test was taken. Most other clinics do not require ID verification of intake information.

DIS in several STD clinics told us that, even if a patient gives false information on the intake form (such as a false name or address), usually one piece of information on the form is correct. For example, a patient might give the correct Social Security number or mother's name and telephone number as emergency contact, even while giving a false name and address for herself. DIS said they usually are able to find patients based on at least one field in the intake form.

Respondents in two different sites said it would be a good idea to ask the patient to confirm or change her personal information after she has received education and counseling on the importance of follow-up for cervical cancer screening. After the patient has been informed of the need for further diagnosis to prevent cancer if the Pap smear results are abnormal, she may be more likely to provide correct information than if she were there only to have an STD treated.

The extent of the patient information gathered and the way it is managed varies by clinic. The clinics that currently offer cervical cancer screening collect the necessary information for managing the program, but in some, the methods of data management will need to be updated for evaluation purposes. In the clinics that do offer cervical cancer screening, only Detroit and Norwalk have computerized systems

that could easily be adapted for evaluation needs. Other clinics will have to develop methods,' whether electronic or manual, to collect and manage the information needed for evaluation of the demonstration project.

Use of the intake information to identify female patients who should receive cervical cancer screening does not appear to be difficult. The only problematic aspect is the patient's ability to provide an accurate self-report of past Pap smears. Clinic personnel in every site told us that women often believe they have received a Pap smear when they have actually only had a pelvic exam. STD clinics will need to go beyond initial written self-report to be more sure of the patient's actual past Pap smear status. One example is the method used by Orange County's STD clinic, which has a field on the intake form where the patient indicates whether or not she has had a Pap smear in the past year. The clinic does not rely solely on this initial self-report. Patients then speak with a communicable disease investigator (CDI) prior to the exam, and the CDI asks additional questions about Pap smear history to more clearly confirm the accuracy of the patient's self-report. At the time of exam, the physician also helps confirm whether or not the patient had a Pap smear,

Based on information gathered from the patient at intake and on pre-exam confirmation, **the** examining clinician should be able to decide whether a Pap smear is indicated. Questions provided in Chapter 5 may assist clinics in making this determination. However, in order to more accurately answer the first research question, demonstration site clinics will need to differentiate whether a woman has received a Pap smear in the last year, one to three years, three or more years, or never. Clinics should also attempt to validate the self report of women who claim to have received a Pap smear in the last year. More detail will be provided in Section 4.2.1 on how to do this.

A concern was raised by multiple respondents, both in STD and family planning clinics: even though **RNs** may be capable of performing Pap smears, they should not make the clinical decision NOT to do a Pap smear based on anything other than what is stated in the written clinical protocol. This stresses the importance for clinics considering a nurse-examiner model to utilize a very detailed clinical protocol with clear decision points.

The other important consideration when determining whether STD clinics are appropriate places to identify women for cervical cancer screening is the education, counseling, and case management procedures and their ability to facilitate patient compliance. Providers in many of the STD clinics we visited said that female STD patients just want to get in, get tested and treated, and get out, without any substantial involvement in the STD clinic. In order to raise the likelihood that female patients will respond to notification of abnormal results and follow referrals, the clinic will have to evaluate its education,

counseling, and case management procedures to see if they are sufficient to convince the patient of the importance of follow-up.

Most of the clinics we visited were not able to quantitatively report their success in contacting and referring patients with abnormal Pap smear results. In Orange County we were told that approximately 20 percent of women with abnormal Pap smear results are unreachable by normal channels and that the clinic sends a public health nurse to the patient's home to notify her and bring her to the clinic. However, they did not report the level of success with this method. Also, this final step is taken only with high-grade test results.

Any clinic involved in the demonstration project will have to plan its education and counseling procedures with the goal of convincing women of the importance of compliance. It will have to implement a case-management and follow-up system that will raise the likelihood of compliance. Also, for purposes of the evaluation, each clinic in the demonstration project will have to implement accurate methods to track and provide data on the success of each of these steps.

3.2.2 Challenges Associated with a Cervical Cancer Screening Program in STD Clinics

The main challenges identified for implementing cervical cancer screening in STD clinics include: (1) deciding which staff members will be responsible for taking the Pap smears, the training they will need in order to do so, and the clinical guidelines they will follow; (2) the time requirements of adding Pap smears to the STD exam and the time it takes to receive test results from the cytopathology lab; and (3) deciding when a patient should have a repeat Pap smear versus a colposcopy and deciding where those procedures should be done.

As mentioned earlier, opinions differ on whether or not **RNs** should take Pap smears. Evidence from our site visits, that shows that **RNs** are capable of carrying out this procedure with the proper training and supervision, indicates that the decision should be left to the clinics. However, in the one site we visited where **RNs** do Pap smears in the STD clinic, it appears that they are able to take the smear but not all are fully comfortable with providing comprehensive education regarding cervical cancer. Because of the importance of proper education to patient compliance, clinics that want to follow a nurse-examiner model will have to put substantial effort into training and mentoring nurses on the techniques of taking Pap smears and preparing the slides as well as on the etiology of cervical cancer and all the procedures used to prevent, detect, and treat it. However, all providers will need some additional training unless they are board-certified gynecologists or gynecologic **NPs** with current skills and knowledge.

Every clinician we spoke with who performs Pap smears told us that the act of **taking the** smear adds an insubstantial amount of time to the clinical exam. Including the additional education provided during the exam on cervical cancer screening and Pap smears, the addition of Pap smear screening to STD exam procedures should not cause any delay in processing patients through the STD clinic.

The time it takes to receive Pap smear results from the cytopathology lab ranged from two days to two weeks. It is better to receive test results as quickly as possible, for two reasons. **The first is the** reported transient nature of many STD patients. The longer the clinic has to wait for lab results, the more difficult it may be to find and contact the patient with the results. Second, some clinics may ask patients to call in for results, and the longer the patient has to wait, the less likely she will call. Because of this, if the cytopathology lab with which the STD clinic establishes a contract takes longer to return results, the clinic may not want to have patients call in for their results. **In all of the STD clinics and family planning clinics** we visited that perform Pap smears, the reference lab calls or faxes all high-grade abnormal results within approximately two days. This alleviates part of the concern over time and should be required of the relationship between any STD clinic and cytopathology lab.

The final challenges that must be considered are deciding when a repeat Pap smear should be done versus a colposcopy and deciding where either procedure should be done. Repeat Pap smears are usually indicated by either an uninterpretable slide or a particular low-grade result (e.g., ASCUS). In all but one of the STD and family planning clinics we visited, patients in need of a repeat Pap smear returned to the original clinic for the procedure. In Brooklyn, patients with uninterpretable slides are brought back to the STD clinic for repeat smears, but those with low-grade results that indicate repeats are referred to another source of care. The common denominator for any result that indicates a repeat Pap smear-is that it is not "normal. " Thus, for purposes of the demonstration project, whichever option an STD clinic chooses for the repeat Pap smear should be tracked so that the clinic confirms that the patient got the repeat Pap smear and was referred for further care if needed.

The presence of Medicaid managed care in the state should be taken into account when deciding where a repeat Pap smear should be done. For example, in Memphis/Shelby County, a protocol will have to be modified so that the choice of a provider for either a repeat Pap smear or further diagnosis can be based upon the insurance status of the particular patient. If the patient is uninsured or has the Health Department as her primary provider, the STD clinic may choose to do all repeat **Pap** smears. **For** patients belonging to any of the many managed care organizations (**MCOs**), with a primary provider other than the Health Department, the STD clinic will have to set guidelines based on **MCO** criteria for where a **patient** should be referred. Again, for the purposes of the demonstration project, with either choice the STD

clinic should obtain information to confirm that the client got a repeat Pap smear and any necessary **follow-up**.

3.2.3 Ability of STD Clinic to Assure that Women with Abnormal Results Receive Appropriate Diagnostic and Treatment Services

In the literature on the subject and in virtually every interview we conducted in the field, there was consensus that the most important and most difficult issue in cervical cancer screening is the effort of making sure women are informed of abnormal Pap smear results and referred for appropriate diagnostic and treatment services. In the STD clinics that do not currently provide cervical cancer screening, similar steps are taken to follow-up on positive STD test results. These usually include telling the patient to call in for results in a certain time period, followed by a contact attempt by the clinic (whether by phone or letter), followed by case finding by DIS. In most of these clinics, however, administrators told us that they would not necessarily follow the same procedures for cervical cancer screening follow-up.

For example, the expectation of clinic administrators, backed up by evidence from some of the STD clinics currently doing Pap smears, is that patients would not be asked to call in for results. The STD clinic would contact the patient to report abnormal results. According to whom one speaks, there is divergence about whether or not the clinic should inform patients of *normal* Pap smear results. Second, for follow-up of abnormal Pap smear results, DIS would not have a central role. Instead, follow-up for abnormal results would be done by a nurse, with possible help from DIS in locating hard-to-reach individuals.

In one site we visited, DIS expressed concern about their own or the clinic's liability when women with abnormal Pap smear results refuse to cooperate with follow-up and referral. These respondents said that if DIS were given the responsibility of finding patients who had not responded to initial contact methods, and the patient also refused to respond to DIS in the field, how would the individual DIS or clinic be protected from a future lawsuit if the patient eventually got cervical cancer? Would the DIS have a way to show that they really did contact the patient and received a refusal to respond to follow-up? The DIS said that a woman who refused to comply with follow-up would be unlikely at that time to sign a form releasing the clinic from liability. These DIS concerns demonstrate the need for clinics to develop procedures to provide protection from future liability for patients who refuse to respond to follow-up and referral.

It was suggested during our site visits that the clinic have female patients sign a form at intake to release the clinic from liability if the patient refuses to comply with recommendations for further care.

Another idea was that a similar form be signed by the patient after comprehensive education on cervical cancer and Pap smear screening was delivered. A third opinion, expressed by respondents across the sites, was that if the STD clinic follows standard procedures of follow-up – such as letter, phone call, certified letter, and possibly sending DIS or nurses to find the patient – and documents those procedures, there is no need for other forms of liability protection. This speaks to the need for a comprehensive information tracking and management system for the cervical cancer screening demonstration projects in the STD clinics.

The issue of incentives to motivate women with abnormal Pap smear results to comply with referrals from the STD clinic was raised in our site visits. In the family planning and Planned Parenthood clinics we visited, staff often use their control over the female patients' birth control pills as a tool to insure compliance. For example, a new patient in these clinics receives a Pap smear as standard procedures during her initial visit. During the initial visit, some clinics only provide the patient with three months worth of birth control pills, so that she has to return to the clinic for refills. If a patient has abnormal Pap smear results and does not respond to clinic attempts to bring her in for a repeat Pap smear or to refer her for colposcopy, she still has to return within three months to get more birth control. In the majority of these clinics, staff refuse to provide additional birth control unless the patient complies with cervical cancer screening follow-up recommendations.

While this is an interesting idea, STD clinics do not have this type of tool for ensuring patient compliance. Our respondents in the STD clinics were not able to provide us with any ideas similar to those used in the family planning clinics. There is not the same continuity of care in STD clinics as there is in family planning and Planned Parenthood clinics. It appears as though STD clinics have to rely solely on following their written protocols for follow-up and referral, without recourse to the type of “power” over patients that family planning and Planned Parenthood clinics have.

Last, a very important issue raised in our site visits was the extent of the STD clinic's responsibility in the cervical cancer screening program. In other words, at what point does the responsibility of the STD clinic to the patient end? There is general consensus among our respondents that STD clinics should at least try to make sure that female patients with abnormal Pap smear results get to the next step of care, whether it be a repeat Pap smear or further diagnosis. We received mixed responses regarding whether or not the STD clinic should proceed further: receiving confirmation that the patient got to the colposcopy appointment; receiving the findings of the colposcopy; receiving information on patients' referral to further treatment; or receiving the findings of the further treatment.

Most respondents said that STD clinics are already burdened with responsibilities ~~and that~~ with the addition of a cervical cancer screening program, they can only be responsible to a certain point. In the opinions of most of our respondents, that is the point at which they are sure the patient got to the next source of care, such as a colposcopy clinic. They expressed the opinion that once a patient becomes part of the clientele of a colposcopy clinic, it should be up to the colposcopy clinic to make sure she receives any additional needed care.

There is general consensus that the STD clinic should at least receive confirmation from the referral clinic (whether for repeat Pap smear or colposcopy) that the patient got to her appointment. For purposes of the demonstration project and evaluation (in order to answer Research Question 3), the STD clinics must also receive information on the results of the repeat Pap smear or colposcopy and, if further treatment is indicated, receive confirmation of treatment and results. STD clinics that develop referral relationships with non-Health Department colposcopy clinics should establish a system of data transfer so that the information we recommend can be collected.

3.2.4 Impact of Cervical Cancer Screening on STD Services

One of the research questions concerns the possible negative impact on current STD clinic services of adding a cervical cancer screening program. As we stated earlier, taking a Pap smear should have no significant impact on the length of the clinical examination. Also, delivering additional education on cervical cancer and Pap smear screening should not add much time to each examination. We do not foresee a significant impact on the workload of DIS, because most of the process of follow-up and referral of patients with abnormal Pap smear results should be the responsibility of someone other than DIS. Our site visits showed that the use of DIS varies across sites and **PHNs** are perceived as better trained to deal with cervical cancer issues, thus DIS would only become involved in situations where it is extremely difficult to locate a woman with a high-grade lesion. The number of women with abnormal Pap smear results who do not comply with other methods of follow-up is not foreseen to be high enough to create an unmanageable addition to DIS workload.

The main impacts that we foresee of adding this screening program would be the need for additional training of clinic staff; the possible addition of a nurse-level staff member to handle tracking, follow-up, and referral responsibilities; and the additional funding needed to operate the screening program.

3.2.5 Overall Economic Impact

The economic impact of cervical cancer screening on the STD clinics will be evaluated during the demonstration project. The areas of potential additional costs include those associated with the exam, processing and evaluating Pap smear slides, tracking women with abnormal findings, and follow-up and referral of those women. We were able to gauge clinic administrators' and staffs opinions on the most substantial additional costs.

Our respondents said that there is no appreciable cost associated with taking Pap smears during the clinical exam. The only cost in this regard would be time added to each exam, which our respondents said would be insignificant. There would be additional cost for this step of the process if clinics were to hire clinicians with more advanced training to perform Pap smears. Since our findings show that **RNs** are able to take Pap smears, the additional cost would be the training and mentoring needed to prepare them for this procedure. In clinics that are currently staffed with **RNs** but would change to more advanced practice nurses to implement Pap smear screening, the main additional cost would be the difference in salary levels between these positions. We anticipate a need for some additional training and mentoring even with more advanced practitioners depending on (1) whether or not this person is board certified in gynecology or as a gynecologic NP, and (2) familiarity and comfort in working with STD clinic patients.

The amount a cytopathology lab charges per slide to process and evaluate Pap smear slides is one of the most substantial new costs that would be incurred by an STD clinic implementing the protocol. The average charge for this service is \$8 per slide, so the cost for any STD clinic would depend on the number of female patients screened there. Under most cytopathology contracts, the cost of Pap smear supplies is included in the per-slide charge, so supplies are not likely to be a separate cost. Another possible cost is the staff time involved in preparing Pap smear slides for shipment to the reference lab and in receiving and logging results. The STD clinics currently conducting cervical cancer screening have been able to incorporate this process into their staff responsibilities without hiring new staff, so this may not represent a new cost. The final cost involved in processing and evaluating Pap smear slides is the time needed for a physician, NP, or PA to make clinical decisions on the results. Even though clinics will have standing orders based on the demonstration project protocol, a qualified physician or mid-level practitioner (in consultation with, or under supervision of, a physician) should review each abnormal result. In clinics with these practitioners on staff, this task would be part of normal responsibilities. For STD **clinics** without these types of staff present, an additional cost could be the hours charged to the clinic by a physician from the family planning program or other place within the Health Department.

Two major cost items are associated with tracking, follow-up, and referral of cervical' cancer screening patients. The first is the cost of modifying current information management systems for the purpose of cervical cancer screening. The second is the possible need for an additional staff position to manage cervical cancer screening cases. This new position would most likely be filled by a PHN, but the amount of time needed for these tasks depends directly on the size of the STD clinic and the number of female patients who receive Pap tests each day. If a new staff member is not added to handle **case-**management activities, then clinic management will need to determine the best approach to shifting current staff responsibilities.

This description of possible additional costs stems from our interviews with Health Department staff in sites that both do and do not currently provide cervical cancer screening in the STD clinic. A more detailed estimate of possible costs can be found in Appendix A.

3.3 Cross-Site Data Tables

The following tables (3.1, 3.2, and 3.3) present in condensed form the data we were able to gather from each of the nine sites (more detailed summaries are compiled in a separate document). Table **3.1** presents data from the three sites where STD clinics are currently offering cervical cancer screening. The Pap smear results from these three sites are not in a standardized format due to the manner in which the sites collect and manage their own data. For example, not all sites record Pap smear results in the Bethesda System of classification; therefore, results are not comparable across sites. Also, the sites do not have computerized data management systems and thus do not have easy access to data on results.

As far as we were able to determine, sites do not have readily accessible data on the current success rate for follow-up of abnormal results, the general time frames involved in various steps of **follow-**up, or the percent of patients who reach their appointments for further diagnosis. These basic outcome indicators will be essential for the evaluation aspect of the demonstration project and any clinics included in the project will have to collect these and other indicators in a consistent and systematic manner. The data presented in the following tables are based on the ability of the Phase 1 clinics to present information at the present time.

Table 3.1 Sites Where STD Clinics Offer Pap Screening

	Brooklyn, NY	Orange County, CA	Wake County, NC
Size (Small, Medium, Large)	Large	Large	Medium
STD Clinic			
Services Offered	Screening for syphilis, gonorrhea, chlamydia, chancroid, herpes, trichomonas, and HIV. The STD clinic has been offering cervical cancer screening since 1977	Screening for syphilis, gonorrhea, chlamydia, herpes, HPV, trichomonas. Cervical cancer screening began in 1965.	Screening for syphilis, gonorrhea, chlamydia, HSV, candida, bacterial vaginosis, trichomonas, and Hep B. Also provide family planning initiation, substance abuse counseling, and psychological services. Have an HIV clinic and provide on-site case management. Began cervical cancer screening in 1996.
Walk-in / Appointment	Walk-in.	walk-in	Walk-in, with some appointments.
Free / Charge	Free of charge	Free of charge	Free of charge
Information Systems	The STD clinic collects information through the District Reporting System and is able to distinguish first-time from repeat visits. There is a morbidity system that has all prior test results and treatment for each patient. Patients' medical records are kept in handwritten charts.	All data are entered into database program, going back 20 years. These data have not been organized or analyzed. Not all of the data related to Pap testing are in the system, nor are all the STD clinic info or positive results. Lab has computer system with all test results. Health Department is developing public Health Data System for future.	Computer system has patient information, chart #, lab results, and prescriptions from all clinics in the facility. Not able to fully track census with computer system. Pap smear follow-up is not computerized for STD clinic.
# of Exam Rooms	7 exam rooms. [Only 4 used at a time due to the presence of only 4 clinicians]	2 rooms for females; 2 rooms for males.	6 rooms for STD exams (including Pap smears). [2 rooms for EIP. 2 rooms for UNC research. 1 room for mental health.]

		Brooklyn, NY	Orange County, CA	Wake County, NC
Census	STD	In September 1997: 945 visits Approx 89% new; 11% repeat 56% male; 44% female.	Average monthly: 1295 visits Approx. 41% new; 59% repeat 54% male; 46% female	Average monthly: 210 patients 3040% new; 60-70% repeat 60% male, 40% female
	Pap Smears'	January 1997: 131 Pap smears 6 with abnormal results (4.6%)	Approx. 236 Pap smears a month Abnormals: Class II • 17% Class III • 7% Class IV • .6% Class V • .04% Unsatisfactory • .5%	Approx. 41 Pap smears a month (12.5% of female patients) Approx. 8.5 abnormal results a month (21%) 3 referred for colposcopy a month (7%)
staffing		1 full-time Physician in Charge 1 full-time physician 1 part-time physician (25hrs/week) 1 part-time physician (16hrs/week) 3 Public Health Assistants 4 clerks 2 microbiologists 2 lab techs 2 DIS supervisors 7 DIS 3 junior public health advisors 1 part-time CBO liaison	3.5 FTE physicians 5 FTE CDIs (DIS) 1 PHN	1 Physician 1 NP (family planning; Pap follow- up) 3 FTE PHNs 1 half-PTE PHN 2 PHI (DIS) 1 Med Tech 3 Clerical 1 Administrative
Examinations		All exams are conducted by physicians, including Pap smears.	All exams and treatment are done by physicians, including Pap smears.	Most exams are done by PHNs; some are done by NP. PHNs and NP do Pap smears.

Pap smear results reported in the format provided by each site. There is not a standardized reporting format across sites.

	Brooklyn, NY	Orange County, CA	Wake County, NC
Education/Counseling	<p>Since patients all come to the STD clinic early in the morning, DIS conduct an educational presentation about STD prevention and behavioral modification at 9:00am for everyone waiting to be seen.</p> <p>Physicians provide some education during exams.</p> <p>DIS give individual counseling for patients testing for HIV, syphilis, or gonorrhea.</p>	<p>Patients receive pre-exam education/counseling from CDIs and counseling during exam by physicians.</p>	<p>PHNs and NP give education during exam. NP gives full cervical cancer education; PHNs give some information, but not comfortable with in-depth cervical cancer education.</p>
Follow-up	<p>At the time of examination, patients are given a call-back slip and told to call the clinic after 8 days to receive their STD results over the phone. Results are given by staff between 2-4 pm every day. For repeat Pap smears, patients are sent a letter informing them of this and are referred to another clinic.</p> <p>All abnormal results in need of colposcopy are assigned to a junior Public Health Advisor. These patients are sent a certified letter by an epi-clerk. Within 72 hours a DIS will make a field visit.</p> <p>When patient returns to STD clinic with abnormal Pap smear results, physician writes referral, gives her copy of results and a self-addressed stamped envelope for colposcopy results to be sent back to STD clinic. Patient decides where to go for colposcopy from list of 3-5 providers.</p>	<p>Follow-up of abnormal Pap smear results is done by a PHN in the STD clinic. All patients in need of colposcopy are referred to the Women's Clinic in the Health Department.</p>	<p>Follow-up of abnormal Pap smear results is done by the NP. Patients in need of colposcopy are referred to women's clinic in Health Department or Wake County Medical Center, depending on severity of result.</p>
I&oratory Services - STDs	<p>[Limited data available from site visit]</p>	<p>The Health Department has an internal lab that does all STDs.</p>	<p>All STD tests are done by central County lab in building.</p>

	Wake County, NC	Orange County, CA	Brooklyn, NY
<p>Pap smear slides are done free of charge by State Health Department lab, just down the street. Takes 2 weeks to get normal Pap results and 3-4 days for abnormal results from the lab.</p>	<p>Pap smear slides are sent to a p lab. It takes 1 week to get Pap results back from lab.</p>	<p>Pap smear slides are sent to pri laboratory. On average it takes between 10-12 days to get result back from the lab.</p>	<p>gy La</p>

Table 3.2 Sites Where STD Clinics Do NOT Offer Pap Screening

	Memphis, TN	Detroit, MI	Kent County, MI
Size (Small, Medium, Large)	Large	Large	Medium
STD Clinic			
Services Offered	Routinely tests for syphilis, gonorrhea, and chlamydia. Test for trichomonas on symptomology. HIV testing by patient request. No testing for HPV.	Screening for syphilis, gonorrhea, chlamydia, trichomonas, gardenerella, herpes, and HIV.	Screening for syphilis, gonorrhea, chlamydia, pubic lice, HIV, mild PID, HPV for men, Hep B referral, and other services. It does not handle gardenerella, trichomonas, herpes, or female HPV.
Walk-in / Appointment	Appointment system.	walk-in,	walk-in.
Free / Charge	\$8.00 charge for all testing and treatment.	Free of charge.	Free of charge.
Information Systems	Medical records are all handwritten. The STD clinic has a computerized list of patients that contains patients' name, date of birth, and medical file number used for pulling medical records.	The STD clinic has a computer system with full patient information, medical history, and test results.	There is no computer system to report demographic status of clients. Charts and client information are handwritten. Lab results are entered into a special computer system.
# of Exam Rooms	12 exam rooms, can handle male or female patients.	3 stations for drawing blood. 9 exam rooms (can handle both male and female exams).	6 exam rooms, all can handle both male and female exams.
Census	Average monthly (based on limited sample): Approx. 1929 patients., 1517 of whom get examined. Approx. 30% only want HIV test. Approx. 60% male; 40 % female.	Average monthly: Between 1400-1800 patients (approx. 1670). [no data on new versus repeat visits] Approx. 65% male; 35% female.	Average monthly: 527 patients. Approx. 75% new; 25% repeat visit Approx. 30% only want HIV test. Approx. 65% male; 35% female.

	Memphis, TN	Detroit, MI	Kent County, MI
staffing	1 part-time physician 1 nurse supervisor 6 nurses 3 medical lab assistants 1 administrative tech 5 clerical staff 15 DIS	2 Physicians (1 ob/gyn ; 1 internist) 5 Clinic Nurse VD 6 Clerical (1 supervisor; 5 clerks) 12 DIS (2 State; 10 contractual) 1 Clinic Operations Coordinator	5 full-time RNs 1 part-time RN 1 full-time LPN 1 fill-time clinic assistant 1 full-time clerk 3 part-time clerks 1 program supervisor 1 epidemiologist 1 DIS (State funded)
Examinations	An MLA draws blood for syphilis and HIV testing. Exams are done by nurses.	Exams are done by Clinic Nurse VDs and physicians. Diffcult cases are handled by nurse supervisor or physician.	Exams are done by RNs .
Education/Counseling	Some education is given during the exam. Post-exam, patient gets dressed and nurse returns and delivers more education. Patients who test positive for syphilis or are syphilis contacts receive additional education and counseling from DIS.	Education and counseling are done by clinicians during exam. Post-exam counseling is also offered by DIS.	Education and counseling are done by the RN during examinations. DIS gets involved with education and counseling only with patients with positive syphilis or HIV results.
Follow-up	Patients are told to call for results in 7 days. If patient does not come back within 3 days of notification, clerical staff seek DIS support.	Follow-up of STD results is initially done by letters automatically generated by computer system. Difficult cases are followed by DIS.	Patients are told to call the clinic in 3 days for results. All results are processed by the lab tech and entered into the computer system by the clinic assistant. Another person puts the results into the patient's chart.
Laboratory Services - STDs	The Health Department lab system consists of the central jlab, branch lab, six primary health center labs, ten satellite testing sites, and four WIC sites. The central lab provides all services except cytopathology.	The central laboratory, located in the building, handles everything but cytopathology .	Grand Rapids is headquarter for 15- county Region 4 lab. Lab does syphilis and HIV serology.

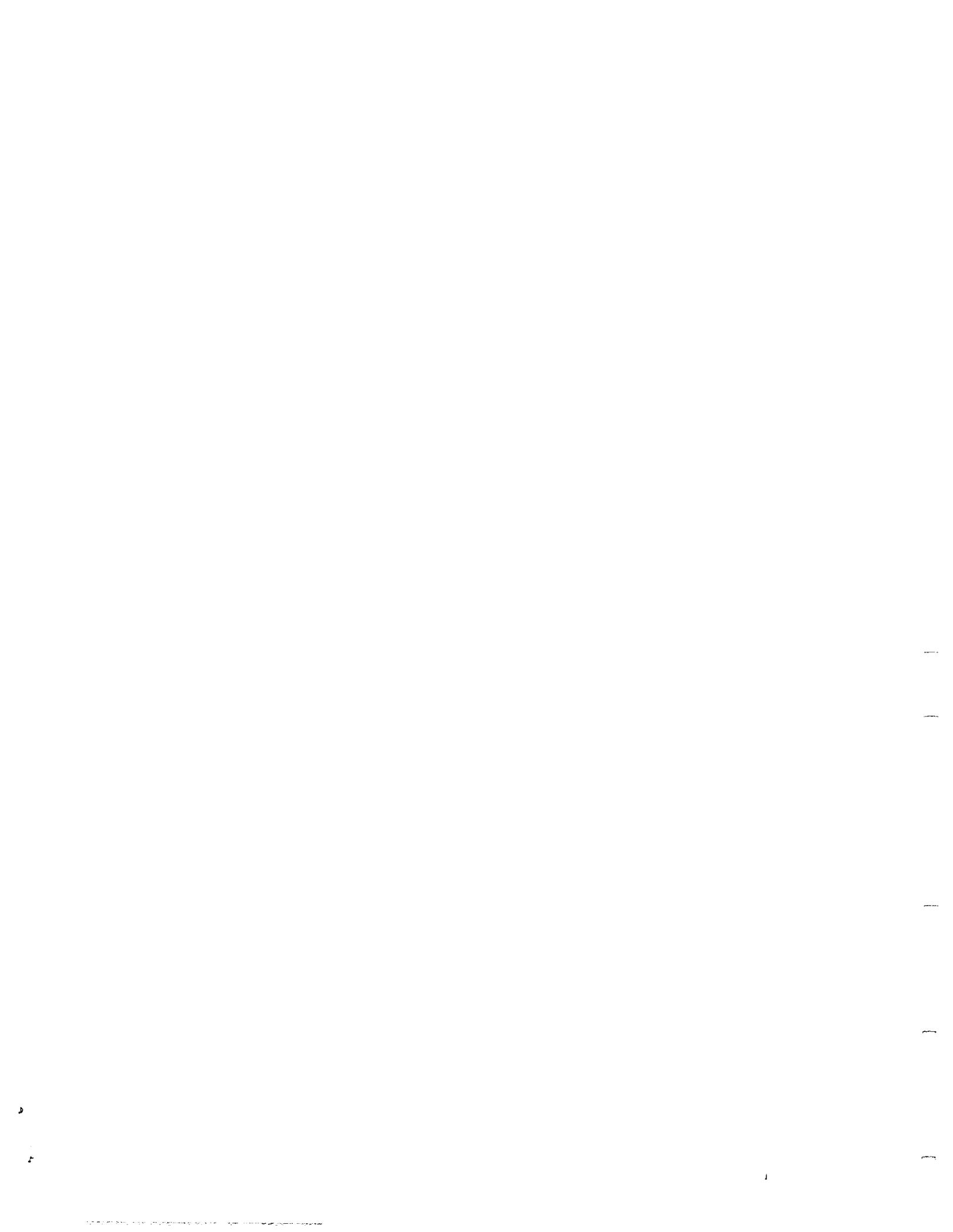
	Memphis, TN	Detroit, MI	Kent County, MI
Cytology Lab Services • Pap smears for family planning clinic	Pap smear slides from the family planning clinics are processed by one of two labs, depending on the client's insurance status. Memphis Pathology Lab is a local reference lab that processes the majority of Pap smear slides and charges \$7.25 per slide. The cost is expected to increase to \$8.00. For patients belonging to the managed care organization Access Med Plus, their Pap smear slides must be processed by SmithKline Beecham , which collects the slides at the Health Department and sends them to Nashville for processing and evaluation.	For Pap smear slides from family planning, the central lab processes them all the way through staining, then sends them to Detroit Medical Center (DMC). DMC charges \$5.00 a slide for interpretation (soon increasing to \$6.50). If DMC were to stain also, they would charge \$8.50 a slide.	Women's Health Network BCCP program sends Pap smear slides to local hospitals, such as Saint Mary's, Blodgett, or Butterworth. Cost for processing and evaluation is approximately \$7.00 per slide. Planned Parenthood sends their Pap smear slides to International Cancer Screening in Texas by Airport Express.

Table 3.3 Sites Where STD Clinics Do NOT Offer Pap Screening

	Clark County, NV	Norfolk, VA	Norwalk, CT
Size (Small, Medium, Large)	Medium	Medium	Small
STD Clinic			
Services Offered	Screening for syphilis, gonorrhea, chlamydia for females 25 years old and under (only by symptoms for people over 25); bacterial vaginosis; and processes slides for yeast infection and trichomonis.	Screening for syphilis, gonorrhea, chlamydia, HIV , trichomonas, and others.	Part-time clinic offers screening for syphilis , gonorrhea, chlamydia, HIV, trichomonas .
Walk-in / Appointment	walk-in.	Walk-in.	STD services are walk-in
Free I Charge	Charge of \$10 per visit covers examination, testing, and treatment. No person is turned away for inability to pay.	Free of charge.	Free of charge.
Information Systems	The STD cliic does not have the information system necessary to differentiate repeat visits from first-time patients. Brothel workers are given separate ID numbers and are tracked separately from other clients. The intake form contains client's name, address, age, birthdate, social security number, marital status, employer, next of kin, allergies, and a place for signature to consent to test. The form is used to pull the patient's chart if a repeater. Staff only ask for patient ID if coming back for HIV test results.	Each local cliic has the number of women examined in the last year, including those who had Pap smears, broken down by age category. Results of Pap smears can be obtained from SKB lab. The Health Department keeps a computerized log of daily census and can distinguish first time visits from repeaters. The STD clinic requires patients to provide a social security number and some form of ID at intake.	All medical records in the clinic are computerized.
# of Exam Rooms	Two exam rooms.	Three exam rooms, one for men and two for women.	Two exam rooms.

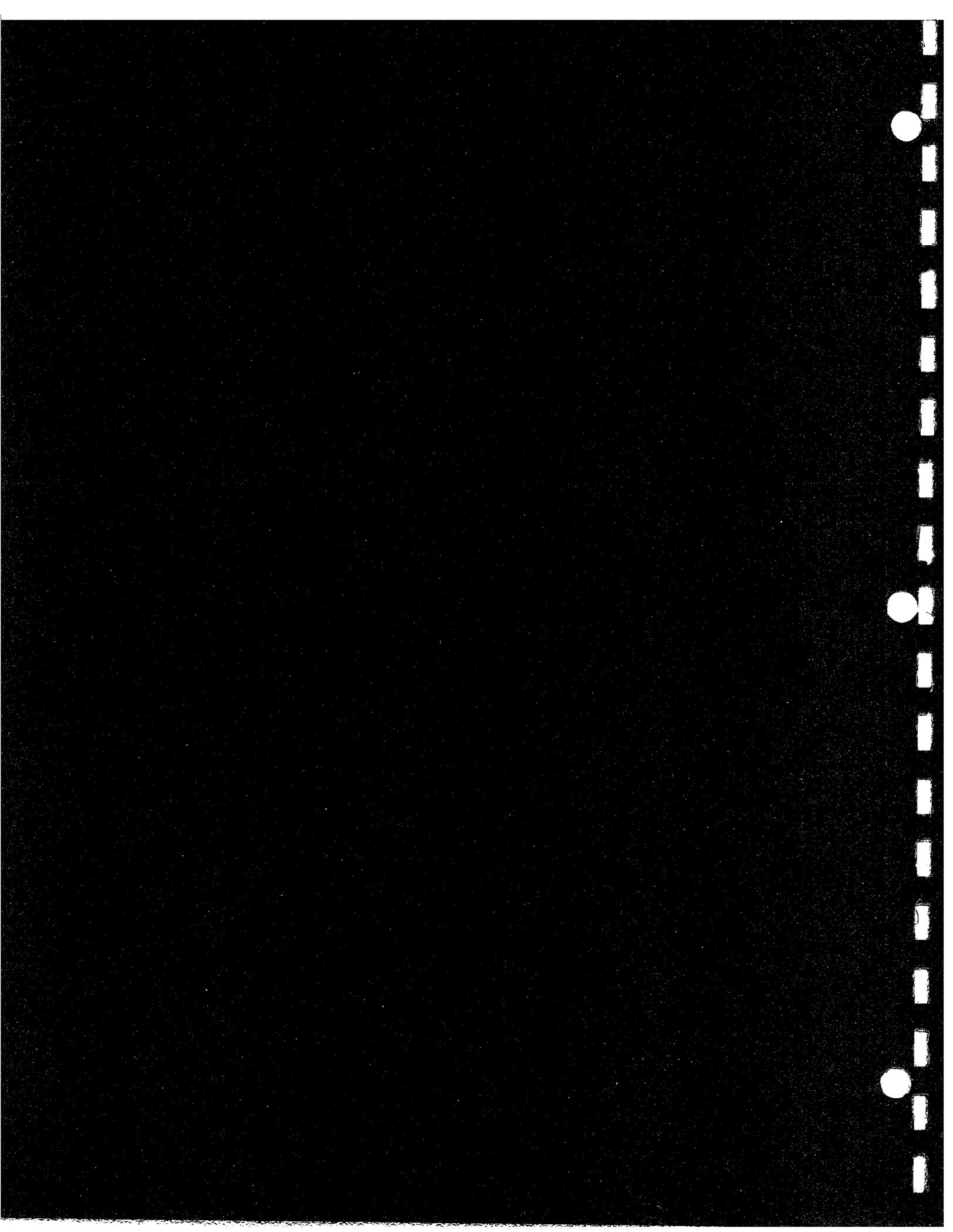
	Clark County; NV	Norfolk, VA	Norwalk, CT
Census	Average monthly: 700-800 patients. Approx. 50% female; 50% male.	Average monthly: 625 patients. Approx 80% new; 20% repeat visits. Approx. 65% male; 35% female.	Average monthly: 70 patients Approx. 60% male; 40% female.
staffing	2 full-time RNs 1 part-time PA 2 full-time clerks 3 CDIs (communicable disease investigators) and 1 Federal advisor A family planning physician from the community comes in one afternoon a week to process charts and help with exams if needed. A dermatologist comes in two half-days a week to see referrals for skins rashes. Administrators are planning to make the PA full-time and to hire an NP. These two staff members will replace the two RNs .	3NPs 2 clerks 1 lab tech 1 physician (available for signing charts) 6 DIS	4 full-time RNs 1 NP (2 days a week) 1 DIS 1 part-time Medical Director (examines male patients on Mondays)
Examinations	RNs perform the exams. They take gonorrhea and chlamydia specimens, draw blood for syphilis, and take blood for HIV testing if the patient requests.	Exams are performed by the NPs . The physician will examine male patients if necessary.	One RN at a time is responsible for STD services, typically seeing 5 or 6 patients each session. The nurse conducts a risk assessment and then performs the exam. Patients at risk for HIV get referred to an on-site HIV counselor.

	Clark County, NV	Norfolk, VA	Norwalk, CT
Education/Counseling	The nurses provide education during the exam as well as afterward. They talk about the importance of condoms and the risk of multiple partners, give educational brochures, and ask patients to bring in sexual partners for testing. If a patient tests positive for syphilis, gonorrhea, or chlamydia, additional education and counseling is provided by CDIs . For positive HIV, post-test counseling is provided by a nurse or counselor from the HIV program.	Patients receive education and counseling from DIS during the intake process. Additional education and counseling are provided during the exam. Nurses inform patients that they are not receiving a Pap smear and if the female patient has not had a Pap smear in the last year the nurse will refer her to the family planning clinic.	Nurses provide education during the exam and when results are given. HIV post-test counseling is only given by State DIS.
Follow-up	CDIs do all contact tracing and partner notification for syphilis. They do not give test results over the telephone.	After initial visit, patients with positive syphilis, gonorrhea, or HIV are phoned or sent a letter, depending on the STD. DIS will track patients who do not respond.	Nurses call the patient “as many times [as necessary] without hounding them.” A registered letter is sent if contact is not made after many tries. As last resort, nurse may refer case to DIS
Laboratory Services • STDs	The Health Department lab handles all STDs except HIV, which is sent out to a contract reference lab.	Each local Health Department clinic has its own lab for testing gonorrhea smears and vaginal secretions. All cultures are sent to the central lab. The central lab handles chlamydia, syphilis, gonorrhea, and other STDs .	The Health Department lab staff spend about half their time on STDs , specifically RPR, gonorrhea smears, wet preps, gram stains, and premarital testing for syphilis and rubella. There is one full-time lab employee and one half-time assistant.
Cytology Lab Services • Pap smears done in family planning clinic	Pap smear slides from family planning are sent to Associated Pathology Laboratories, Inc. (APL), paid for by a regional family planning grant. The contract with APL is for the entire Health Department with discounted rates; \$10.20 per slide.	The State Health Department has contracted with SmithKline Beecham for cytopathology processing and evaluation. A courier takes Pap smear slides from each of the local clinics and sends to SKB. It takes around two weeks to receive test results.	The lab at Norwalk Hospital is able to process and evaluate Pap smear slides.



4.0 Development of a Demonstration Project for
Criminal Justice Screening in Publicly Funded SCD

CHINA



4.0 Development of a Demonstration Project for Cervical Cancer Screening in Publicly Funded STD Clinics

In this chapter, we present the issues that must be considered for implementing the demonstration project protocol for cervical cancer screening in a publicly funded STD clinic. Because the starting point for the protocol is the assumption that no cervical cancer screening activities are occurring in the STD clinic, we outline steps for initiating and implementing the service. The end-point is confirmation that a patient with an abnormal Pap smear result has been seen by an appropriate provider for diagnosis and has **proceeded** to and received treatment if indicated.

Some of the clinics that will use the protocol already have in place a number of the services discussed. They may use the protocol to enhance these services or to implement new services or systems discussed in this protocol but not yet used at the particular STD clinic, such as improvements to the systems for information gathering and management and patient tracking.

4.1 Planning and Initiation of Screening

When initiating any new service, it is necessary to carry out several steps: (1) assessing the current situation in the clinic relative to services, (2) identifying gaps in resources, (3) developing information and data management systems, (4) establishing necessary relationships with outside agencies, and (5) developing a site-specific plan for carrying out the protocol.

These initial steps should begin with a meeting of stakeholders who would be involved in cervical cancer screening. Obvious participants are Clinic/Program Manager, Clinical/Medical Director, DIS supervisor, and nursing supervisor. We recommend that all clinic staff participate at least in the start-up meeting and one other meeting shortly before implementation. It is likely that the state Area Project Manager and the CDC Project Officer will wish to have input. Finally, there should be input from Health Department agencies such as family planning or Breast and Cervical Cancer Early Detection Program (BCCEDP) early in the process. Despite this broad-based input, we recommend that the “nuts and bolts” of assessing and planning be conducted by the key players in the clinic (i.e., Clinic/Program Manager, Clinical/Medical Director, DIS supervisor, and nursing supervisor) or their direct designees.

4.1.1 Assessing Current Situation

Those who perform the assessment must consider (1) resources, (2) cervical cancer screening services currently in place, (3) staffing patterns, (4) information systems, and (5) relationships with current or potential clinics for patients who require referral. The components of this assessment are presented in Table 4.1.

Table 4.1 Situational Assessment

Component	Considerations
Resources	<ul style="list-style-type: none"> ▪ Funding ▪ Equipment Number of exam rooms that can accommodate female patients ▪ Supplies Swabs, brushes, spatulas, slides, fixative, etc. ▪ Educational materials Brochures, pamphlets, pictures, videos (available in more than one language)
Services currently in place	<ul style="list-style-type: none"> ▪ Assess current level of screening in STD clinic Take history and refer if Pap needed Pap smear testing Referral for diagnosis Follow-up to see that diagnosis has been obtained Follow-up beyond diagnosis ▪ Assess intensity of screening What steps can be enhanced? What would be necessary to enhance those steps?
Staffing patterns	<ul style="list-style-type: none"> ▪ Intake and data collection Intake clerk Pm-exam counselor Pm-exam history taker ▪ STD examiners RN, NP, PA, MD ▪ Examiners allowed to do Pap smears. RN, NP, PA, MD ▪ Medical decisions RN, NP, PA, MD Under what circumstances? Legal constraints? ▪ Education and counseling ▪ Staff available to find women who do not return after notification of abnormal Pap smear result ▪ Estimate of current clinic census and possible need for additional staff ▪ Estimate the number of women who will be eligible for screening ▪ Estimate the number of women who will have abnormal results

Component	Considerations
Information systems	<ul style="list-style-type: none"> ■ Manual ■ Computerized ■ Combiion
External relationships	<ul style="list-style-type: none"> ■ Providers currently accepting referrals from STD clinic ■ Potential providers for women with abnormal Pap smear results <li style="padding-left: 20px;">Providers currently accepting referrals from Pap screening program in family planning clinic <li style="padding-left: 20px;">Managed care considerations ■ Cytopathology laboratory agreements in place

4.1.2 Assessment of Services Currently in Place

Each demonstration site should consider what it already has in place in terms of the structures and services needed to carry out the demonstration project. Those that have most of the essential services in place need to consider how they can enhance those services. For example, would additional staff for follow-up mean fewer women lost to follow-up? Or would a more sophisticated tracking system mean fewer losses? While capital costs are not part of the protocol for this project, enhancing information systems is, and in a setting where Pap testing has been in place for some time, it may be all that is needed. Another enhancement may mean improving agreements with laboratories and establishing new ones with clinics that can provide colposcopy or other diagnostic services at a cost affordable to the women being referred.

Other clinics will need to “start from scratch.” Even so, there may be systems **in place**, such as a computerized tracking system or an agreement with a reference laboratory that can be folded into the demonstration site’s own adaptation of this protocol. These decisions are an extension of the situation assessment.

4.1.3 Development of Data Management System

The demonstration protocol requires a comprehensive system of tracking patients from the time of **intake through the follow-up of all patients with abnormalities**. In addition, the evaluation component of the protocol requires several data-collection activities. Ideally, the clinic has a computerized information system; however, manual systems of data management can be adapted for this protocol. The information

system must be able to manage data that will assist in providing service and in evaluating the demonstration project. Specific key data points are presented in Section 5.1.

The system for tracking the follow-up of patients with abnormal results will be discussed more fully in Section 4.2.5. and is shown graphically in Figure 5.1. Individual clinics may want to add other components to the information system.

Computerized systems should be password-protected, such that only those staff with authority to enter the system are able to do so. It is expected that a fair amount of information will need to be shared with agencies outside the STD clinic, specifically the reference laboratory and the referral clinics. In these cases the patient's name and other identifying information may be shared among staff who utilize the proper passwords. In all other situations, such as when evaluation data are being shared with CDC or its contractor, coded identifiers should be used to protect the patient's confidentiality. In other words, data not related to particular clinical services as shared by authorized staff should only be transferred in such a way that the person receiving services is anonymous. The system for sharing information should be discussed with the patient in the Patient Confidentiality Agreement.

4.1.4 Staffing Patterns

One of the most important decisions to be made is who should actually perform Pap testing. Our findings from North Carolina suggest that public health nurses (**PHNs**) who are experienced **RNs** with additional training can perform the Pap test if they are also **mentored** at the clinic. (The training plan will be discussed in Section 4.1.6.) Some jurisdictions do not allow **RNs** to conduct this **level of** testing. In these situations, a Nurse Practitioner (NP) or Physician Assistant (PA) may do the test, unless state regulations preclude any non-physician performing Pap smears. If this is the case, the clinic must consider the cost of using higher-level clinicians for testing. The clinics should avoid using more than one examiner for a patient (i.e., RN for STD testing followed by NP, PA, or MD for Pap testing). Women should be with one examiner throughout the examination. A nursing, medical, laboratory, or public health assistant may also be needed to assist in the collection, labeling, and sending of specimens.

Follow-up is crucial to the success of this project. We suggest that a PHN coordinate follow-up and function as the case manager for all women with abnormal results. Follow-up, casefinding, and outreach are normal functions for public health staff, and the public health nurse has the advantage of clinical knowledge concerning the etiology, prevention, and care of cervical cancer or precancerous lesions. If a PHN is not available for this position, then the case manager should be someone who can

perform follow-up, casefinding, and outreach, as well as communicate clinical information to patients as well as referral sources. The PHN or other follow-up case manager may be assisted by clerical and junior level public health staff (e.g., junior public health advisors). Another key person may be a DIS, experienced in finding difficult-to-locate patients, who will have time specifically allotted to finding women with high-grade lesions or carcinoma or to finding women with low-grade lesions who do not respond to other methods of notification.

4.1.5 Establishment of External Relationships

The clinic needs to set up relationships with two kinds of external agencies: the cytopathology laboratory and the referral settings for women with abnormal Pap smear results. In addition, the STD clinic may need to identify outside sources of technical assistance for information systems and sources of training for staff who will be carrying out the protocol.

When a clinic becomes a part of the demonstration project, sufficient time should be allotted to building relationships with the cytopathology laboratory and referral sites. It is very important that these partnerships be established in such a way that fosters communication so that turn-around time is enhanced at the laboratory and so that patient needs are met at the referral sites, as well as the STD clinic case manager's need for information regarding the disposition of women she refers.

Cytopathology Lab

Early in the process of **initiating** cervical cancer screening, the STD clinic should identify a cytopathology laboratory that follows CLIA 88 regulations. For some clinics, the state reference laboratory may provide this service in the most cost-effective and time-efficient manner, while for others a private reference laboratory may be more appropriate. STD clinic management need to consider cost, turn-around time, and the track record of the laboratory for meeting quality control (QC) standards. Although a laboratory that normally takes 10-14 days to send its results may be adequate, there must be a system for quickly receiving results of high-grade lesions, whether by phone, fax, or a printer in the STD clinic that is on-line with the laboratory. The STD clinic should also have its own QC standards in place. We recommend that the laboratory send a monthly summary to the clinic, in addition to sending individual reports on Pap smear results as they are completed. This monthly summary should be checked against the computerized log and the patients' charts in order to identify any gaps or any conflicting information.

In some jurisdictions, it may be necessary to use more than one laboratory (e.g., one for patients who are uninsured and another for those on Medicaid managed care). This occurs because particular contracts, in place for managed care patients, may not be cost-efficient for those with other coverage or without coverage. Whenever possible, though, the STD clinic should work with one reference laboratory in order to keep communication as simple as possible.

Referral Sites

Ideally, the STD clinic should have one main setting to which it sends patients in need of follow-up for diagnosis and treatment. The advantage to the STD clinic, and to the patient, is that the PHN/case manager will establish a strong relationship with one liaison at the referral clinic. This will facilitate communication between them. However, in some cities it may be preferable to have a list of referral clinics, or in some states it may be necessary to work with providers who are associated with the state's Medicaid managed care program. In either case, the referral network should consist of clinics that: (1) can do colposcopies on-site; (2) have a sliding-fee scale with a low base rate or can make arrangements to diagnose women without funds or coverage; (3) are accessible by public transportation; (4) have accessible hours of operation, such as evenings or weekends; (5) will see patients with high-grade results with minimal waiting time; (6) have experience working with women from the same target population that the STD clinic serves; and (7) can be relied upon to send information on the status of the woman back to the STD clinic. While it is important that the patient receive as many services as possible in the same setting to avoid fragmenting care, the most important thing to consider is meeting her immediate needs - both medical and financial.

Working with the patient, STD clinic staff should set the referral appointment. If a woman has a preferred provider, the STD clinic should certainly respect her wishes and refer her to that clinician. In some cases, the PHN/case manager may determine that this provider cannot meet the woman's needs and will work with her to find another setting. If so, the PHN/case manager should still communicate with the woman's primary care provider so that all future care can be coordinated by this source. If the woman goes to someone outside the clinic's referral network, the **PHN/case** manager should also see to it that the STD clinic receives confirmation that the patient did arrive at the follow-up appointment. For purposes of the demonstration project, the STD clinic must also receive the results of the further diagnosis, as well as the results of any necessary treatment.

In most jurisdictions, a memo of understanding (MOU) is the best method for **sealing agreements** with referral settings. For some jurisdictions, a simple letter of agreement may be adequate. In all cases, we anticipate that a formal release of medical records will be signed by each patient receiving a Pap smear so that appropriate information can be gathered by the STD clinic. Since funds will not be exchanged, we do not anticipate that a formal contract will be necessary.

Outside Technical Assistance

Other kinds of relationships may be necessary. The STD program is likely to need assistance from outside the clinic in establishing and maintaining its information system, especially if it is implementing or upgrading a computerized system. For some clinics, this assistance will come from the Health Department, while other clinics will need to set up their own maintenance contracts. Also, the clinic staff may need training in use of software from a vendor or other source.

The other major relationship will be with staff trainers and preceptors. This will vary depending on the needs of the clinic, especially the type of provider who will be performing the Pap smear. This type of assistance may come from elsewhere in the Health Department or from an outside agency.

Once the situational assessment is complete, clinic management can proceed with filling in the gaps noted or initiating the entire process. For some clinics, that will mean identifying sources and developing systems for most of the items in the assessment. For clinics that do not currently conduct cervical cancer screening, two more components must be addressed before the service can be initiated: (1) adoption of a standard set of clinical guidelines, and (2) a plan for training staff to carry out the protocol. STD clinics that are presently engaged in cervical cancer screening may want to take this opportunity to re-assess their clinical guidelines and to enhance staff training.

4.1.6 Adoption of Clinical Guidelines

The clinical guidelines are the written procedures staff use to guide the process of conducting the examination, taking the Pap smear, and preparing the slide to be shipped to a cytopathology lab. There are many options for clinical guidelines, such as those developed by CDC, the Planned Parenthood Federation of American (PPFA), state and local Health Department programs, such as family planning, and others. For purposes of the demonstration project, STD clinics should use the CDC clinical guidelines for cervical cancer screening in STD clinics, last updated in 1997, as a standard. However, the STD

clinic may want to convene its committee to see that the guidelines address the special needs of its target population.

For the purpose of the demonstration project, the STD clinic and reference laboratory, must use the Bethesda system of classification.

4.1.7 Plan for Carrying Out Staff Training

All Pap test providers should receive training in obtaining the smear, except those who are gynecologists or certified gynecological nurse-practitioners. The intensity of training will vary, however, depending on whether the provider will be an experienced RN, an NP, a PA, or an MD. The training, especially for non-physicians, may entail time away from the clinic. However, this training does not need to occur in full-day sessions. The training needs to include Pap smear technique as well as interpretation and communication with patients. Each clinic may need to make a contract with an agency that provides this training, such as Planned Parenthood, school of nursing, or school of medicine. Otherwise, an advanced practice nurse or other staff member hired to be the case manager and to supervise the cervical cancer screening program in the STD clinic may be able to provide the necessary training. After completing any training, the provider should also be mentored. If staff are available in the STD clinic who are experienced in performing Pap smears, they can provide mentoring on-site. Otherwise, a contract will need to be made with a gynecologist or gynecological nurse-practitioner to mentor the practitioner in the clinic. This may mean that, for STD clinics first initiating Pap smear testing, it may take 1-2 months before the service can be offered fully.

Staff other than providers will need training. Registration and intake workers will need to understand any new duties involved with setting up the patient chart and collecting information for the evaluation. Anyone handling information will need to be trained on inputting data into the information system. Any staff member involved with counseling and educating patients should have basic knowledge of cervical cancer, Pap testing, and the various kinds of results that may be obtained.

Those staff providing follow-up services need more extensive training on this subject. At a minimum staff should know that: (1) sexually active women need a Pap smear each year; (2) the Pap smear can tell if there is a problem which should be evaluated further; (3) the problem is usually not cancer; and (4) if the problem is not treated it can eventually become cancer. Women should come away from the clinic with the knowledge that Pap testing is an excellent defense against cancer if action is taken when the test detects a problem.

Sources of basic knowledge regarding education and counseling, such as the American Cancer Society (ACS) or Planned Parenthood, may be located throughout each clinic's community. It is important that staff training be geared towards the clinic's target population. Sources of such training can be staff from STD clinics with established cervical cancer screening, the Health Department family planning clinic, or chronic disease/cancer prevention staff within the Health Department. Another way of enhancing counseling and education skills is to obtain basic knowledge from an external source and to then conduct inservice education concerning the special needs of the STD clinic population.

4.2 Implementation of Services

Once all the necessary systems are in place, guidelines are established, and staff are trained, the clinic may begin to implement cervical cancer screening. The implementation of services also requires careful planning, so that clinic flow remains smooth and the patient receives the best services and **follow-**up possible, with serious problems quickly identified and referred. The implementation plan needs to address (1) intake, (2) clinical examination, (3) counseling and education, (4) laboratory procedures, and (5) tracking, referral, and follow-up.

As each step in this process is carried out, the person responsible for that step should enter the action taken and any results into the patient's medical record. For data obtained on intake, details may be noted in a separate form, the patient intake form. Clinics may wish to use specific data forms for other parts of the patient care process. Whether or not such specific forms supplement the patient medical record, data obtained on intake, clinical diagnosis, laboratory results, all attempts to locate patients, and all contacts with clinics to which patients have been referred should be entered into a cervical cancer screening information system.

If information is not noted in the medical record, the clinic staff may be held liable for not carrying out a procedure. Therefore, it is important that each of the steps enumerated here be documented. In addition, refusals by patients for screening or referral should also be noted within the medical record, and a waiver signed if possible. The waiver can be included in the Informed Consent form.

4.2.1 Intake Procedures

Building on existing STD clinic procedures, it should be possible to implement this protocol in either a walk-in or appointment based clinic. In most clinics, each patient will receive a number when entering the clinic and will be seen by a registration clerk. It is crucial that the clerk obtain accurate locating information from the patient. The intake form should have a section for the patient to indicate if she has had a Pap test in the past 12 months, one to three years, more than three years, or never. Since we anticipate that there will not be additional charges for Pap testing (regardless of whether there are fees for other services in the STD clinic), the clerk does not need to determine whether the patient will receive Pap testing at this point. Decisions about whether or not a woman should receive a Pap test should be made by clinical or specially trained program staff.

For purposes of the demonstration project, Pap smears will only be offered to female patients 18 years of age and older. Although most STD clinics see patients 13 years of age and older, and patients in the STD clinics can be assumed to be sexually active, there are factors that lead us to limit the population to be included in this study to 18 years of age and older. One factor is the issue of confidentiality. If a female patient under 18 years old were to have an abnormal Pap smear result, the STD clinic would have to contact her legal guardian in order to refer her for further diagnosis or treatment. This is because Pap smears are not part of standard practice in an STD clinic. This would inform the guardian that the minor female patient was a client in the STD clinic, thereby breaking confidentiality. Since we do not know the age breakdown of female patients in the STD clinics, this limitation to screening only women 18 years of age and older will not be considered when calculating sample size or budget estimates.

In most clinics, the medical history will be taken by the examining clinician. In some clinics, especially those that have long wait times for examination, the history will be taken by a clinical or program staff member before the exam. Further information gathering about the patient's most recent Pap test should be part of the regular medical history for women. If the woman responds that she has had one previously, the clinician should probe to be sure that the woman indeed had a Pap smear by asking questions on the circumstances where it was done and whether she received any results. It is likely that, for some women, it will not be clear whether she received a Pap smear or simply a pelvic exam.

In order to facilitate answering Research Question 1¹, STD clinics should attempt to validate patients' self-report of past Pap smears. Each female patient will indicate on the intake form whether she has had a Pap smear in the last 12 months, one to three years, more than three years, or never. When patients report they have received a Pap smear previously, but that it was more than one year prior to the current exam, validation may be limited to the additional questions during the medical history. However, for patients who report that they received a Pap smear in the last 12 months, STD staff should collect information from the patient on where the previous exam was done. Staff should also have those patients read and sign a release of medical records so that the self-reported Pap smear can be validated. Examples of medical records release forms can be found in Appendix C.

Whether or not a patient receives a Pap smear in the STD clinic should not be contingent upon her signing a medical records release form. Clinical judgment will be needed to determine if a Pap is indicated at this visit; this judgment will be made largely on the further questioning of the patient regarding past Pap smears and the risk assessment of the patient. The only reason not to do a Pap smear, other than having had one within the last 12 months, is that the woman has heavy menses. If the woman has a heavy discharge or other signs of infection, it should be addressed through good clinical technique in obtaining the Pap smear. If the woman is menstruating, she should be given an appointment to return to the clinic in one week for her smear, or she may receive her Pap smear when indicated for follow-up of her STD.

A woman who has had a recent Pap and reports that it was abnormal should be questioned further about the type of abnormality and whether or not she received the appropriate follow-up services. Women who have not received such services should be referred to the PHN or other Pap screening case manager for referral to a clinic that can provide the indicated services or to their own primary care-providers.

The STD clinic should follow standard CDC guidelines for Pap testing and follow-up in women who are HIV positive.

Information for locating the woman should be obtained at registration. The history form should include fields for gathering information on prior Pap history, on whether or not a Pap is taken at this visit, for results of Pap, and for follow-up. This information will be used both clinically and for program

¹ Are STD clinics an appropriate location for identifying women who have not been screened in the **past** one to three years for cervical cancer?

evaluation purposes. The client will need to sign Informed Consent for both the Pap test **and for data gathering.**¹

4.2.2 Clinical Examination and Obtaining the Smear

Demonstration project clinics should follow CDC clinical guidelines for Pap smear testing in STD clinics. Some clinics may wish to supplement these guidelines with those developed in their local or state Health Departments, or with guidelines from major organizations such as Planned Parenthood. CDC guidelines for Pap testing are the standard for the demonstration project, but there is also flexibility for meeting local needs.

The importance of effective sample collection is highlighted in the cervical cancer screening handbook for North Carolina's Breast and Cervical Cancer Early Detection Program (BCCEDP) by the statement that "approximately two-thirds of 'false negative' Pap smears of the cervix are due to sampling (i.e., collection) problems, while one-third is due to laboratory error" (1995). As with any testing, the provider should have all materials ready, including a slide labeled with the woman's name and accession or identification number and be sure to note the procedure in the patient's record.

While we leave it to the clinic to develop its own guidelines regarding which provider type (experienced RN, NP, PA or MD) may obtain the Pap, in all cases the patient should be seen by the same provider throughout the entire STD examination, including the Pap test. The only exception is when the provider is being **mentored** and the mentor must check a finding of the primary provider. In such situations, the reason for having two examiners should be explained to the patient at the beginning of the examination, and the examiners should avoid talking about the patient as if she were not in the room.

4.2.3 Counseling and Education

Every step in the cervical cancer screening process is an opportunity for counseling and education. On intake the patient learns of the need for an annual Pap smear. She may first learn that not all pelvic examinations include a Pap test, and a plan for obtaining correct information may be worked out if the patient is unsure of her own history. During history-taking the patient may learn the meaning of past

¹ **The Informed Consent should explain that the patient's identification will be protected. No patient will be denied a Pap test if she withholds consent for data gathering.**

results. When a risk assessment is done, the message should be delivered that certain behaviors put a woman at increased risk for developing cervical cancer or precancerous lesions. The risk behaviors are:

- exposure to Human Papilloma Virus (**HPV**) - this may not be diagnosed at each clinic, and many women with HPV do not have clinical symptoms so this risk factor may not be evaluable for all patients'
- intercourse at an early age
- multiple sexual partners
- compromised immune systems
- smoking

These risk factors should be discussed not as judgments of behavior but to help the patient understand the importance of sticking to guidelines should she be in a high-risk category.

The examination is a key time for counseling and education. While the exam is occurring, the practitioner should explain each step of the process in language that is understandable to the patient, avoiding sexual or intrusive terms that may make a patient anxious. At the end of the exam, the clinician should invite the patient to ask questions and should also take a moment to reinforce the importance of returning should the results indicate a problem. The main message here, and throughout the process, is that abnormal results usually do not mean that cancer is present, but they often indicate a problem that can turn into cancer if it is not treated.

If the woman is seen by a DIS for her STD, the message regarding the need for complying with any recommendations made as a result of the Pap test should be reinforced. Otherwise, the last person to see the patient before she exits (as per the usual clinic flow in that STD clinic) should remind the patient of the follow-up procedure. The patient should be told whether or not she will be contacted in the event of a normal smear and that she will receive either a phone call or a letter if there is a problem. Contact information should be verified, and the patient should be given the opportunity to mention any special confidentiality concerns (e.g., avoid calling at a specific time of day, use a code name). When the patient leaves, she should have a list of practitioners to contact in one year assuming that this Pap smear is normal.

If a patient is a repeat visit, that is, if she returns for STD services less than one year from the date of the Pap test, all cervical cancer screening messages should be reinforced at each step of the process as outlined above. If the woman is seen in the clinic one year later, it is preferable that she have a Pap at

¹ **In fact, as noted in Chapter 1, strains of HPV with the clearest association with cervical cancer tend to lead to only subclinical infection. Therefore, most women at greatest risk will not know that they have this risk factor, and the STD clinic may not have specific tests for HPV (e.g., DNA probe).**

the clinic unless she has clearly established a relationship with a primary care provider. It **can** be assumed that repeat visit patients are at high risk of exposure to HPV and therefore in the key target population for this demonstration project.

Brochures, pamphlets, and written materials are best used as an adjunct to verbal counseling. It is also helpful to have attractive materials in the waiting room in languages spoken by members of the clinic's population. A simple reading level can be made interesting through attractive illustrations and a plot or story line. Posters concerning Pap testing, cervical cancer, and the problem of HPV also help to reinforce prevention and care messages.

4.2.4 Sending and Receiving Specimens

Before taking the sample, the clinician needs to have a labeled slide. The exact method for slide preparation should be described in the clinical guidelines chosen by the STD clinic. Generally, the slide is divided in two sections, half of which is covered with cervical and endocervical material and half of which is covered with vaginal material. Hairspray should not be used to fix the material. When the smear is dry, it should be packaged according to good laboratory practices (GLP) in place at the STD clinic.

When developing the contract with the cytopathology laboratory, the STD clinic needs to go over procedures for shipping and mailing. Generally, the Pap smears collected for the day will be picked up each evening from the reference lab. The laboratory should send reports at least once a week, telephoning, faxing, or using an on-line printer. Results should be communicated sooner for high-grade abnormalities. The clinic should also receive a monthly summary statement from the laboratory, which it can check as a part of its own QC procedures.

4.2.5 Tracking, Referral and Follow-up

The purpose of follow-up is to assure that the patient receives subsequent diagnostic testing and, if necessary, is treated for abnormalities found to be due to pathological conditions. Good follow-up depends on a system of tracking that can be defined as "the act of effectively following a client to assure that care appropriate to her needs is provided . . . The mechanism for following many individuals in an organized

manner is a tracking system.” Thus, tracking is a mechanism for assuring that the process of follow-up has occurred. In this section, we will discuss what needs to be done in order for follow-up to be adequate and make some recommendations for optimal follow-up. Table 4.2 presents this information in tabular form.

For each step in this process, we will suggest an appropriate method of tracking the progress of the client through the health care system. We will also recommend appropriate personnel. By and large, the entire tracking, follow-up, and referral process should be the responsibility of one person. In most cases, this person can be a public health nurse (**PHN**), provided a physician reads each report and makes the clinical decision regarding the appropriate next step for all abnormal readings. Some jurisdictions may choose to allow **NPs** to make clinical decisions so long as they can easily consult with a physician.

Step 1: Establish a process for retrieving and logging Pap smear results

The person responsible for retrieving Pap smear results when they arrive from the laboratory and for logging the results may be a specially trained clerk under the supervision of the PHN. The clerk should: (1) enter the fact that the results have been received into a log, (2) place the results in the patients' charts in a manner that allows the physician easy access to them, (3) retrieve the charts after physician review and enter each result and the physician's disposition into the log, and (4) deliver the charts of patients requiring follow-up to the PHN.

It is the physician's responsibility to read all results and to decide which require follow-up and what type of follow-up is indicated. The physician should flag the charts of these **patients** to alert the PHN and clerk that further steps are necessary. The physician can do this by hand or can enter the information into the tracking system. For this step, tracking is accomplished through the computerized or manual Pap smear log.

¹ **The North Carolina Comprehensive Breast and Cervical Cancer Control Coalition. Cervical Cancer in North Carolina: A Handbook for Providers. June 1995.**

Step 2: Establish policy and procedures concerning normal Pap smear results

We present two options. The first option recognizes that women who attend STD clinics may have special confidentiality concerns. In this option, often referred to as the “no news is good news” option, there is no communication with women whose Pap smear results are normal.

In the second option, the STD clinic takes advantage of the fact that communication with the woman can help her establish the habit of obtaining an annual Pap smear. In this option, the STD clinic sends the woman a post card¹ notifying her that the test was normal and reminding her that she should see her health care provider in one year for the next Pap smear. Ideally, a note would be sent in one year with a list of providers. However, this may be impractical and not worth the cost if clinic data show that users of the clinic move frequently.

If option 2 is used, the fact that notification was sent is entered into the Pap smear log; under option 1, no steps need be taken.

Step 3: Establish procedures for follow-up of abnormal Pap smear results

As noted above, all clinical decisions are to be made by a physician, a nurse-practitioner, or physician assistant in consultation with or under supervision of a physician. Once the decision is made, the PHN/case manager will expedite the process of finding the woman. This process assumes that the PHN/case manager will not carry out each step herself, but that any woman with an abnormal result is a part of her case load. Women with serious abnormalities or those who are difficult to find will require intensive follow-up, possibly with the assistance of DIS. Clerical tasks such as mailing letters may be delegated to clerks. When the patient enters the clinic, we recommend that she be counseled and given her follow-up options by the PHN/case manager. In some clinics, a health educator or public health advisor may have this function.

Table 4.2 defines each follow-up procedure in detail, describing the manner of tracking, the steps to be taken for contacting patients, and the time frame for each step. The follow-up procedures become increasingly intense, reflecting the increasing seriousness of the abnormality as defined by the Bethesda

¹ A post-card should only be sent if it can be folded over and sealed to protect confidentiality. Otherwise, all notifications of results should be sent in sealed envelopes.

System. This protocol is based on the premise that the STD clinic has a responsibility to further educate and counsel women with abnormalities and to see that they get to an appropriate setting for diagnosis.

Closing a case without notification that the patient received follow-up diagnosis is a serious step. STD clinic staff should attempt to resolve all problems within a six-week period. For a woman who refuses follow-up, one more call after she has signed a waiver can be made within two weeks of the last contact.

Once the patient has obtained definitive diagnosis, the diagnosing clinic takes over the process of follow-up and referral in liaison with the PHN/case manager at the STD clinic. For purposes of the demonstration project, the STD clinic must receive confirmation that the patient attended the diagnostic appointment and must receive notification of the patient's diagnosis. Also, for any patients needing treatment, the STD clinic must receive information on the treatment services the patient obtained. This may include some activity on the part of the STD clinic case manager to assist the patient in navigating the health care system and to obtain needed data. Because of this research-based need for information, STD clinics will need to have Pap testing patients sign a release of medical records form.

STD clinics should establish relationships with diagnostic clinics so that information on colposcopy results can be easily transferred to the case manager in the STD clinic. This relationship can also be used to inform the STD clinic about where a patient is referred for treatment so that the patient's progress can be followed and the medical record release forms can be sent to the appropriate locations.

4.3 Continuing Education

The committee that oversees initiation of the project in each site should be re-convened at quarterly intervals to assess the progress of the program. Issues can be addressed by clinic staff or by outside technical assistance.

The STD clinic management must plan to reinforce staff education concerning (1) clinical practices, (2) data management, and (3) follow-up or case management. An ongoing relationship with a clinical mentor is useful where new staff are being taught to do Pap smears. Staff should have funds to attend annual conferences on a rotating basis. Data management issues may be addressed through **on-the-**job training or through a vendor of computerized systems.

Follow-up and case management issues may be best discussed in a peer review context. This may involve conference calls **with** other STD clinics **that** are involved with the demonstration project in order to hone policy and procedures. Such conference calls can begin with presentation of a difficult case.

4.4 Protocol Decision Points

In this section, we provide the information presented above in a format that can be used as a guide for clinic staff as they plan and implement the demonstration project in their site.

4.4.1 Planning and Initiation

A meeting of stakeholders involved in planning a cervical cancer screening program in **the** STD clinic may involve **the** STD Clinic/Program Manager, STD Clinic/Medical Director, STD nursing supervisor, DIS supervisor, and Laboratory Director. The planning meeting(s) also could include family planning clinic/Program Manager and others from Health Department programs that currently offer cervical cancer screening.

Assess the current situation

- Services currently in place
- Staffing patterns
- Information systems
- External relationships
- Resources

Adopt a standard set of *clinical* guidelines

- Use as minimum standard, CDC clinical guidelines for cervical cancer screening in STD clinics, updated in 1997

Develop a data management system

Each clinic must **develop** a data management system that can accurately track the following points:

- The number of *patients* who visit the STD clinic per month (separated by male/female)
- The number of *patients examined* in the STD clinic per month
- The number of *female* patients examined in the STD clinic per month
- The number of female patients examined who are *first-time visits* versus repeat visits¹
- The number of first-time female patients who *have not received a Pap smear elsewhere* in the past year, one to three years, more than three years, or never
- The number of female patients who *receive a Pap smear in the STD clinic*
- Whether or not the patient *changed contact information* after receiving education and counseling on cervical cancer
- *The length of time* it took to receive Pap smear results from reference lab (for each patient)
- The number of female patients with *normal Pap smear results*
- The number of female patients with *abnormal Pap smear results* (broken down by the Bethesda system)²
- By result, the number of female patients to get *repeat smears* and the number of female patients to get *colposcopy*
- The number of *contact attempts per patient*, the *time* of each contact attempt, and the *method of actual contact*³
- *The date when contacted* the patient with the result

¹ Although different STD clinics define “first-time visit” and “repeat” differently, for purposes of the demonstration project “first-time visit” will be anyone who has not been seen in the STD clinic in the past year.

² Data on unsatisfactory slides should be broken down further in order to determine, for evaluation purposes, whether it was due to infection or improper preparation of slide. Improper preparation of slide is a training issue, whereby the presence of infection is a feasibility issue of conducting cervical cancer screening in STD clinics.

³ Include data on refusals and inability to locate patients.

- The number of female patients with abnormal results who were *referred by the STD clinic to further diagnostic services (e.g., colposcopy)*
- Whether these female patients went *to the first colposcopy appointment* or had to be *rescheduled*
- *When* the patient got the colposcopy (to compare with the date when contacted with result)
- The number of female patients referred for further diagnosis who have *conditions serious enough for further treatment*
- Whether these patients *got to the appointment* for treatment
- The *result* of the further treatment

Identify any needs for outside technical assistance

Possible needs for outside technical assistance include:

- Developing and maintaining information systems
- Staff training and preceptors

Develop a plan for training staff

Decide needs for training STD clinical staff to take Pap smears and prepare slides

- Decide needs for training lab staff to process Pap smear slides for shipment to cytopathology lab and to receive lab results
- Decide needs for training STD clinic staff to carry out patient education and counseling regarding cervical cancer screening (including any staff who will have contact with patients at any time)
- Decide needs for training STD clinic staff to handle contacting, referral, and tracking patients with abnormal Pap smear results

Establish external relationships

Cytopathology Laboratory	
Options for choosing a cytopathology lab	Any cytopathology lab must do the following:
<ul style="list-style-type: none"> ▪ STD clinic piggybacks onto existing contract/relationship between the Health Department (i.e., family planning clinic or BCCEDP program) and cytopathology laboratory ▪ STD clinic establishes a new contract with a cytopathology laboratory (usually, this option is available only if there is no existing contract within the Health Department) 	<ul style="list-style-type: none"> ▪ Follow the Clinical Laboratory Improvement Act (CLIA) 1988 regulations ▪ Report Pap smear results to the STD clinic using the Bethesda Classification System ▪ Provide results to the clinic in a timely manner (including shortened period for abnormal results) ▪ Provide monthly summary reports of results
Colposcopy clinic(s)	
Options for choosing referral and colposcopy clinic(s)	Any referral and colposcopy clinic must do the following:
<ul style="list-style-type: none"> ▪ Use family planning program or BCCEDP referral network; modify as needed (STD clinic follow-up staff will still need to establish a direct relationship with clinic(s)) ▪ Develop relationships with new clinics (especially if the Title X program is outside the Health Department) <p>[Some sites will have to establish their list of referral sites based on local Medicaid managed care standards]</p>	<ul style="list-style-type: none"> ▪ Include at least one choice that will provide colposcopies at a reduced rate for low-income patients and provide payment schemes for patients who cannot pay immediately ▪ Be accessible by public transportation ▪ Have accessible hours of operation, such as evenings or weekends ▪ Include at least one choice that will see patients with high-grade results with minimal waiting time ▪ Have case management abilities in place to inform patients of colposcopy results and refer patients to additional treatment if needed ▪ Agree to consistently report back to the STD clinic whether or not patients referred from the STD clinic got to their appointments and report patient results back to the STD clinic

4.4.2 Implementation

Integrate these steps into clinic flow

- 
 - Obtain accurate demographic and locating information from each patient
 - Obtain self-reported Pap smear history from each female patient (past 12 months, 1-3 years, over 3 years, or never)
 - Record patient information in a data management system
- **Medical History:**
 - Utilize the supplemental patient history survey
 - Have patient sign medical records release (for confirmation of Pap smear within past 12 months and/or for gathering information from referral sites)
 - Deliver some counseling and education regarding cervical cancer screening
 - Follow clinical guidelines for deciding whether a Pap smear should be done
 - Have patient sign waiver form limiting the clinic's liability if the patient refuses to comply with follow-up and referral recommendations
- **Exam:**
 - Follow clinical guidelines for Pap smear technique and methods of slide preparation
 - Inform the patient when and how to expect Pap smear results
- **Counseling and education:**
 - Provide education to patient on the following points (make available low-literacy publications as well as materials in various relevant languages):
 - Risk factors for cervical cancer
 - The purpose and process of Pap smear screening and the need for annual Pap smears

The fact that abnormal Pap smear results do not mean cancer but indicate a need for further diagnosis

The purpose and process of colposcopy

The steps that will be followed for informing the patient of Pap smear results and follow-up if results are abnormal

- **Laboratory procedures:**

- Sending Pap smear slides

Follow standard procedures for packaging Pap smear slides for delivery to cytopathology laboratory

Record the following information: Name, address, and telephone number of cytopathology lab to which specimen is sent

- Receiving Pap smear results

Record the date when each Pap smear result came back to the clinic

Pull patient records and enter the results so that clinical decisions for follow-up can be made

Record the results in the data management system

- **Management of Pap smear results:**

- Tracking and data management

Match Pap smear results to patient information

Record all results in the data management system

Record each attempt to contact the patient with abnormal results

On the day the patient is informed of results, record the date and action taken

Record when a referral for repeat Pap smear or further diagnosis is made

Record whether or not the patient got to the appointment at the referral site

Record the results of further diagnosis

Record whether or not the patient is to receive treatment **and** what treatment is indicated

Record whether or not the patient got to the appointment for treatment

Record the outcome of treatment

- Follow-up

STD clinic must try to contact patient at least three times within six weeks of receiving results, if Pap smear results are unsatisfactory or show ASCUS or worse. Select one of the two options presented below in Table 4.2:

Table 4.2 Follow-up and Referral

The follow-up procedures are separated into two options: one for STD clinics that inform the patient that clinic staff will contact her with results and one for STD clinics that inform the patient to contact the clinic for results within a specified period of time. For the second option, the clinic will tell the patient a certain number of days to wait before contacting the clinic, based on the standard time it takes to receive test results back from the cytopathology laboratory. Notice, however, that for abnormal results of LSIL and higher, the follow-up procedures become the same under either option. This is because of the urgency indicated by these results and that most cytopathology labs will return these types of results to the clinic in less time than it normally takes to report other results. In this situation it would not be acceptable for the clinic to wait for the patient to call for results.

Results (Bethesda System)	Referral Options	Follow-up Procedures (options)	
		In clinics where the patient is informed that clinic staff will make the initial contact with Pap smear results	In clinics where the patient is instructed to call the clinic within a specified period of time for her Pap smear results
Within normal limits	<ul style="list-style-type: none"> ▪ None needed 	<ul style="list-style-type: none"> ▪ “No news is good news” - patient has been informed that if she has not received a response within a specified period of time, she can assume her results are normal <li style="text-align: center;">▪ OR ▪ ▪ Send a card or letter informing patient of normal results and need for annual Pap smears (include educational material on cervical cancer and Pap smear screening) 	<ul style="list-style-type: none"> ▪ Inform the patient of normal results when she calls (remind patient of need for annual Pap smears)

Results (Bethesda System)	Referral Options	Follow-up Procedures (options)	
		In clinics where the patient is informed that clinic staff will make the initial contact with Pap smear results	In clinics where the patient is instructed to call the clinic within a specified period of time for her Pap smear results
Unsatisfactory slide	<ul style="list-style-type: none"> ■ Bring patient back into STD clinic for repeat smear <li style="text-align: center;">- OR - ■ Refer patient to other source of care for repeat smear <p>[Repeat Pap smear will most likely be performed within 3-6 months of original Pap smear]</p>	<ol style="list-style-type: none"> 1. Send letter indicating need for patient to call the clinic for an appointment for repeat smear or for a referral for repeat smear 2. Follow with phone call if no response within 1 week 3. Follow with certified letter if no response to phone call within 2-3 weeks <p>[If repeat will be done at STD clinic, before the appointment send a confirmation letter and educational materials]</p> <p>[For each of these steps, it is advisable to provide educational materials on cervical cancer, Pap screening, and colposcopy]</p>	<ol style="list-style-type: none"> 1. When (if) patient calls, make an appointment for her to return to the clinic for repeat smear or make referral for repeat smear 2. If patient does not call, follow with phone call within 1 week 3. Follow with certified letter if no response to phone call within 2-3 weeks <p>[If repeat will be done at STD clinic, before the appointment send a confirmation letter and educational materials]</p> <p>[For each of these steps, it is advisable to provide educational materials on cervical cancer, Pap screening, and colposcopy]</p>

Results (Bethesda System)	Referral Options	Follow-up Procedures (options)	
		In clinics where the patient is informed that clinic staff will make the initial contact with Pap smear results	In clinics where the patient is instructed to call the clinic within a specified period of time for her Pap smear results
Benign cellular changes indicative of infection	<ul style="list-style-type: none"> ▪ Bring patient back into STD clinic for treatment of infection, then repeat Pap smear after period specified in clinical protocol [Most likely within 3-6 months of original Pap smear] 	<ol style="list-style-type: none"> 1. Send letter indicating need for patient to return to clinic for treatment of infection 2. Follow with phone call if no response within 1 week 3. Follow with certified letter if no response to phone call within 2-3 weeks <p>[When patient is treated, make an appointment for repeat Pap smear, either at the STD clinic or at referral site]</p>	<ol style="list-style-type: none"> 1. When (if) patient calls, instruct her to return to the clinic for treatment of infection 2. If patient does not call, follow with phone call within 1 week 3. Follow with certified letter if no response to phone call within 2-3 weeks <p>[When patient is treated, make an appointment for repeat Pap smear, either at the STD clinic or at referral site]</p>
ASCUS	<ul style="list-style-type: none"> ▪ Bring patient back into STD clinic for repeat smear <li style="text-align: center;">- or - ▪ Refer patient to other source of care for repeat smear <li style="text-align: center;">- or - ▪ Depending on patient's Pap history, pathologist recommendation, or perceived level of patient compliance, may want to refer for colposcopy immediately 	<ol style="list-style-type: none"> 1. Send letter indicating need for patient to call the clinic to make an appointment for repeat smear or for referral for repeat smear <li style="text-align: center;">- or - 1. Send letter indicating need for patient to return to clinic for referral to colposcopy clinic 2. Follow with phone call if no response within 1 week (repeat as necessary) 3. Follow with certified letter if no response within 3 weeks of phone call <p>[For each of these steps, it is advisable to provide educational materials on cervical cancer, Pap screening, and colposcopy]</p>	

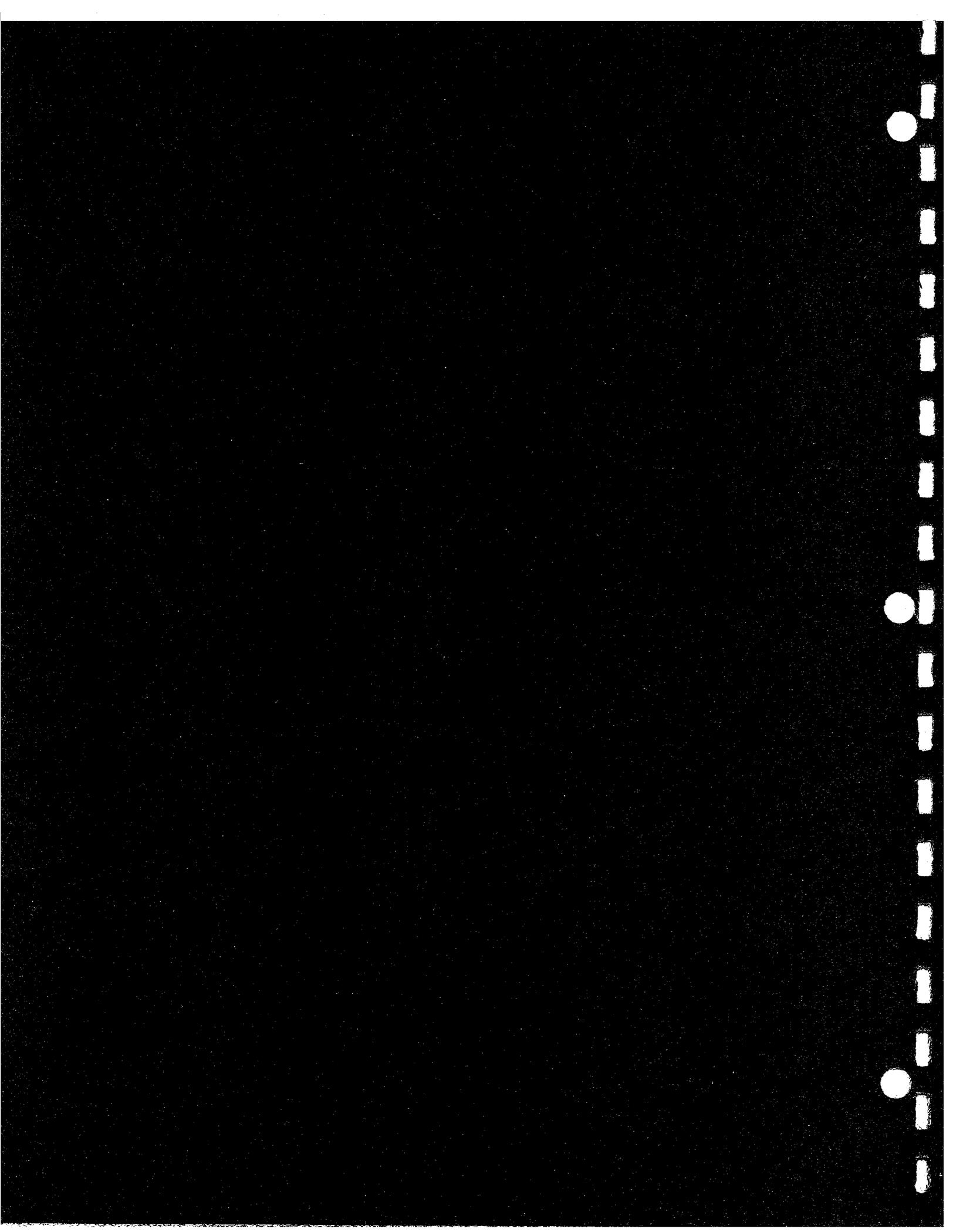
Results (Bethesda System)	Referral Options	Follow-up Procedures (options)	
		In clinics where the patient is informed that clinic staff will make the initial contact with Pap smear results	In clinics where the patient is instructed to call the clinic within a specified period of time for her Pap smear results
Low-grade SIL	<ul style="list-style-type: none"> ■ Bring patient back into STD clinic for repeat smear <li style="text-align: center;">- or - ■ Refer patient to other source of care for repeat smear <li style="text-align: center;">- or - ■ Based on clinical protocol or pathologist recommendation and/or perceived level of patient compliance, may want to refer for colposcopy immediately 	<ol style="list-style-type: none"> 1. Call patient by telephone for return to clinic for repeat smear or for referral for repeat smear (repeat calls as many times as necessary) <li style="text-align: center;">- or - 1. Call patient by telephone for return to clinic for referral to colposcopy clinic (repeat calls as many times as necessary) 2. Within 1 week, dispatch DIS or PHN to visit patient's home for notification of Pap smear results 3. If patient is not located through a field visit and does not respond to request to return to the clinic, send a return receipt certified letter notifying patient of results and need for referral <p>[For each of these steps, it is advisable to provide educational materials on cervical cancer, Pap screening, and colposcopy]</p>	

Results (Bethesda System)	Referral Options	Follow-up Procedures (options)	
		In clinics where the patient is informed that clinic staff will make the initial contact with Pap smear results	In clinics where the patient is instructed to call the clinic within a specified period of time for her Pap smear results
High-grade SIL	<ul style="list-style-type: none"> ▪ Refer patient to colposcopy clinic 	<ol style="list-style-type: none"> 1. Call patient by telephone for return to clinic for referral to colposcopy clinic (repeat calls as many times as necessary) 2. Within 3 days, dispatch DIS or PHN to visit patient's home for notification of Pap smear results 3. If patient is not located through a field visit and does not respond to request to return to the clinic, send a return receipt certified letter notifying patient of results and need for referral <p>[For a patient with HSIL, it is advisable to expend all possible effort to notify her of her results and to get her to further diagnosis and treatment]</p> <p>[For each of these steps, it is advisable to provide educational materials on cervical cancer, Pap screening, and colposcopy]</p>	

Results (Bethesda System)	Referral Options	Follow-up Procedures (options)	
		In clinics where the patient is informed that clinic staff will make the initial contact with Pap smear results	In clinics where the patient is instructed to call the clinic within a specified period of time for her Pap smear results
Squamous cell carcinoma	<ul style="list-style-type: none"> ■ Refer patient to colposcopy clinic 	<ol style="list-style-type: none"> 1. Call patient by telephone for return to clinic for referral to colposcopy clinic (repeat calls as many times as necessary) 2. Immediately dispatch DIS or PHN to visit patient's home for notification of Pap smear results 3. If patient is not located through a field visit and does not respond to request to return to the clinic, send a return receipt certified letter notifying patient of results and need for referral <p>[For a patient with suspected cancer, it is advisable to expend all possible effort to notify her of her results and to get her to further diagnosis and treatment]</p> <p>[For each of these steps, it is advisable to provide educational materials on cervical cancer, Pap screening, and colposcopy]</p>	
AGUS	<ul style="list-style-type: none"> ■ Refer patient to colposcopy clinic 	<ol style="list-style-type: none"> 1. Send letter indicating need for patient to return to clinic for referral to colposcopy clinic 2. Follow with phone call if no response within 1 week 3. Follow with certified letter if no response within 2-3 weeks <p>[For each of these steps, it is advisable to provide educational materials on cervical cancer, Pap screening, and colposcopy]</p>	

5.1 Framework for the Administrative Project

Evaluation Plan



5.0 Framework for Demonstration Project Evaluation Plan

In this chapter, we present to CDC our recommendations for data collection activities to be conducted for the Phase 2 demonstration project. These data-collection activities will support the evaluation analysis to be conducted as Phase 3 of this project. Phase 2 data-collection activities will be the responsibility of each of the demonstration site clinics.

We anticipate that many of the forms already in use at the clinics will be modified to accommodate the project. Below, we give examples of some of the data fields that are needed for tracking clients and some of the questions to be asked on intake or on exit. New forms or worksheets may be needed to track the referral component of the program. These modifications should not require special clearances unless approval from the demonstration clinic's own Health Department is needed. If so, it will be necessary to allocate time to the clearance or approval process.

It is likely that the demonstration sites will need technical assistance (TA) in making the suggested modifications. We recommend that clinics conduct internal needs assessments - an aspect of formative evaluation - which may also require TA. We anticipate that, as participants in a demonstration project, each of the sites will be required to send progress reports to CDC at regular intervals. For Phase 2, then, we see a limited role for external evaluators but a more extensive one for CDC or other TA providers.

The evaluation of the demonstration project will be completed in Phase 3. This will entail analyzing the data collected in Phase 2. In addition, we recommend some new data-collection activities during Phase 3, to give a fuller picture of the challenges and facilitators associated with implementing the demonstration project. These activities would mean a return to the demonstration sites by an evaluation team for a series of qualitative interviews. We recommend designing the Phase 3 qualitative evaluation activities during Phase 2, in order to allow time for any necessary clearances. At the same time, we avoid conducting these activities during Phase 2, so that the clinics can focus on service delivery and on developing their information systems in order to collect basic quantitative data and track cervical cancer screening patients. Also, a preliminary review of data collected during Phase 2 will help to sharpen development of questions to be asked in a final set of qualitative interviews.

In Section 5.1, we reiterate the basic information that must be collected at each clinic in order to support both the tracking of patients and evaluation of the demonstration project. This is the most basic information necessary for evaluating the demonstration project. In Section 5.2, the evaluation plan is

further conceptualized in terms of processes and outcomes that correspond to the research questions presented in Chapter 1 and discussed in Chapter 3. The accompanying tables provide a menu of data collection activities, including some that are required and some others that are desirable but possibly not within time and resource allocations.

5.1 Key Data Points

Key data points to be gathered in each STD clinic in the demonstration project, whether through a computerized system, by hand, or through a combined electronic/manual system, are:

- The number of *patients* who visit the STD clinic per month (separated by male/female)
- The number of *patients examined* in the STD clinic per month
- The number of *female* patients examined in the STD clinic per month
- The number of female patients examined who **are first-time visits** versus repeat visits¹
- The number of first-time female patients who have *not received a Pap smear elsewhere* in the past year, one to three years, more than three years, or never
- The number of female patients who *receive a Pap smear in the STD clinic*
- Whether or not the patient *changed contact information* after receiving education and counseling on cervical cancer
- *The length of time* it took to receive Pap smear results from reference lab (for each patient)
- The number of female patients with *normal Pap smear results*
- The number of female patients with *abnormal Pap smear results* (broken down by the Bethesda system)²

¹ Although different STD clinics define “first-time visit” and “repeat” differently, for purposes of the demonstration project “first-time visit” will be anyone who has not been seen in the STD clinic in the past year.

² Data on unsatisfactory slides should be broken down further in order to determine, for evaluation purposes, whether it was due to infection or improper preparation of slide. Improper preparation of slide is a training issue, whereby the presence of infection is a feasibility issue of conducting cervical cancer screening in STD clinics.

- By result, the number of female patients to get *repeat smears* and the number of female patients to get *colposcopy*
- The number of *contact attempts per patient*, the *timeframe* of each contact attempt, and the *method of actual contact*¹
- *The date when contacted* the patient with the result
- The number of female patients with abnormal results who were *referred by the STD clinic to further diagnostic services (e.g., colposcopy)*
- Whether these female patients went *to the first colposcopy appointment* or had to be *rescheduled*
- *When* the patient got the colposcopy (to compare with the date when contacted with result)
- The number of female patients referred for further diagnosis who have *conditions serious enough for further treatment*
- Whether these patients *got to the appointment* for treatment
- The *result* of the further treatment

In Phase 1, the research team discovered that most clinics would presently find it difficult to break out each of these data points, especially differentiating first-time visits from repeat visits. However, many of these data are kept in some manner, and the main issue would be one of streamlining systems already in place. In Chapter 4, we stated that these data are crucial for tracking patients from intake through **follow-up**. From an evaluation perspective, they form a picture of the clinic population and provide a measure of who receives services versus how many women are lost to follow-up. Assessing the clinic's ability to reach women and "shepherd them through the system" is the most basic component of an evaluation of the demonstration project.

The demonstration project needs an information system that can handle all the key data elements, intake information, exam results, laboratory results, tracking, and results of follow-up. It does not have to be computerized, although this would be preferable. Figure 5.1 shows where in the flow of each clinic the key data collection points are likely to occur.

¹ **Include data on refusals and inability to locate patients.**

flow. Data to evaluate the effectiveness of the STD clinic in identifying women who require Pap smears are outlined below. Table 5.1 details the data elements for this research question.

Pap Smear History

The medical history should elicit data on (1) sexual risk factors specific to cervical cancer, (2) usual sources of health care, and (3) whether or not the patient has had a Pap smear in the past 12 months, one to three years, more than three years, or never. Risk factors specific to cervical cancer were discussed in Chapter 4.¹

We prefer that the woman be questioned regarding her usual sources of medical care during the medical history rather than during intake. A question regarding the patient's regular provider, if she has one, flows easily into a series of questions designed to determine her Pap test history. Below is a series of questions that can be asked of each woman in order to help in this determination.

- Did you receive a pelvic - internal examination - in the past year? Y N DK
(It may be necessary to briefly explain what a pelvic exam is.)
 - *If yes:* Did the doctor or nurse say that you had received a Pap smear at that time? Y N DK
 - *If yes:* Did you ever find out what your Pap smear said? Y N DK
 - *If yes:* Were you told that it was normal? Y N DK
 - *If no or don't know:* Were you told that there was a problem? Y N DK
 - If there was a problem, what was it?
 - Did you see a doctor about the problem with the Pap smear? Y N DK
 - What did the doctor tell you that the problem meant?
- What is a Pap smear used for? (While this question may appear awkward at the end of the survey, it is meant as an entry-point for education and counseling.)

The above questions may prove most useful for patients who report having received a Pap smear, but over a year prior to the exam in the STD clinic. For those who report having received a Pap smear within the past 12 months, it is also important for the clinician to gather information on where the patient received this care so that a release of medical records form can be sent to validate the self-report.

¹ **The risk factors are: (1) exposure to HPV (the patient may not know if this applies to her), (2) age at first sexual intercourse, (3) multiple sexual partners, and (4) compromised immune status. Another risk factor is cigarette smoking, which can also be assessed during the medical history.**

5.2 Research Questions and Data Elements

The key data points addressed in Section 5.1 will provide the most basic measure of the project's ability to deliver cervical cancer screening to women who need the service and see that women who have abnormal results are served. In this section, we recommend process and outcome measures or descriptors that correspond to the project's overall research questions. A set of data elements for each research question was proposed at the outset of Phase 1. Some of these data elements were addressed in the Phase 1 study, and a few were shown to be unconvincing or irrelevant. These will be dropped from the evaluation plan. A few others, mainly those associated with challenges and facilitators, are considered to be data elements for the Phase 3 evaluation of the project. In many cases, we combined elements proposed earlier, because Phase 1 has shown that such a grouping would be logical.

In this section, we discuss the revised data elements for each research question. In the narrative, we summarize our proposed plan, while the accompanying tables detail the data elements, data sources, measures or descriptors, recommended outcomes, and the timing of data collection for the research question. The outcomes are derived from a composite picture of the findings for Phase 1 and of literature reviewed. Some are rather ambitious, but they do represent a standard of care for which STD clinics will wish to aim.

5.2.1 Are STD clinics an appropriate location for identifying women who have not been screened in the past 1 to 3 years for cervical cancer or precancerous lesions?'

A key goal of this research questions is to assess the need for offering cervical cancer screening in STD clinics. Thus it is important to gather as accurate information as possible on the Pap testing history of female patients in the demonstration project clinics. As part of the demonstration project, each STD clinic will ask women if they have received a Pap smear elsewhere in the past 12 months, one to three years, more than three years, or never. A discussion of how to gather and validate this information can be found in Section 4.2.1.

If there is convincing evidence that the woman has received a Pap smear in the 12 months before the STD visit, she should not receive screening in the STD clinic. However, such women should still receive cervical cancer prevention education. If a woman has not received a Pap smear within the 12 months prior to the STD clinic visit, she should be offered one unless she is experiencing heavy menstrual

Data Element	Data Source(s)	Measure(s) or Descriptor(s)	Outcome(s)	Timing of Data Collection
Factors Affecting Use of Clinic (continued)	<ul style="list-style-type: none"> ▪ Patient surveys if possible 	<ul style="list-style-type: none"> ▪ Description of reasons why patients did not (or would not) respond or follow through 	<ul style="list-style-type: none"> ▪ Recommendations for improvements in serving women 	<ul style="list-style-type: none"> ▪ If patient interviews (survey) are conducted this will be done in Phase 3 but clearances will be obtained during Phase 2
Counseling, Education and Training	<ul style="list-style-type: none"> ▪ Needs Assessment 	<ul style="list-style-type: none"> ▪ The presence or absence of cervical cancer prevention counseling and educational materials; The presence or absence of training for staff involved in Pap testing and cervical cancer prevention counseling and education 	<ul style="list-style-type: none"> ▪ Each clinic develops a plan to deliver cervical cancer counseling and education using trained staff and appropriate (culture, language, age) educational materials 	<ul style="list-style-type: none"> ▪ Beginning of Phase 2
Challenges and Facilitators in Identifying Women in Need of Cervical Cancer Screening	<ul style="list-style-type: none"> ▪ Phase 3 interviews 	<ul style="list-style-type: none"> ▪ Description of what went well during implementation, of challenges and solutions, and of continuing barriers 	<ul style="list-style-type: none"> ▪ Programmatic improvements can be made based on perceptions of staff, especially where these perceptions correspond with issues ascertained through analysis of data from information systems 	<ul style="list-style-type: none"> ▪ Phase 3

Table 5.1 Are STD clinics an appropriate location for identifying women who have not been screened in the past 12 months or longer for cervical cancer or pre-cancerous lesions?

Data Element	Data Source(s)	Measure(s) or Descriptor(s)	Outcome(s)	Timing of Data Collection
Pap Smear History	<ul style="list-style-type: none"> ▪ Medical history ▪ Addendum to medical history ▪ Medical records release 	<ul style="list-style-type: none"> ▪ The proportion of individual women examined who have not had a Pap smear within the past 12 months, one to three years, more than three years, or never ▪ The proportion of women who were unsure as to whether or not they had received a Pap test or who said they had one but upon further questioning it became reasonable to assume that they had not had one ▪ Validation of self-reported Pap smear in the past 12 months 	<ul style="list-style-type: none"> ▪ Any woman whose most recent Pap smear was done 12 or more months prior to history receives a Pap smear unless she is menstruating ▪ The clinic is able to identify women who had misinformation about Pap testing, test them, and provide education to correct the misinformation ▪ Ability to more accurately assess the need for Pap testing in STD clinics 	<ul style="list-style-type: none"> ▪ Initial question during intake; Full history before exam (Duration of Phase 2) ▪ Full history before exam (Duration of Phase 2) ▪ Duration of Phase 2
Factors Affecting Use of Clinic	<ul style="list-style-type: none"> ▪ Phase 1 findings ▪ Tracking system 	<ul style="list-style-type: none"> ▪ Perception of respondents of appropriateness of STD clinic for identifying and serving women in need of cervical cancer screening ▪ Proportion of women who do not respond by 3rd attempt to notify them; Proportion of women who do not keep appointment at referral clinic 	<ul style="list-style-type: none"> ▪ STD clinic can be an appropriate location for cervical cancer prevention services ▪ Women will come to clinic by 2nd attempt to notify them of results; Women will keep follow up appointments 	<ul style="list-style-type: none"> ▪ Phase 1 ▪ Each attempt to reach woman and results of follow-up appointments to be entered in Phase 2 log

evaluation. Phase 3 qualitative evaluations may address the effects of these Phase 2 activities upon clinical practice.

Challenges and Facilitators in Identifying Women in Need of Cervical Cancer Screening

This data element can be assessed in two ways. First, the data collected in Phase 2 can be analyzed for gaps. If gaps are found in the data during the course of the Phase 2 demonstration project, then TA should be provided that would enable the clinic to collect these data. If the data still cannot be collected, there may be a legitimate concern of whether the STD clinic can identify the women in need of cervical cancer screening. The second approach would be to ask staff about the challenges and facilitators they encountered through open-ended questions, to be conducted as part of Phase 3. We recommend both approaches.

5.2.2 What are the challenges associated with cervical cancer screening, follow-up, referral, diagnosis, surveillance, and education in STD clinics?

Table 5.2 presents the data elements, data sources, measures and descriptors, and proposed outcomes for the information summarized below.

Staffing Mix

The clinic will need to decide which staff are necessary to implement cervical cancer screening, using the demonstration site protocol (Chapter 4) as a guide. This decision will be affected by regulations and norms in the clinic's jurisdiction regarding which level of staff may perform the Pap smear. Once the mix has been determined, it will be difficult to evaluate the relative effectiveness of one staffing pattern versus another. For example, if productivity (patients seen per hour including the number who receive Pap smears) is used to determine how well staff are performing, there may be intervening variables in each clinic that affect the rate of productivity. Also, higher productivity could mean less counseling. Therefore, the evaluation plan we propose includes only recording a description of the type of staffing in each demonstration clinic. An assessment of the challenges associated with determining the staffing mix will be collected through qualitative data during the interviews proposed for Phase 3.

Another data point that would contribute interesting information is the number of women who were unable to answer the questions concerning Pap testing history, were unsure whether they had been screened in the past, or were unsure about the results of prior screening. This would show if the STD clinic is finding women who may not have been screened even if they had received pelvic examinations in the past year.

Factors Affecting Use of the Clinic

In Phase 1, we considered whether the ability of women to get to the STD clinic and factors affecting their willingness to keep appointments would affect the usefulness of the STD clinic for cervical cancer screening. All of the STD clinics we visited were accessible by public transportation and had available parking. For those where there is cost for parking, we are recommending that the STD clinics provide an incentive of reimbursement for parking costs for any patients returning to the clinic for a repeat Pap smear or referral. We are also recommending that the STD clinics reimburse for the public transportation fare for the same circumstances, in order not to penalize women without automobiles. Further assessment of factors that have an impact on whether women return for follow-up appointments and keep the referral appointments should be considered for Phase 3 of the demonstration project, because such a study would require a great deal of preparation, including **OMB** and **IRB** clearances.

In Phase 2, all key data on women who do not respond to calls and letters to return to the clinic and who do not keep referral appointments will be tracked. Ideally, the Phase 3 study would involve locating a sample of these women and interviewing them regarding the obstacles to keeping the appointments. If this approach requires more time and resources than are available, the PHN and DIS can be asked about the feedback they get from women concerning both the STD clinic and the clinics to which they are referred.

Counseling, Education, Training

A variety of elements will be assessed by the clinic as a part of its own Needs Assessment. This includes the presence or absence of cervical cancer prevention counseling, the types of educational materials available, and the type of training needed by and available to staff. These elements are more relevant to the readiness of the STD clinic to implement cervical cancer screening, or the kinds of enhancements that may be needed in a clinic already conducting Pap testing, than to the Phase 2

Data Element	Data Source(s)	Measure(s) or Descriptor(s)	Outcome(s)	Timing of Data Collection
Effectiveness of method for contacting patient	<ul style="list-style-type: none"> Tracking system 	<ul style="list-style-type: none"> The mean number of contacts per patient; The mean time between contact and the patient's return to clinic 	<ul style="list-style-type: none"> The maximum amount of time between the clinic's receipt of an abnormal result and the patient's return to clinic will be 3 weeks; Problems detected early in the project will be corrected 	<ul style="list-style-type: none"> Duration of Phase 2
Repeat smears (any reason)	<ul style="list-style-type: none"> Pap smear log 	<ul style="list-style-type: none"> The number of unsatisfactory slides each month 	<ul style="list-style-type: none"> The number of unsatisfactory slides will decrease during the time span of the project 	<ul style="list-style-type: none"> Duration of Phase 2
	<ul style="list-style-type: none"> Patient chart; Pap smear log 	<ul style="list-style-type: none"> Confirmation that a patient requiring a repeat smear received one 	<ul style="list-style-type: none"> Patients receive repeat smears when indicated 	<ul style="list-style-type: none"> Duration of Phase 2
Implementation of follow-up	<ul style="list-style-type: none"> Tracking system; Responses from referral clinics entered in patient's chart 	<ul style="list-style-type: none"> The average amount of time between notification of an abnormal result and the patient's arrival at the referral clinic 	<ul style="list-style-type: none"> Women will receive follow-up service within 6 weeks of notification of abnormal result (2 weeks for high-grade lesion); Patterns of delays will be addressed 	<ul style="list-style-type: none"> Duration of Phase 2
	<ul style="list-style-type: none"> Interviews with case managers 	<ul style="list-style-type: none"> Description of process of follow-up and referral 	<ul style="list-style-type: none"> Modification to protocol if indicated; Suggestions for dealing with difficult situations 	<ul style="list-style-type: none"> Phase 3
Reaction of women to having Pap test done in clinic	<ul style="list-style-type: none"> Questions asked during post-exam counseling 	<ul style="list-style-type: none"> Satisfaction of women with service; Evidence that misinformation was corrected or new information obtained 	<ul style="list-style-type: none"> Improvement to clinical, educational and counseling services if indicated; Recommendations for modification to protocol if indicated 	<ul style="list-style-type: none"> At end of STD clinic visit throughout Phase 2
Challenges and facilitators to carrying out tasks	<ul style="list-style-type: none"> Interviews with staff 	<ul style="list-style-type: none"> Description of what went well, of challenges and solutions, and of remaining barriers 	<ul style="list-style-type: none"> Recommendations for improving program 	<ul style="list-style-type: none"> Phase 3

Table 5.2 What are the challenges associated with cervical cancer screening follow-up, referral, diagnosis, surveillance and education in STD clinics?

Data Element	Data Source(s)	Measure(s) or Descriptor(s)	Outcome(s)	Timing of Data Collection
staffing mix	• Needs Assessment	• Number and type of staff capable of providing any cervical cancer screening services	• Clinic management can identify sources of staff training and new staff lines if necessary	• Beginning of Phase 2
	• Progress reports	• List of staff conducting services	• All areas discussed in protocol are being carried out by appropriate staff	• Throughout demonstration project
	• Staff Interviews	• Description of advantages and disadvantages of staffing mix used by clinic	• Recommendations of particular staff mixes for carrying out cervical cancer screening in STD clinics	• Phase 3
Staff Training	• Activity evaluation forms	• Quality of training activities as noted by staff	• Improvement of training activities	• Duration of demonstration project
	• Staff Interviews	• Relevance of training to performance of job-related functions	• Recommendations for improving training for staff in STD clinics involved in cervical cancer prevention	• Phase 3
Laboratory Results	• Tracking system	• The mean time for receiving results; The presence or absence of a method for notifying the STD clinic quickly if high-grade lesions are found	• Receipt of all results within 10 days; Receipt of reports of high-grade lesions within 3 days	• Duration of Phase 2
	• Monthly reports from reference lab	• Identification of gaps or discrepancies in information logged as compared with monthly summary from reference lab	• Any gaps or discrepancies will be addressed immediately so a woman in need of services will be notified and located; Clinics finding problems will implement a procedure to correct the problem either within the clinic or with the laboratory	• Duration of Phase 2

Repeat Smears

The number of repeat smears per month will be entered into the Pap smear log. This log should include the reasons for the repeat smears, which will allow clinic staff to assess the need for inservice education if an excessive number of repeat smears are due to unsatisfactory slides.

Implementation of Follow-Up

The assessment of the follow-up protocol will be accomplished in two ways. One will be through the tracking system, which can flag delays in reaching women and sending them on for referral. The second will be through questions in the Phase 3 interviews that will be targeted to the case managers concerning their use of the protocol.

Clinical Providers Favored by Women

This information can be assessed through the tracking system if women have a choice of providers. However, since the choices will probably be limited, this may not be a useful data element for the project.

Reaction of Women to Having Pap Test Done in STD Clinic

As part of an exit discussion conducted when the patient receives her final instructions and cervical cancer prevention messages are reinforced, a few simple questions can be asked regarding the patient's reaction to having received this service. Although the responses may be biased by the fact that the patient will be speaking with a representative of the provider whom she has just seen, answers to a few simple questions should prove useful for evaluation purposes and may also provide a good opportunity to reinforce education and counseling received at the clinic that day. **Suggested** questions are:

- If you had not received a Pap smear in the clinic today, would you have gone elsewhere for the test? Y N DK
 - *If yes, Where would you have gone for the test?*
- Did you find it convenient to have the Pap test at the same time you were tested for an STD?
YNDK
 - What was convenient about this?
 - What was inconvenient about this?

Staff Training

The type of training required for implementation or enhancement will be determined by the STD clinic when it conducts its own needs assessment. The quality of staff training can be assessed through staff evaluation of any training program. Evaluation by supervisors of the manner in which the clinician carries out his or her duties is part of the clinic's own self-assessment and would be confidential. Further evaluation can be conducted through interview questions during Phase 3.

Impact of Time Needed to Obtain the Pap Smear

Phase 1 findings show that this impact is negligible. It is not included as a data element for Phase 2.

Laboratory Results

For Phase 2, the important data are those entered into the tracking system that show the amount of time required to receive results. The clinic will need to note any discrepancies between results received initially and those that show up in the monthly report to be used as a QC check (see Section 4.1 .5) and to reconcile and correct any errors. Issues regarding the working relationship between the STD clinic and the reference laboratory can be assessed through the qualitative interviews proposed for **Phase 3**.

Effectiveness of Method for Contacting Patient

All contacts with the patient will be logged into the tracking system so that a mean number of contacts and the mean time between contact and return to clinic can be determined during the Phase 3 analysis.

Table 5.3 When abnormal Pap results are reported, can the clinic assure that women receive appropriate diagnostic and treatment services?

Data Element	Data Source(s)	Measure(s) or Descriptor(s)	Outcome(s)	Timing of Data Collection
Tracking of referral and follow-up	- Tracking system	- The mean time to referral setting; The mean time for clinic to receive notification that patient was seen; The number of women lost-to-follow-up	- Women will be seen by follow-up clinic within 6 weeks (2 for high-grade lesion); STD clinic will receive notification of arrival at clinic for patients referred; No woman with a high grade lesion will be lost to follow-up	- Duration of Phase 2
Evidence of cultural and age sensitivity	- Demographic data collected during intake	- Percent of women according to race, ethnicity, age (below 18, 18-25, 26-35, 36-45, >45)	- Clinic (with TA if indicated) will be able to assess if problems of referral and follow-up are found in a particular racial, ethnic or age group and take steps to remedy this	- Duration of Phase 2
	- Educational materials	- Materials will be culturally and linguistically appropriate	- Patients will be given materials as part of counseling session	- Duration of Phase 2
Effect of patient's insurance status	- Intake	- Proportion of women with Medicaid, private insurance, in managed care, other coverage, no coverage	- Data will be analyzed to uncover any gaps in referral based on type of insurance; Women will be referred to appropriate providers whether or not insurance is an issue	- Duration of Phase 2
Proximity of diagnostic and treatment services	- Needs Assessment	- Location of diagnostic and treatment services	- Establish referral network with liaison at each diagnostic site	- Beginning of Phase 2
	- Tracking system	- Identification of clinics which patients do not utilize when referred there	- Consider whether location or another issue is the problem; Develop plan to correct the problem or delete clinic from network	- Duration of Phase 2

Challenges and Facilitating Factors to Carrying Out Tasks

As noted earlier, this information will be covered in the Phase 3 staff interviews.

5.2.3 When abnormal Pap results are reported, can the clinic assure that women receive appropriate diagnostic and treatment services?

Many of the items covered in Section 5.2.3 overlap with data elements to be collected in Section 5.2.2., because this research question is really a sub-question of the previous one. In other words, the ability of a clinic to assure that a woman receives appropriate diagnostic and treatment services is a facet of its ability to handle the challenges associated with all phases of providing screening and follow-up services. However, this issue is so important that it does require added focus. Table 5.3 details the elements of this focus.

Tracking of Follow-up and Referral

The tracking system should include data on the number of contacts per patient, the timeframe for each contact attempt, the method of actual contact, who makes the contact, and the amount of time elapsed between when the clinic received results and the patient received follow-up counseling at the STD clinic and referral services at the referral clinic. As above, we also recommend interviewing staff in Phase 3 concerning challenges that may be discovered when implementing the protocol.

Evidence of Cultural/Age Sensitivity

We recommend collection of descriptors and indirect data concerning the issue of cultural competency and sensitivity to age-related issues. During Phase 2, clinics will collect data on **race/ethnicity** and age as part of the demographic portion of the regular intake procedure. Another source of data would be progress reports stating the kinds of educational materials used (languages, story line) and the types of providers in the referral network.

If Phase 2 data uncover specific problem areas, then a detailed observational and interview study can be planned for Phase 3. If these data-collection activities include patient data, time will need to be allowed for OMB and IRB clearances.

Effect of Patient's Insurance Status

Data should be collected on the type of insurance patients possess. This may be done either at intake or when referring patients with abnormal Pap smear results. Matching insurance data with follow-up data will allow an assessment of which health care providers take referrals of patients who possess particular types of insurance, Medicaid, or no coverage. The mean time of diagnosis can be measured in order to determine whether inequities are associated with the kind of coverage the patient possesses.

Use of Incentives

While we saw no evidence of the use of incentives in STD clinics to ensure that women receive Pap tests, return for follow-up counseling, or keep referral appointments, some respondents felt that patients should be reimbursed for bus fare or parking for returning to the clinic. This cost will be included in the budget estimates in Appendix A.

Protection Against Liability

Although Phase 1 results did not show serious concern with this issue, we recommend several steps: (1) requiring all patients to sign informed consent before the examination; (2) requiring that the patient sign a medical waiver if she refuses medically indicated treatment, especially if she has a **high-grade** lesion; and (3) requiring that results be interpreted by a physician or by a gynecological **nurse-practitioner** with easy access to a consulting physician. Since this is an implementation and not an evaluation issue, it is not discussed in Table 5.3.

Data Element	Data Source(s)	Measure(s) or Descriptor(s)	Outcome(s)	Timing of Data Collection
Proximity of diagnostic and treatment services (continued)	<ul style="list-style-type: none"> • Interviews with STD clinic staff; Patient interviews if possible 	<ul style="list-style-type: none"> • Description of effect of proximity on willingness of patients to use facilities 	<ul style="list-style-type: none"> - Adjust referral network if necessary 	<ul style="list-style-type: none"> • Phase 3
Use of incentives	<ul style="list-style-type: none"> • Clinic policy 	<ul style="list-style-type: none"> - Clinic does/does not provide reimbursement for bus/cab fare or parking for return or referral appointments 	<ul style="list-style-type: none"> - Assess whether clinics that provide incentives achieve a greater rate of compliance with referrals than those that do not 	<ul style="list-style-type: none"> • Duration of Phase 2
Inservice Training	<ul style="list-style-type: none"> • Collect dates and times of inservice events 	<ul style="list-style-type: none"> - Presence or absence of inservice training; Frequency of training; Types of training 	<ul style="list-style-type: none"> - A regular schedule of inservice training supplemented by specific activities to address emergent problems 	<ul style="list-style-type: none"> • Duration of Phase 2
Challenges and facilitators in assuring that women with abnormal Pap smears are diagnosed	<ul style="list-style-type: none"> • Interviews with staff; Patient interviews if possible 	<ul style="list-style-type: none"> - Description of what has gone well in the referral process, of challenges and facilitators, and of continuing barriers 	<ul style="list-style-type: none"> • Challenges will be addressed and facilitators enhanced in order to improve the ability of STD clinics to assure that women with abnormal Pap smears are diagnosed and treated 	<ul style="list-style-type: none"> • Phase3

Table 5.4 Would the addition of comprehensive cervical cancer screening service in STD clinics have a negative impact upon the delivery of primary STD prevention, diagnosis, treatment and epidemiologic services?

Data Element	Data Source(s)	Measure(s) or Descriptor(s)	Outcome(s)	Timing of Data Collection
Existing Environment	- Phase 1 site reports	- Description of each STD clinic	- None (may be used as part of clinics own needs assessment)	-Phase 1
	- Staff interviews	- Description of changes made due to implementation of, or enhancement of, cervical cancer prevention services	- Recommendations to STD clinics regarding adding cervical cancer screening	-Phase 3
Services and Staffing	- Needs assessment	- Listing of present services and staff by FTE	- Assess whether new staff lines are needed or changes in assignment required	- Beginning of Phase 2
	- Progress report	- List of additional services (or any deleted) and staff by FTE	- Assess changes in staffing patterns that may be attributed to implementation of cervical cancer screening	- Duration of Phase 2

In-Service Training

Clinics can document and report on the kinds and frequency of inservice training to address diagnostic and treatment issues. Phase 3 evaluation interviews can address the usefulness of this training with staff.

Challenges and Facilitators in Assuring that Women with Abnormal Pap Smears are Diagnosed

This can be addressed as part of the Phase 3 evaluation interview questions.

52.4 Would the addition of comprehensive cervical cancer screening service in STD clinics have a negative impact upon the delivery of primary STD prevention, diagnosis, treatment and epidemiologic services?

Table 5.4 details the data elements concerned with the impact of implementing cervical cancer screening upon STD services already in place.

Description of Existing Environment

The current environment was assessed thoroughly in Phase 1 and is presented in the site reports. The Phase 1 site reports also show that each clinic was able to cope with the addition of new services, mainly HIV counseling and testing, although some did feel that the additional service created pressure on staff. Specific questions about the advantages and disadvantages of adding cervical cancer screening can be addressed in the interviews to be conducted in Phase 3.

Services and Staffing

As a part of Phase 2 planning, the STD clinic's needs assessment should address current services and type of staff. This assessment should note the number of staff for intake, clinical care, counseling and education, tracking, follow-up, and referral. Estimates for any new staff lines will be compared with the actual staff hired to implement cervical cancer screening or to enhance what is already in place. Phase 3 qualitative interviews will ask staff members about their own perception of the impact of implementing or enhancing cervical cancer screening upon the STD services already in place. These interviews will also

Table 5.5 What would be the overall economic cost of providing this additional service?

Data Element	Data source(s)	Measure(s)	Outcome(s)	Timing of Data Collection
Cost of screening	- Budget	- Comparison of estimated and actual cost	- Actual costs reflect estimated costs	- Duration of Phase 2
Costs associated with processing and evaluating slides	- Budget	- Comparison of estimated and actual cost	- Actual costs reflect estimated costs	- Duration of Phase 2
Costs associated with staffing and staff training	- Budget	- Comparison of estimated and actual cost	- Actual costs reflect estimated costs	- Duration of Phase 2
Costs associated with tracking, follow-up and referral	- Budget	- Comparison of estimated and actual cost	- Actual costs reflect estimated costs	- Duration of Phase 2

contain questions concerning the adequacy of the clinic's staffing pattern for carrying out all of its functions.

5.2.5 What would be the overall economic cost of providing this additional service?

This will be evaluated by comparing the estimated costs with actual costs for screening; processing and evaluating slides; staffing and training; and tracking, follow-up, and referral (see Table 5.5).

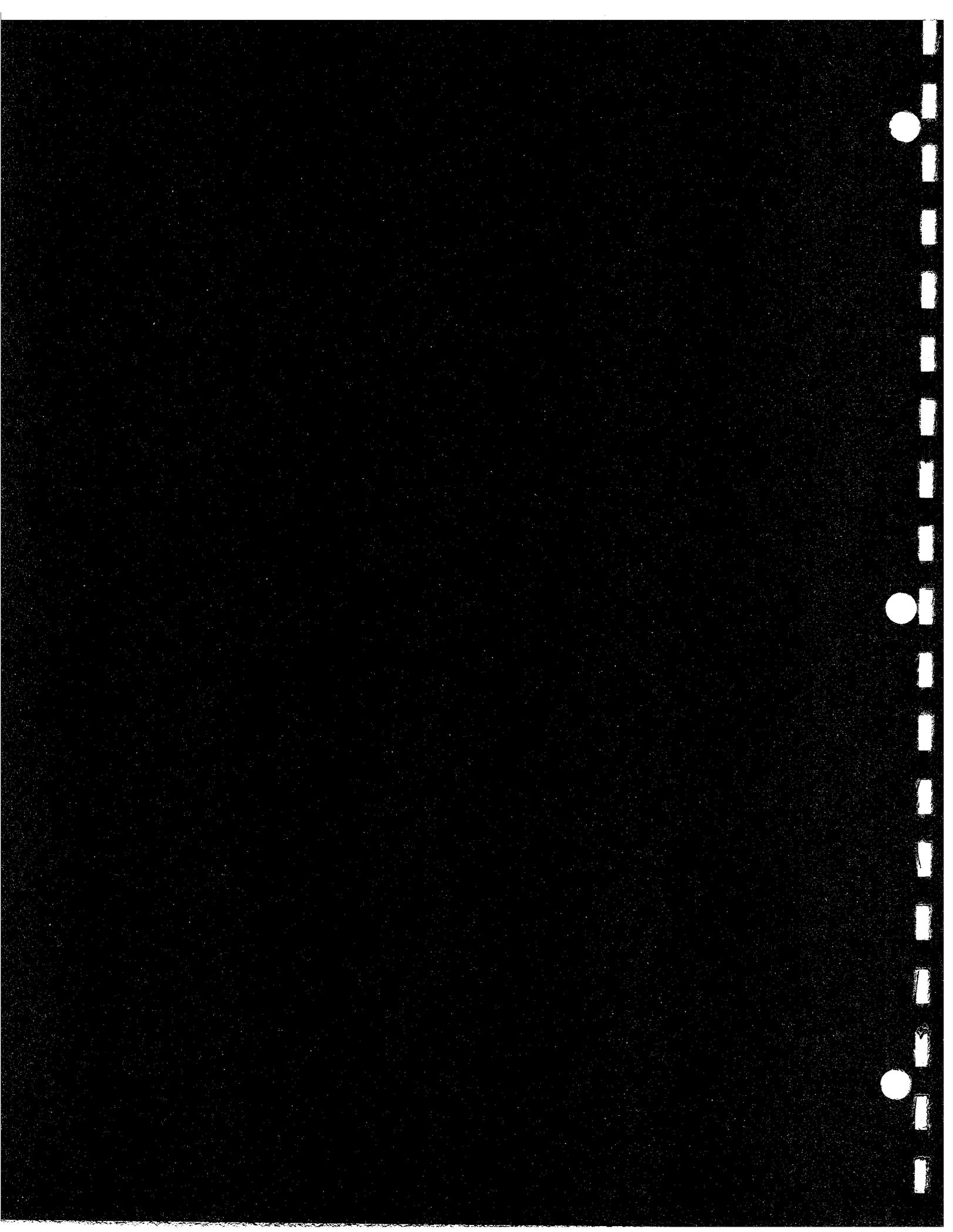
5.3 Conclusion

In this chapter, we presented a plan for evaluating the ability of publicly-funded STD clinics to conduct cervical cancer screening activities. These activities include the identification of women in need of the service, carrying out testing and sending slides for processing, collecting necessary data, and tracking and following women who require referral for further diagnosis and possibly treatment. The evaluation plan is meant to correspond to the protocol presented in Chapter 4, but it is flexible enough to allow individual clinics to modify aspects of the protocol to meet their own local contexts. The protocol, in turn, was developed **from** the findings of the Phase 1 project, presented in Chapter 3, and from literature concerning the screening of women for cancerous and precancerous lesions of the cervix.

As long as demonstration sites systematically collect the key data points (at a minimum) and implement the questions listed in Sections 5.2.1 and 5.2.2, many aspects of the feasibility of including cervical cancer screening in publicly-funded STD clinics should be **evaluable**. Clinics may also decide to collect even more detailed information, which would assist the Phase 3 evaluation even further. Qualitative interviews of clinic administrators and staff (and possibly a sample of clients) during Phase 3 should round out the feasibility assessment for the full project.

The Phase 1 project demonstrated that cervical cancer screening is an appropriate activity for STD clinics. However, it is an activity that may not belong in all clinics. For example, some small clinics may make better use of their resources by improving liaison with other providers such as family planning clinics. Other clinics, capable of providing the testing, may have limited ability to conduct data collection and tracking of women with abnormal results. Such a clinic may wish to participate in the demonstration project, seeing it as an opportunity to upgrade its system, or it may prefer to focus on systematizing data

already collected concerning **STDs**. Each clinic's management will need to decide in consultation with its Health Department which staff members will be allowed to perform the test and will need to create a training plan. For some, this will be a relatively straightforward task, but for others political or other factors may mean that it is unwise to implement Pap testing at this time. Despite these caveats we believe that cervical cancer screening does have a place in the STD clinic, and we saw that there is overwhelming support for the idea among the people with whom we spoke.



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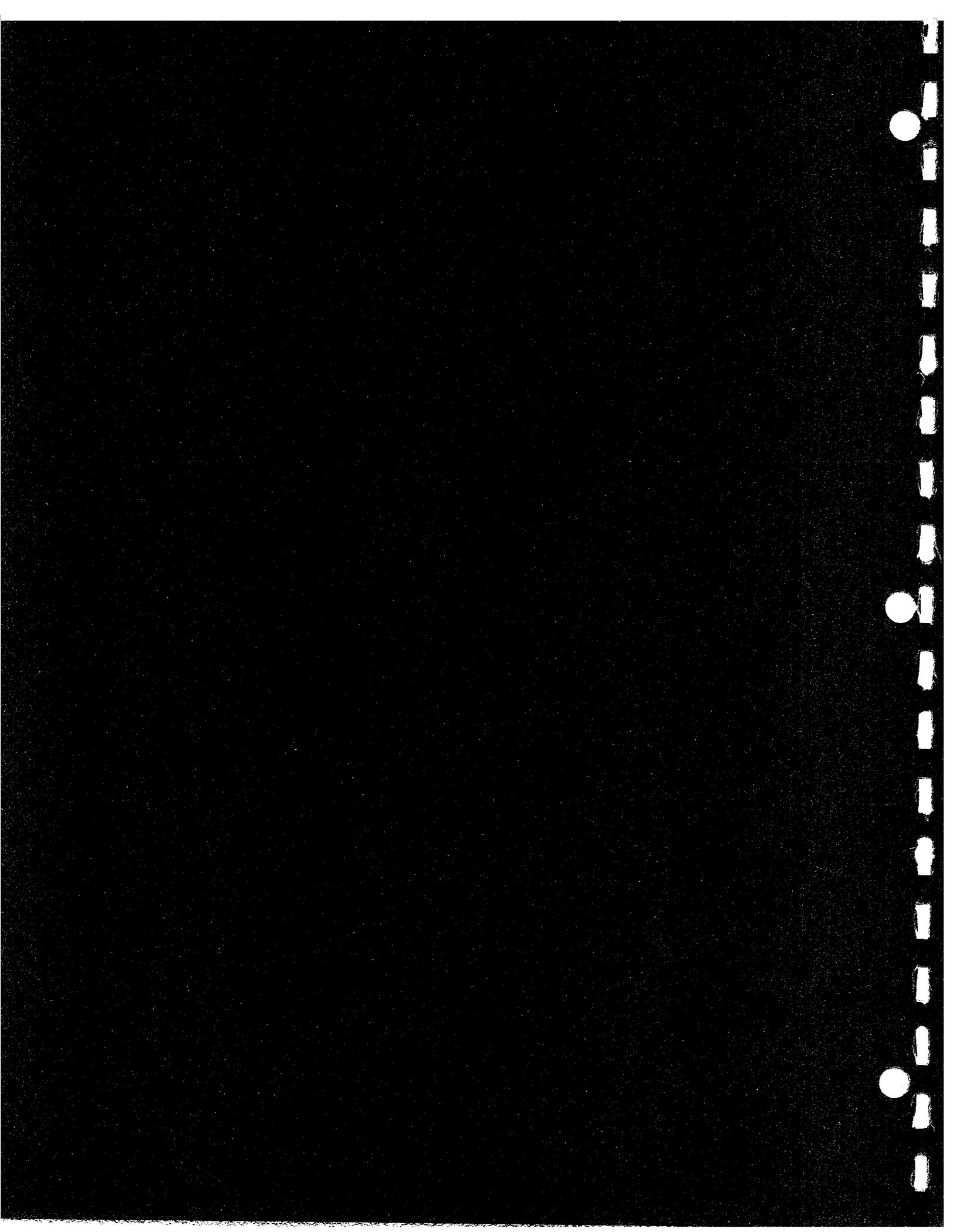
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Appendix A - Budget

A. Total Number of Patients Examined

As described in Chapter 3, the average number of patients who visit the STD clinic per month varied across sites, from 70 in small clinics to 1929 in large clinics. It must be noted that in some cases these monthly census numbers include patients that were not examined but sought only an HIV test, a refill for a prescription, or were visiting to collect some information. From our observation up to 30 percent of those registered may not actually be examined. For that reason, it is extremely important to use only the total number of patients examined in this calculation.

B. Percent Repeat Visitors

It is important to include only those patient who are first-time visits rather than repeat visits in this budget. After an introductory period repeat clients will have already been screened and should not be factored into the rest of this calculation. The percent of repeat visits varied across sites from 11 percent in Brooklyn to approximately 60 percent in Orange County and Wake County.

Assumption

- Battelle assumes that 40 percent of each STD clinic's total monthly census would be new patients. For the purposes of the demonstration, first time visits will be anyone who had not been seen at the STD clinic in the past year.

C. Percentage of Female Patients

From the site visits we learned that there is variation among clinics in the gender distribution of their patients. Whereas the breakdown in Norfolk is approximately 70 percent male and 30 percent female, it is 50/50 in Clark County. In all other sites, the breakdown is around 60-65 percent male and 35-40 percent female.

Assumption

- Battelle assumes that women comprise 40 percent of the STD clinic clientele and that this distribution is reflected in the number of new patients each month.

Appendix A - Budget

In Appendix A, Battelle presents a four-step model for estimating the cost of implementing cervical cancer screening in publicly-funded sexually transmitted disease (STD) clinics. Below, the **step-by-step-process** is described, including all relevant assumptions and calculations. These assumptions are based upon selected findings from the nine sites Battelle visited and upon relevant literature. All findings presented below have been previously discussed in Chapter 3 and displayed in Tables 3.1-3.3. **Eight** hypothetical budgets are displayed following this description of the methodology and assumptions used to develop them. Each budget reflects changes in key parameters that affect cost. It must be noted that these budgets are only reflective of implementing a new program, not enhancing one that is already operational. Such programs have different needs. For example, one STD clinic currently providing cervical cancer screening may need funding to develop site-specific educational materials and refine its current follow-up procedures to meet the requirements of the demonstration project. Another STD clinic currently providing cervical cancer screening may need computer programming support to enhance its program. Consequently, those sites should be budgeted separately.

STD clinics embarking upon implementing cervical cancer screening will have different budgets. Differences in STD clinic volume, staffing patterns, and local salaries, as well as the volume of women requiring follow-up will account for most of the expected variation in costs across sites.

I. Estimate Number of Female Patients Who Get a Pap Smear Per Month

The first step in determining the cost of implementing a program of Pap smear testing and **follow-up** is to estimate the volume of female patients who get a Pap smear in the STD clinic each month. There are three components that must be considered when assessing this number. These include (1) the total number of patients examined, (2) the percent of those patients who are new, and (3) the percent of those patients who are female. This figure, when calculated, sets the stage for the magnitude of all other costs, including the amount of resources needed for processing and evaluating the Pap smear slides and for conducting tracking, follow-up, and referral.

III. Estimate Cost of Follow-up and Referral

The third step in developing a budget for implementing cervical cancer screening in STD clinics is to estimate the cost associated with follow-up and referral. These costs are based on three components (1) the number of women requiring follow-up, (2) labor costs associated with follow-up and referral, and (3) costs of postage and mailing associated with each recommended follow-up procedure.

A. Number of Women Requiring Follow-up

The total number of women requiring follow-up is calculated using the number of women who get screened (see Step 1) and the percentage of women requiring follow-up. The latter is defined as the percentage of women who do not have normal results and require a repeat smear, treatment for a subclinical infection, or a referral for further diagnosis. The percentage used in this budget is based on data collected from the Brooklyn, Memphis, Wake County, and Orange County site visits and on relevant literature (Eckert et al 1995; and Schwebke and Zajackowki 1997). It must be noted that although the Bethesda System is widely used among cytopathology labs, STD clinics often report results using a different system, thus making it difficult to compare Pap results across sites. Although Brooklyn reported a five percent abnormality rate (January 1997 data), it is unclear whether these results include unsatisfactory slides and/or ASCUS or whether this figure is representative of an annual average. Data from the Memphis pilot study showed that 17.5 percent of women required follow-up. On the other hand, Wake County and Orange County indicated that 20 and 25 percent, respectively of women screened required follow-up. These data are comparable to those (24.7%) reported in Chicago STD clinics (Schwebke and Zajackowski 1997).

Assumption

- Battelle assumes that 20 percent of all women who were **screened** at the STD clinic will require some sort of follow-up.

For example, $160 \times .20 = 32$ women who will require some sort of follow-up.

Calculation

Number of female patients who receive a Pap smear/month = **A** (total number of patients examined/month) x **B** ([.40] percent new patients) x **C** ([.40] percent women)

For example, $1000 \times .40 \times .40 = 160$ women who receive a Pap smear/month

II. Estimate Monthly Cytopathology Lab Costs

The second step in developing a budget for implementing cervical cancer screening in STD clinics is to calculate cytopathology lab costs. Lab charges for each Pap smear slide processed and evaluated range from \$5.00 to \$11.00 per slide. In order to calculate the STD clinic's monthly and annual cytopathology cost, multiply the total number of women who receive a Pap smear by the cost of processing and evaluating each slide.

Assumption

- **Battelle** assumes that all women who are examined each month are 100 percent eligible for Pap testing.

Assumption

- Based on data collected across sites currently offering Pap testing services, Battelle assumes that processing and evaluating Pap smears slides cost \$8.50.

Calculation

Monthly Cytopathology Cost = **number** of females who get a Pap smear each month x \$8.50

Annual Cytopathology Cost = Monthly Cytopathology Cost x 12

Assumption

- Due to the level of skills necessary to carry out the follow-up component of this demonstration project, Battelle assumes that the above-mentioned staff have at least 5 years experience.

Assumption

- Battelle assumes that salaries for new FTEs include an additional 28 percent to reflect the national average paid in fringe benefits in 1997.

Assumption

- Battelle assumes no fringe benefits when a contracted position is added.

Calculation

Labor Cost (each position) = (Salary x 1.28) x %FTE

C. Postage and Mailing Associated with Follow-up and Referral

As a major part of follow-up, there will be direct costs associated with contacting patients with their Pap smear results. See Table 4.2 for the steps of patient contacting and referral.

Assumption

- Battelle assumes that postcards are **\$.20**, letters are **\$.32** and certified letters (\$1.35) including returned receipt (\$1.10) and postage (**\$.32**) are \$2.77.

Assumption

- Battelle assumes that there will be no additional cost associated with staff time for making phone calls to contact patients because it is already included in the labor cost for case manager.

Assumption

- Battelle assumes that approximately 50 percent of all women requiring some sort of follow-up will require all steps of follow-up (i.e, certified letters have to be sent) (for example, see Mandelbaltt et al. 1997; Tavelli et al. 1985).

B. Labor Costs Associate with Follow-up and Referral

For the purposes of this demonstration, Battelle has identified two major positions that should be staffed.

Case manager. For tracking, follow-up, and referral, there was general agreement across all sites that these functions should be done by public health nurses, nurse practitioners, or a combination of **PHNs** and DIS. This staff member would be responsible for sending out initial letters and certified letters, tracking Pap results, calling patients, ensuring someone does patient home visits if necessary, and functioning as clinic-level contact for this demonstration project.

Pap Smear Interpreter. Interpretation of Pap smear cytopathology findings should be completed by a physician or NP or PA under supervision of a physician. This staff member will also be responsible for conducting training and providing quality assurance.

Sites should have latitude in selecting the appropriate staff for these positions. **In some** cases these positions can be filled by one adequately trained staff. In other sites, these positions may be split up among public health nurses and NP/physicians.

Assumption

- Battelle assumes that it would require 1 FTE staff time to conduct tracking, follow-up, and referral and 1/4 FTE staff time for interpretation, review, and QA.

B. Incentives

In order to reduce the disincentive for returning to the STD clinic for repeat Pap smear or referral, Battelle has included in the budget an incentive of reimbursement of bus fare or parking.

Assumption

- Battelle assumes an average cost for round-trip bus fare or parking is \$4.00.

Calculation

Monthly cost of travel incentive = Number of women requiring follow-up x **\$4.00**

Annual cost of travel incentive = Monthly cost of travel incentive x 12

c. supplies

Battelle has identified supplies that are required to implement Pap smear testing in **publicly-**funded STD clinics. These supplies include cytobrushes, spatulas, slides, and fixative: In the majority of STD clinics where the Health Department has a contract with a cytopathology lab, the contracted lab provides Pap smear supplies as part of the overall costs.

Assumption

- Battelle assumes that all costs for Pap smear supplies will be a part of the overall lab costs.

D. Labor

Sites should estimate any additional labor costs needed to implement this demonstration program. Staffing patterns in the STD clinics correspond to certain functions: intake; education and counseling; examination; and tracking, follow-up, and referral. Most of these functions, as they relate to cervical cancer screening, are currently operational and may not require any major modifications. Battelle does not expect much, if any, labor time added to the intake/registration process, education and counseling program, nor the actual examination itself. Health care providers across sites reported that providing

patient education and counseling during and/or after the exam is presently a part of clinic **flow**.¹ More importantly, these respondents felt that adding Pap testing and cervical cancer education would not add much additional time to their day. With respect to which staff member would be responsible for actually taking the Pap smear, there is not agreement as to whether it is appropriate for **RNs**, even with some additional training.

Initial training will be needed to instruct staff on appropriate data to be collected for this demonstration program. Throughout the duration of the demonstration project, training must be continued to ensure overall quality control of the data collection process. In addition, training will also be provided to ensure quality assurance in the collection of Pap smear specimens. Also, staff involved in patient education (clinicians and DIS) will need to be trained to up-date their **knowledge** on cervical cancer, Pap testing, and abnormal results.

Finally some sites may need technical **assistance** to systematize, enhance, or streamline their information management systems to accommodate new cervical cancer screening reporting requirements. CDC may choose to provide sites with this help or allocate funds to secure an outside contractor.

Assumption

- Battelle assumes \$2,000 for training costs.

Assumption

- Battelle assumes that STD clinics will need technical assistance to systematize their information management system at the beginning of this demonstration project.

F. Postage and Mailing Associated with Validation of Self-Reported Pap Smears in the Last 12 Months

There will be some costs associated with medical records release to validate self-reported Pap smears in the last 12 months. However, because we are not able to estimate the percentage of women who will report having received a Pap smear in the past 12 months', we are not able to calculate cost for this parameter.

¹ **This percentage addresses one of the major research questions, the need for cervical cancer screening in public STD clinics.**

Assumption

- Battelle assumes that costs associated with validating self-reported Pap smears in the last 12 months will be covered by the overall demonstration budget.

Budget I

Budget Line&m	Cost
Cytopathology Lab Costs (@\$&SO/slide)	\$16,320
<u>Costs for Follow-up and Referral</u>	
Labor	
1 FTE PHN (28% fringe)	\$48,634
1/4 NP	\$12,409
Postage and Mailing	\$1,146
<u>Direct Costs</u>	
Technical Assistance	\$5,000
Brochures	\$2,000
Incentives	\$1,536
Training	\$2,000
Total	\$89,045

Assumptions

1000 patients
 40% new patients
 40% of patients are women
 Case Manager- 1 FTE PHN
 Pap Smear Interpreter- 1/4 NP (contracted position, no fringe benefits included)
 20% of women screened will require follow-up
 50% of women requiring some sort of follow-up will require all steps of follow-up
 Patients with normal results sent a letter

Salary Data¹

PHN baseline salary with 5 years experience \$37,995
 NP baseline salary with 5 years experience \$49,637
 Physician baseline salary with 5 years experience 77,495

¹ These data come from the Office of Budget Services at the Virginia Department of Health and represent schedules of standard rates of pay effective November 25, 1997.

Budget II

Budget Line Item	Cost
Cytopathology Lab Costs (@\$8.50/slide)	\$16,320
<u>Costs for Follow-up and Referral</u>	
Labor	
1 FTE PHN (28 % fringe)	\$48,634
1/4 Physician	\$19,374
Postage and Mailing	\$1,146
<u>Direct Costs</u>	
Technical Assistance	\$5,000
Brochures	\$2,000
Incentives	\$1,536
Training	\$2,000
Total	\$96,010

Assumptions

1000 patients
 40% new patients
 40% of patients are women
 Case Manager- 1 FTE PHN
 Pap Smear Interpreter- 1/4 Physician (contracted position, no fringe benefits included)
 20% of women screened will require follow-up
 50% of women requiring some sort of follow-up will require all steps of follow-up
 Patients with normal results sent a letter

Salary Data¹

PHN baseline salary with 5 years experience \$37,995
 NP baseline salary with 5 years experience \$49,637
 Physician baseline salary with 5 years experience 77,495

¹ These data come from the Office of Budget Services at the Virginia Department of Health and represent schedules of standard rates of pay effective November 25, 1997.

Budget III

Budget Line Item.	.. cost
Cytopathology Lab Costs (@\$8.50/slide)	\$16,320
Costs for Follow-up and Referral	
Labor 1 FTE NP (28% fringe)	\$63,535
Postage and Mailing	\$1,146
Direct Costs	
Technical Assistance	\$5,000
Brochures	\$2,000
Incentives	\$1,536
Training	\$2,000
Total	\$91,537

Assumptions

1000 patients
40% new patients
40% of patients are women
Case Manager/Pap Smear Interpreter- 1 FTE NP
20% of women screened will require follow-up
50% of women requiring some sort of follow-up will require all steps of follow-up
Patients with normal results sent a letter

Salary Data¹

PHN baseline salary with 5 years experience \$37,995
NP baseline salary with 5 years experience \$49,637
Physician baseline salary with 5 years experience 77,495

¹ These data come from the Office of Budget Services at the Virginia Department of Health and represent schedules of standard rates of pay effective November 25, 1997.

Budget IV

Budget Line Item	Cost
Cytopathology Lab Costs (@\$8.50/slide)	\$16,320
Costs for Follow-up and Referral	
Labor	
1 NP (28% fringe)	\$63,535
1/4 Physician (28 % fringe)	\$19,374
Postage and Mailing	\$1,146
Direct Costs	
Technical Assistance	\$5,000
Brochures	\$2,000
Incentives	\$1,536
Training	\$2,000
Total	\$110,911

Assumptions

1000 patients
 40% new patients
 40% of patients are women
 Case Manager- 1 FTE NP
 Pap Smear Interpreter- 1/4FTE Physician (contracted position, no fringe benefits included)
 20% of women screened will require follow-up
 50% of women requiring some sort of follow-up will require all steps of follow-up
 Patients with normal results sent a letter

Salary Data¹

PHN baseline salary with 5 years experience \$37,995
 NP baseline salary with 5 years experience \$49,637
 Physician baseline salary with 5 years experience 77,495

¹ These data come from the Office of Budget Services at the Virginia Department of Health and represent schedules of standard rates of pay effective November 25, 1997.

Budget V

Budget Line Item	Cost
Cytopathology Lab Costs (@\$8.50/slide)	\$16,320
<u>Costs for Follow-up and Referral</u>	
Labor	
1 FTE PHN (28% fringe)	\$48,634
1/4 NP (28 % fringe)	\$15,884
Postage and Mailing	\$1,146
<u>Direct Costs</u>	
Technical Assistance	\$5,000
Brochures	\$2,000
Incentives	\$1,536
Training	\$2,000
Total	\$92,520

Assumptions

1000 patients
 40% new patients
 40% of patients are women
 Case Manager- 1 FTE PHN
 Pap Smear Interpreter- 1/4 NP
 20% of women screened will require follow-up
 50% of women requiring some sort of follow-up will require all steps of follow-up
 Patients with normal results sent a letter

Salary Data¹

PHN baseline salary with 5 years experience \$37,995
 NP baseline salary with 5 years experience \$49,637
 Physician baseline salary with 5 years experience 77,495

¹ These data come from the Office of Budget Services at the Virginia Department of Health and represent schedules of standard rates of pay effective November 25, 1997.

Budget VI

Budget Line Item	Cost
Cytopathology Lab Costs (@\$&SO/slide)	\$16,320
<u>Costs for Follow-up and Referral</u>	
Labor	
1 FTE PHN (28% fringe)	\$48,634
1/4 Physician (28 % fringe)	\$24,799
Postage and Mailing	\$1,146
<u>Direct Costs</u>	
Technical Assistance	\$5,000
Brochures	\$2,000
Incentives	\$1,536
Training	\$2,000
Total	\$101,435

Assumptions

1000 patients
 40% new patients
 40% of patients are women
 Case Manager- 1 FTE PHN
 Pap Smear Interpreter- 1/4 Physician
 20% of women screened will require follow-up
 50% of women requiring some sort of follow-up will require all steps of follow-up
 Patients with normal results sent a letter

Salary Data¹

PHN baseline salary with 5 years experience \$37,995
 NP baseline salary with 5 years experience \$49,637
 Physician baseline salary with 5 years experience 77,495

¹ These data come from the Office of Budget Services at the Virginia Department of Health and represent schedules of standard rates of pay effective November 25, 1997.

Budget VII

Budget Line Item	Cost
Cytopathology Lab Costs (@\$8.50/slide)	\$16,320
Costs for Follow-up and Referral	
Labor	
1 NP (28% fringe)	\$63,535
1/4 Physician (28% fringe)	\$24,799
Postage and Mailing	\$1,146
Direct Costs	
Technical Assistance	\$5,000
Brochures	\$2,000
Incentives	\$1,536
Training	\$2,000
Total	\$116,336

Assumptions

1000 patients
40% new patients
40% of patients are women
Case Manager- 1 FTE NP
Pap Smear Interpreter- 1/4FTE Physician
20% of women screened will require follow-up
50% of women requiring some sort of follow-up will require all steps of follow-up
Patients with normal results sent a letter

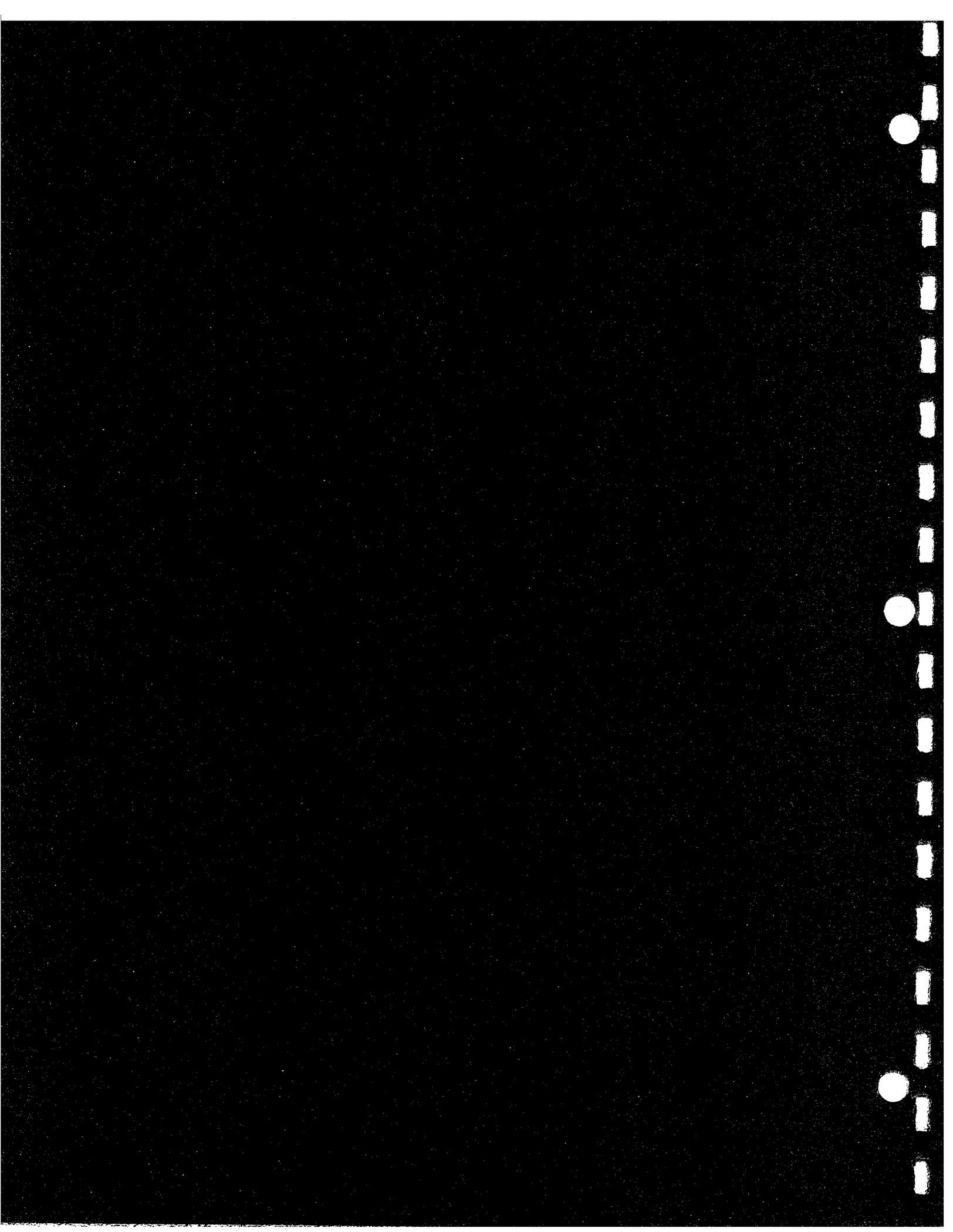
Salary Data¹

PHN baseline salary with 5 years experience \$37,995
NP baseline salary with 5 years experience \$49,637
Physician baseline salary with 5 years experience 77,495

¹ These data come from the Office of Budget Services at the Virginia Department of Health and represent schedules of standard rates of pay effective November 25, 1997.



Appendix B - Summary of Cases



Appendix B - Glossary of Terms'

Abnormal Pap smear - evidence of cellular changes that may or may not be indicative of a cancerous or pre-cancerous state.

AGUS (atypical glandular cells of undetermined significance) - Changes in glandular epithelium that are beyond the changes normally observed in a reactive process. May be benign or may indicate a pre-malignant change. (See Table B. 1)

ASCUS (atypical squamous cells of undetermined significance) - Abnormalities associated with the squamous epithelium that are usually followed with repeat smears. If categorized as **ASCUS/reactive** are considered benign; if ASCUS/favor malignant change patient is referred for colposcopy. (See Table B. 1)

The **Bethesda System (TBS)** - A uniform terminology for reporting the results of Pap tests developed by a National Institutes of Health (NIH) consensus panel in 1988. Each category contains (1) an estimation of the adequacy of the smear, (2) a categorization of the smear as normal or abnormal, and (3) a descriptive diagnosis (e.g., LSIL, HSIL). (See Table B. 1)

Carcinoma-in-situ (CIS) - Equivalent to Class IV Pap Smear, Cervical intraepithelial neoplasia³ (**CIN3**), High grade intra epithelial lesion (**HSIL**), or Stage 0 Cancer. Abnormal cells are found only in the first layer of cells lining the cervix. Literature shows variation in findings regarding rate at which CIS progresses to invasive cancer, but thorough evaluation is always indicated.

Cervical dysplasia (CIN) - Abnormal development of cells and/or tissue of the cervix.

Cervical intra-epithelial neoplasia (cervical dysplasia) - refers to histologic findings and are separated into three categories:

CIN I - mild dysplasia; may indicate HPV infection

CIN II - moderate dysplasia

CIN III - severe dysplasia to carcinoma in situ

CLIA 88 (Clinical Laboratory Improvement Amendments of 1988) - Set of standards designed to improve the quality in all laboratory testing and includes specifications for quality control, quality assurance, patient test management, and personnel and proficiency testing.

Clinic size - Since Battelle was unable to obtain reliable estimates of the patient volume prior to site selection, clinic size was tied to the size of the city or county in which it was located. We used the local nomenclature as to whether the clinic was a city or county clinic and used the following parameters:

Small - located in a city/county with a population less than 200,000.

Medium - located in a city/county with a population between 200,000 and 999,999

¹ The terminology reflects the sources used throughout the report and cited in the References. In addition, clinical terminology was verified in: DeVita VT, Hellman S, and Rosenberg SA. Cancer: Principles and Practices of Oncology, vol 1, 4th edition, 1993: 1168-1172

Large - located in a city/county with a total population of 1,000,000 or greater.

Colposcopy - Procedure used to evaluate a cervix for a more definitive diagnosis after an abnormal Pap smear is reported. The entire transformation zone (squamo-columnar junction) must be visualized, since most cervical cancers begin in this area. The colposcope magnifies the cervix 10 to 20 times so special attention can be paid to the transformation zone.

Cytopathology - Discipline which studies the pathologic changes in cells.

Diagnostic evaluations - Most commonly a colposcopic examination of the cervix along with biopsies of representative areas of the cervix usually including an endocervical curettage (scraping of the interior wall of the cervix). Diagnostic **conization** of the cervix (removal of a cone of tissue) may also be required if the location of the lesion makes colposcopy unsatisfactory, if the diagnosis from an endocervical curettage so indicates, or if the cytologic and histologic findings **conflict**.

First visit - Unless specified as having another meaning for a particular STD clinic visited for this project, a first visit refers to a patient seen at the clinic for the first time in a calendar year.

Follow-up - As used in the protocol (Chapter 4), follow-up consists of those procedures meant to assure that the patient receives subsequent diagnostic testing, and if necessary, is treated for abnormalities that were found to be due to pathological changes.

High-grade squamous intra epithelial lesions (HSIL) - Encompasses moderate and severe dysplasia, and carcinoma-in-situ. Indicative of changes that require thorough diagnostic evaluation. (See Table B. 1)

Human papillomavirus (HPV) - A common sexually transmitted agent of which several varieties have been shown to induce changes in the transformation zone of the cervix.

Information system - A system that contains and organizes all of the information on individual patients, including demographics, Pap smear history and results and referrals. This system can be either **paper-based** or electronic.

LEEP (Loop Electrosurgical Excision Procedure) - procedure done to remove dysplastic tissue from the cervix.

Low-grade squamous intra epithelial lesion (LSIL) - A squamous abnormality equivalent to mild dysplasia that may indicate infection with HPV. (See Table B. 1)

New patient - Unless specified as having another meaning for a particular STD clinic visited for this study, a new patient is someone who is being seen at **the STD** clinic for the first time ever.

Pap smear - A cellular specimen removed from the lower female genital tract is used in routine screening for cervical cancer.

Patient examinations - This refers to patients who receive an STD examination while at the clinic.

Patient visits - Encounters at the clinic; patients who come to the clinic for any reason.

Precancerous lesions - Cellular changes that may progress to cancer if untreated.

Referral network - As used in the protocol (chapter 4), is the provider or panel of providers who are available for diagnostic and treatment services for women who received Pap smears at the STD clinic.

Repeat visit - A return visit to the clinic made by an individual during the same calendar year in which she first presented to the clinic.

Site (as in “**site visit**”) - As used in this report, the site is the STD clinic chosen for this study.

Title X Family Planning clinic - Clinic that receives public funding for family planning services.

Tracking - As used in this protocol (chapter 4), the tracking system is an organized mechanism for following many women through the clinic flow, follow-up and referral.

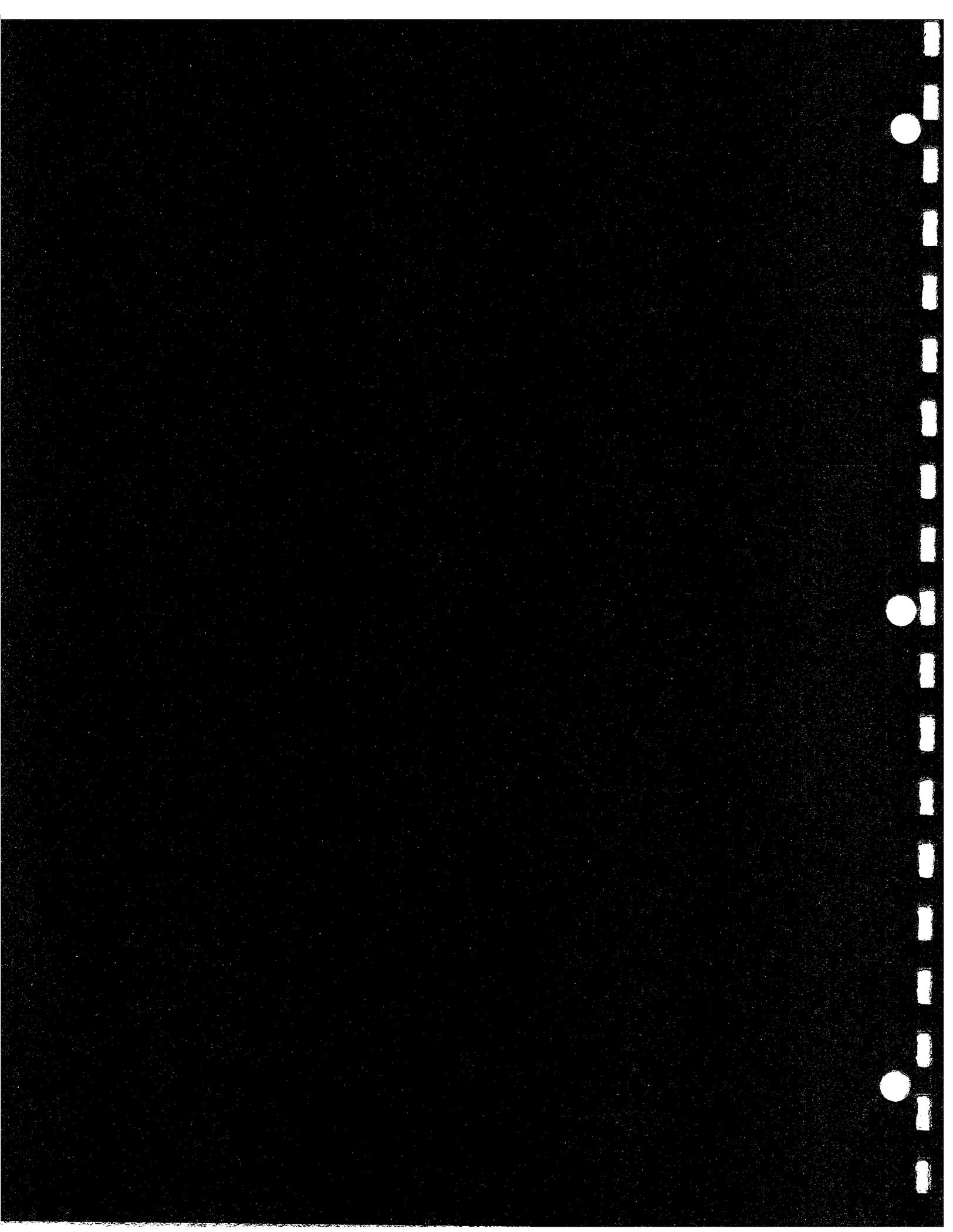
Table B. 1 The 1991 Bethesda System

<p>Adequacy of the Specimen</p> <ul style="list-style-type: none"> ■ Satisfactory for evaluation ■ Satisfactory for evaluation, but limited by (specify reason) ■ Unsatisfactory for evaluation (specify reason)
<p>General Categorization (Optional)</p> <ul style="list-style-type: none"> ■ Within normal limits ■ Benign cellular changes; see descriptive diagnosis ■ Epithelial cell abnormality; see descriptive diagnosis
<p>Descriptive Diagnoses</p> <ul style="list-style-type: none"> ■ Benign cellular changes <ul style="list-style-type: none"> ■ Infection <ul style="list-style-type: none"> Trichomonas vaginalis Fungal organisms morphologically consistent with Candida sp Predominance of coccobacilli consistent with shift in vaginal flora Bacteria morphologically consistent with Actinomyces sp Cellular changes associated with herpes simplex virus Other ■ Reactive changes ■ Reactive cellular changes associated with: <ul style="list-style-type: none"> Inflammation (includes typical repair) Atrophy with inflammation (“atrophic vaginitis”) Radiation Intrauterine contraceptive device (IUD) Other ■ Epithelial cell abnormalities <ul style="list-style-type: none"> ■ Atypical squamous cells of undetermined significance (ASCUS): qualify* Low-grade squamous intraepithelial lesion (LSIL) encompassing HPV**, mild dysplasia/CIN 1. High-grade squamous intraepithelial lesion (HSIL) encompassing moderate and severe dysplasia, CIS/CIN 2, and CIN 3. squamous cell carcinoma ■ Glandular cell <ul style="list-style-type: none"> Endometrial cells, cytologically benign, in a postmenopausal woman. Atypical glandular cells of undetermined significance: qualify* Endocervical adenocarcinoma Endometrial adenocarcinoma Extrauterine adenocarcinoma Adenocarcinoma, not otherwise specified ■ Other malignant neoplasms: specify ■ Hormonal evaluation (applies to vaginal smears only) <ul style="list-style-type: none"> ■ Hormonal pattern compatible with age and history ■ Hormonal pattern incompatible with age and history; specify ■ Hormonal evaluation not possible due to.. (specify)

* Atypical squamous or glandular cells of undetermined significance should be further qualified as to whether a reactive or a premalignant/malignant process is favored.

** Cellular changes of HPV (previously termed “koilocytotic atypia” or “condylomatous atypia”) are included in the category of low-grade squamous intraepithelial lesion.

Appendix B - Examples of Terms and Dates



Appendix C - Examples of Forms and Letters

In this appendix we have included a small sample of letters and forms from some of the STD clinics we visited that are presently offering cervical cancer screening. Included are:

- Follow-up letter from Wake County STD Clinic
- Simple follow-up letter from Orange County STD Clinic
- More detailed follow-up letter from Orange County STD Clinic
- Follow-up letter from Orange County family planning clinic
- Referral form Orange County colposcopy clinic uses for referral to further services. This type of form could be used by an STD clinic to refer a patient for colposcopy. The form comes in triplicate (one for patient's chart, one for referral site, one to be returned to STD clinic with results) and contains space for the referral site to provide information back from the referring clinic.
- Referral/follow-up form from Wake County STD Clinic used to refer patients to colposcopy clinic. Like Orange County's, this also comes in triplicate for the same reasons.
- Authorization to release medical records from Orange County. This form is used when/if the referral site does not return the copy of the referral form with patient results. If the patient fills out this form, the STD clinic can send this form and get the patient's results from the referral site.
- Permission to release medical records from Wake County. Can be used for the same reason as that of Orange County.

Any of these forms and letters can be used by the demonstration project sites as examples for them to develop their own versions. Battelle will provide [with the final report] a tabular worksheet/form for demonstration project sites to report key data points for Phase 3 evaluation. This worksheet/form will contain fields for each of the key data points and can also be used by demonstration sites to help develop an electronic information management system or as the method they use in-clinic to track patients.



WAKE COUNTY
Human Services
Public Health Center

Date:

Dear _____:

Please be aware that your Pap Smear on _____ showed _____ This is an abnormality that means you need:

- special testing called **Colposcopy**
- repeat Pap Smear in 3-6 months with your regular doctor or Clinic F ((250-3877))
- repeat Pap Smear as soon as possible
- medication to treat this infection: _____
- Other: _____

Please call 250-3075 and leave a message on my voice mail that you have received this letter and where and when you can be reached if you have questions.

Thank you,

Gail Lieblang, FNP
Clinic A

cc: chart

"Caring Today for Healthy Tomorrows"

(919) 250-4400 Fax: **(919) 250-3984**
10 Sunnybrook Road P.O. Box **14049** Raleigh, NC 27620-4049



PUBLIC HEALTH

TOM URAM
DIRECTOR

HUGH F. STALLWORTH, M.D.
HEALTH OFFICER

1725 WEST 17TH STREET
SANTA ANA, CA **92706**

TELEPHONE: **714/834-7700**
MAILING ADDRESS P.O. BOX **6099**
SANTA ANA, CA **92706**

Date
Fecha

Dear:

Please contact me in regards to your pap smear results. Call 834-8772 at your convenience. My office hours are Monday **8:30 am** to **4:00pm**, Tuesday **9:30am** to **5:30pm**, or Wednesday **8:00am** to **12:00pm**

Chart number:

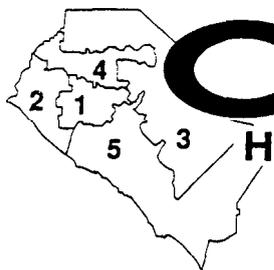
Thank you
Special Diseases

Querido paciente:

Favor de llamarme con referencia a su prueba de papanicolao (prueba de cancer de la matriz). Llame al 834-8772 . El horario es Lunes **8:30am** a **4:00pm**, Martes **9:30** a **5:30pm**, o Miercoles **8:00am** a **12:00pm**

Numero de expediente:

Gracias
Enfermedades Especiales



COUNTY OF **O** RANGE HEALTH CARE AGENCY

PUBLIC HEALTH

TOM URAM
DIRECTOR

HUGH F. STALLWORTH, M.D.
HEALTH OFFICER

1725 WEST 17TH ST
SANTA ANA, CA 92706

TELEPHONE: 714/834-7700
MAILING ADDRESS: P.O. BOX 6099
SANTA ANA, CA 92706

Date:

Dear:

Your last Pap smear, dated _____, -was a Class II which means probable inflammation was present It is recommended that you have a repeat Pap test in the month of _____. Please come to the Special Disease Clinic on a Tuesday between 10: **00AM** and 5 : 30 PM or on a Wednesday or Thursday between **8** : 00AM and **4:00PM**. for a Pap Test If you have any questions, please call (714) 834-8772.

Thank you,

Special Diseases Services

Chart Number:

Fecha:

Querido Paciente:

Su ultimo Papanicolao fue Clase II, fecha _____, el **cual** significa una probable inflamacion. Se recomienda que **usted** repita **su** Papanicolao **en el mes** de _____. Favor de **venir** a la **clinica** de Enfermedades Especiales, en Martes entre las 10: **00AM** y 5 : **30PM** o en Miercoles o Jueves, **entre 8** : 00AM **y 4** : 00 PM por su **examen**. Si tiene preguntas, favor de **llamar** al (714) 834-8772.

Gracias

Enfermedades Especiales

Numero de Expediente:

COUNTY OF ORANGE, CA
PUBLIC HEALTH

MATERNAL CHILD & ADOLESCENT
HEALTH SERVICES

LAB RESULTS

Please call us at (714)_____. It is important that you contact our office so we can speak with you about:

- To schedule another PAP appointment in _____
- PAP smear results
- Colposcopy/Cryosurgery/LEEP procedure
 - Schedule an appointment for _____
 - Reschedule missed appointment
- Blood Test
- Other- _____

Por favor llamenos al (714)_____. Es importante que nos llame para:

- Hacerie cita para otra prueba de Papanicoiao en _____
- Los resultados de su prueba de Papanicoiao
 - Hacerle otra cita porque no vino a su ultima cita
 - Hacerie una cita para _____
- Colposcopia/Cryocirurgia/Procedimiento LEEP
- Prueba de sangre
- Otro _____

COUNTY OF ORANGE, CALIFORNIA
HEALTH CARE AGENCY
REFERRAL FOR HEALTH SERVICES

I. REFERRAL SOURCE AND PATIENT INFORMATION:

A. DATE OF REFERRAL _____

B. TO _____
NAME TITLE

AGENCY/DEPT PHONE SLOG #

C. FROM _____
NAME TITLE

AGENCY/DEPT. PHONE SLOG #

D. SEND REPLY TO _____
(IF NOT SAME AS REFERRAL SOURCE)

AGENCY/DEPT BLOG # PHONE

PATIENT _____ M/F
LAST NAME BIRTHDATE SEX

PATIENT CHART # _____ UCI-PF # _____

PARENTS/SPOUSE
LEGAL GUARDIAN _____
NAME BIRTHDATE

MOTHERS MAIDEN NAME (if applicable) BIRTHDATE

ADDRESS _____
STREET APT #

CITY LANGUAGE ZIP

PHONE _____ LANGUAGE PREFERENCE _____

NEXT APPT DATE: _____ CLINIC _____

II. REASON FOR REFERRAL: Appt. Date (if made) _____ **PLEASE REPLY BY** _____
Date

Signature and Title Phone #

III. REPORT FROM REFERRAL RESOURCE/RECOMMENDATIONS: _____
Date

Signature and Title Phone #

Distribution: White = chart with reply, Yellow = Referral Resource, Pink = Patient's Chart

REFERRAUFOLLOWUP

Date: _____

To: _____

Name of Person Referred:
Address:
Telephone:

Parent or Guardian of Person Referred (if applicable):
Address:
Telephone:

Reason(s) for Referral:
Signature:

Diagnosis/Findings/Recommendations:

Date	Signature	Title
------	-----------	-------

RETURN FORM TO: (Specify name and address)

Phone: _____

- White ••• To recipient of referral. Return to referral source
- Yellow ••• To recipient of referral for retained copy
- Pink --- Retain as file copy until white is returned



R A N G E

HEALTH CARE AGENCY

**AUTHORIZATION TO RELEASE INFORMATION
 AUTHORIZACION PARA DAR INFORMACION**

RECORDS REQUESTED FROM:
 RECORD REQUERIDOS DE: _____

PLEASE MAIL RECORDS TO:
 POR FAVOR ENVIE LOS RECORD A: _____

Attention: Atencion: _____

Attention: Atencion: _____

This is to request and authorize the release of any information you may have regarding the:
 Esto es para solicitar y autorizar cualquier clase de información acerca de:

- Counseling Records or Information
 Records o información psiquiátrica
- Medical Records or Information
 Records o información médica
- Acquired Immune Deficiency Syndrome
 Síndrome de Inmunodeficiencia Adquirida

- Legal Records or Information
 Records o información legales
- HIV Antibody Test Result & Related Tests
 Resultado del análisis de anticuerpos de sida
- Only the Following: _____
 Solamente lo siguiente:
- Social Security #
 Seguro Social #

 (Last Name) (Apellido) (First Name) (Nombre) (Middle Name) (Segundo Nombre)

Male Masculino Female Femenino Date of Birth: _____
 Fecha de Nacimiento: _____

Other Names (Maiden Name, Name by Prior Marriage, etc.):
 Otros nombres (Apellido de soltera, nombre de matrimonio anterior):

 (Last Name) (Apellido) (First Name) (Nombre) (Middle Name) (Segundo Nombre)

Release of these records is required for the following purpose:
 Entrega de estos records es necesario por la siguiente razón:

It is requested that release of these records shall be limited to the following individuals and/or organizations and only materials specified above shall be released:
 Es necesario que la entrega de estos records sean limitados a los siguientes individuos y/o organizaciones y únicamente materiales especificados arriba serán entregados:

Note to patient. You have the right to receive a copy of this authorization. You may withdraw your authorization to release information at any time, unless information has already been released on the basis of this authorization. This authorization shall be terminated when withdrawn, except:

Nota al cliente: Puede cancelar esta autorización de entregar información en cualquier momento, a menos que esa información ya haya sido entregada en la base de esta autorización será terminada cuando se solicite y será anulada en la fecha que se le de, de alta, excepto:

 (Patient Signature) (Firma del cliente)

 (Signature of Witness) (Firma del testigo)

 (Responsible Party's Signature) (Firma de la persona responsable)

 (Date Signed) (Fecha firmada)

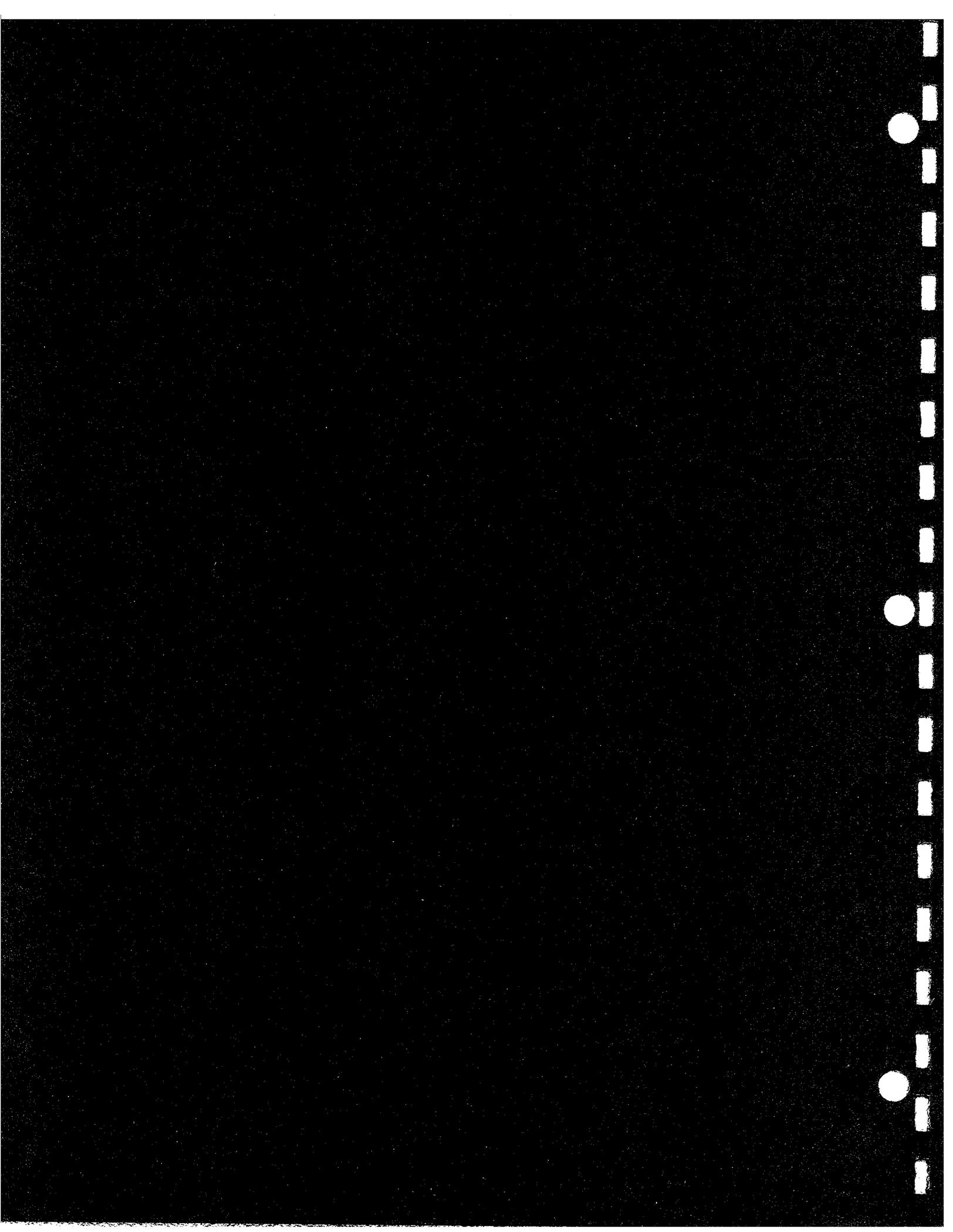
 (Address) Dirección

 (City) Ciudad

 (Telephone No) Teléfono

- Responsible Party Please Specify Legal Capacity:
- Legal Representative of the patient, if the patient is a minor or an incompetent.
 Representante legal del paciente. Si acaso el paciente es menor de edad o incompetente.
 - Spouse of the patient or the person financially responsible for the patient.
 Esposo del paciente o persona financieramente responsable del paciente.
 - Beneficiary or personal representative of a deceased patient.
 Beneficiario o persona representante del paciente difunto.

Figure 1. - Same as Figure 2, but for the



Appendix D: Sample Size Considerations

The issue of sample size determination for the demonstration sites was not a specific research question for the project. However, it is helpful to develop a model which can be used to determine (1) whether the demonstration project has had a desired effect, and (2) the length of the demonstration project.

In this discussion, we propose three types of desired effects. We recommend choosing one of these effects in order to make a determination of the duration of the demonstration project, based on sample size considerations where possible. This recommendation is not made *instead of the* data collection proposed in the main body of the document. This Appendix merely supplements what we have already said concerning tracking of patient follow-up and evaluation of the project.

The three types of desired effects are:

- **Effect 1:** The demonstration project identifies women who would not have received a Pap smear through another source.
- **Effect 2:** The demonstration project identifies abnormal cases that require follow-up.
- **Effect 3:** The demonstration project refers and tracks women through treatment, preventing loss to follow-up. Women are diagnosed and treated who may not have received these services had they not received the case management associated with the demonstration project.

Effect 1 - Identification of Women in Need of Pap Testing

We do not have any baseline information concerning the usual sources of Pap testing for women seen in STD clinics. This information will have to be collected during Phase 2 of the project. While we have no statistical basis for recommending a length of time for the project based on the desired effect being reaching women who would not have received screening from another source, we would advise collecting these data for at least one year. Considering at least **two** months for project start-up, and doubling that time to four months in case of unanticipated issues at start-up, this means a demonstration project of at least 16 months. At the end of the 16 months, we could say that the project identified [N] women who would not have received cervical cancer screening elsewhere.

Effect 2 - Identifying Abnormal Cases

There are three possible conditions of interest when considering whether cases are found through the demonstration project. These conditions are:

- *Condition 1:* Finding all abnormalities
- *Condition 2:* Finding cases of LSIL or higher
- *Condition 3:* Finding high-grade lesions only (HSIL or higher)

We ran three sets of calculations using *Epilnfo* 6 to determine the minimum sample needed for each of these three conditions. The sample size calculation was based on the assumption used in Appendix A (budget estimates), that is, the average estimated number of women examined in each clinic per year would be 1,920 based on a clinic census of 1000 patients per month, 40 percent of whom are new patients and 40 percent of whom are women. Using data from the literature (Kamb 1995), as well as data from our own site visits presented in Chapter 3 of this document, we are assuming that 20 percent of women would be lost to follow-up. The prevalence rates for each condition are also based on a model developed from Kamb's analysis of data from STD clinics in seven locations, and were considered reasonable in light of the data we were able to collect in Phase 1 of the project.

The calculations we used for determining the sample size are displayed in Table D-1. It should be noted that we took steps in order to be conservative. We divided the expected rate for each condition by half, and multiplied each sample size by 1.25 in order to account for the 20 percent loss to follow-up. The confidence level for the sample size for each condition is 0.95.

Table D.1 Sample Size Estimates for Demonstration Project Using Case Finding as the Desirable Programmatic Effect

All Abnormais	LSIL, HSIL, Carcinoma	HSIL or Carcinoma
Expected rate = 0.20	Expected rate = .08	Expected rate = .02
Minimal acceptable rate = 0.10	Minimal acceptable rate = .04	Minimal acceptable rate = .01
Sample before correction = 60	Sample before correction = 162	Sample before correction = 541
Factor used to correct for 20% loss to follow-up = 1.25	Factor used to correct for 20% loss to follow-up = 1.25	Factor used to correct for 20% loss to follow-up = 1.25
Sample size = 75	Sample size = 203	Sample size = 676

Determining the duration of the demonstration project. The above calculations tell us how many patients would need to receive a Pap smear in order to find cases within each condition of interest assuming that 1,920 women are screened each year. In order to suggest the length of time that the demonstration project should last, we went back to the raw data presented in Chapter 3 of this report. These raw data were the reported censuses from each of the STD clinics visited during Phase 1 of this project. Using these average monthly censuses, we can estimate the number of female patients who may be eligible for a Pap smear at each clinic. However, we cannot say with any confidence how many women would actually *need* a Pap smear, based on not having one in the preceding 12 months. Therefore, as shown in Table D.2, before calculating the length of time that the demonstration project should last, we are dividing the estimated number of women eligible for testing in each clinic by 50 percent. This leaves us with a range of from 14 to 303 women, with a mean of 182 women receiving Pap smears in any given month. Even this range should be read with caution because of inconsistencies in the way that the STD clinics kept data on the number of new as opposed to repeat visits each month, and each year. Using estimates of women receiving Pap smears in each clinic, we can calculate the length of time that the demonstration project should last to obtain cases with each condition. We caution that this does not address the issue of the public health impact of finding cases since we have no comparison group.

Table D.2 Estimation of the Duration of the Demonstration Project

	Estimated # Women Eligible for Screening per Month ¹	Estimated # of Pap Smears Obtained Per Month	Length of Time Needed to Obtain Sample Size for Desired Programmatic Effect
Norwalk, CT	28	14	C1 ² =5.4 months C2= 14.5 months C3= 48.3 months
Wake Co., NC	29	15	C1=5.0 months C2= 13.5 months C3 = 45 months
Kent Co., MI	138	69	C1=1.1 months C2=2.9 months C3=9.8 months
Norfolk, VA	175	88	C1= < 1 month C2= 2.3 months C3=7.7 months
Orange Co., CA	244	122	C1= < 1 month C2= 1.7 months C3=5.5 months
Brooklyn, NY	370	185	C1= < 1 month C2=1.1 months C3=3.7 months
Clark Co., NV	375	188	C1= < 1 month C2=1.1 months C3=3.6 months
Detroit, MI	585	293	C1= < 1 month C2= < 1 month C3=2.3 months
Memphis, TN	607	303	C1= < 1 month C2= < 1 month C3=2.2 months

¹ These estimates were made by using all available information on the number of patient visits, as presented in Tables 3.1, 3.2, and 3.3 in Chapter 3 of this document. The number of patient visits was multiplied by the percent that were “new” patients, and then by the percent female. For Norwalk, Clark Co., and Detroit we could not distinguish the number of new from the number of repeat visits, so the estimates for these STD clinics are probably inflated.

² C1 is Condition 1, or finding all abnormal. C2 is Condition 2, or finding LSIL or higher. C3 is Condition 3, or finding HSIL or carcinoma.

Based on the information available, the time needed to find cases of interest, depending on the condition (all abnormal, LSIL, HSIL) would be as little as 2 months or as long as 4 years. No matter which condition is chosen, we recommend adding 4 months for project start-up. For example, if using Condition 2, then to include even the clinic with the lowest census, the demonstration project would need to last 19.5 months - or 20 months if rounded to the next full month.

Effect 3 - Follow-up and Referral

In this scenario, the outcome of interest is the proportion of women who are referred and receive appropriate follow-up care, including treatment if indicated. Again, we have no baseline information to make any comparison with another group. We would therefore recommend that during the first six months of the demonstration project, CDC obtain data concerning follow-up through another source such as the Breast and Cervical Cancer Early Detection Program (**BCCEDP**) in each of the states where cervical cancer screening in STD clinic demonstration sites will be located. At that time further calculations can be made concerning the sample size needed for comparing the “track record” of follow-up in demonstration sites with that of another source for which there is reliable data.

A drawback of this recommendation is that the length of time needed to determine an effect will not be known **until** after the demonstration project has begun, so that the duration of the demonstration project will not be known until it has already been in progress for at least six months. If adjusting the length of the project is not possible, such data can still be used to at least make a simple comparison between the two programs that may point to the relative success of the demonstration project. If the scenario described above were used, for example a demonstration project designed to capture all cases of LSIL or higher in any size clinic, we would recommend adding 6 months to the 20 months needed to obtain the necessary sample size. This would mean that the duration of the demonstration project would be 26 months allowing for time for the follow-up process to be completed for all women with a finding of LSIL or higher.

Recommendation

As noted above, since there is a lack of reliable baseline data, it is difficult to make a complete recommendation regarding the number of women each clinic should see during the demonstration project,

or the length of time the project should run. Based on the information we do have, a demonstration project lasting 26 months would be reasonable. However, if the desirable programmatic effect is identifying women who have not had a Pap smear in the past 12 months to three years, it is possible that the length of the project could be shorter. In any event, each STD clinic must have sufficient time to collect the information discussed in the main body of the report for tracking patient follow-up (whether or not these data are used to develop sample size estimates), and for the evaluation of the project as whole.

Final Report

Contract No. 200-96-0599

Task 8

**A Project to Assess the Feasibility and Need for Support of Cervical Cancer Screening
in Public STD Control Clinics
(Site Reports)**

to

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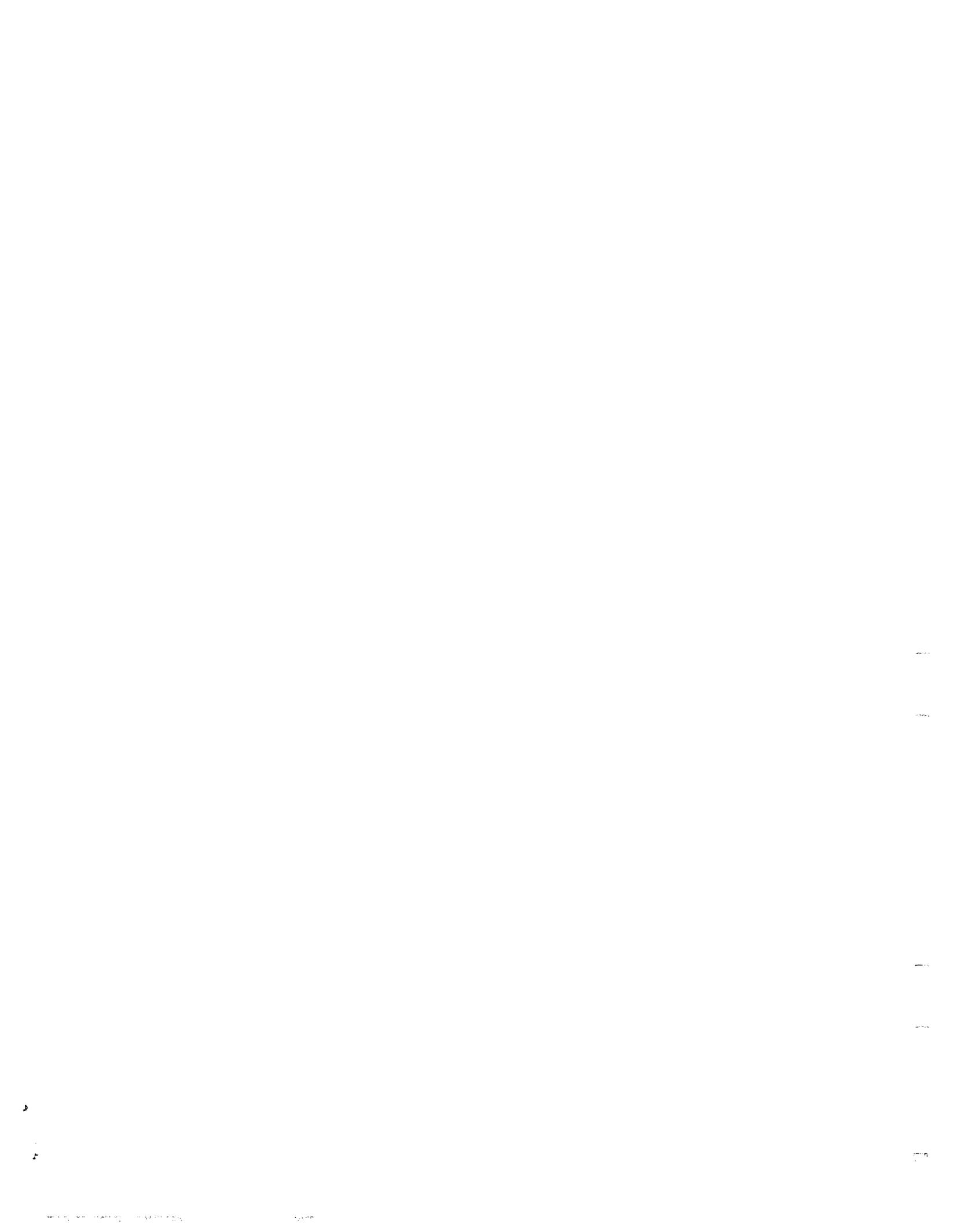
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Brooklyn, New York - Site Report

Community Background

Fort Greene is one of several historic neighborhoods in Brooklyn, New York. Adjacent to Manhattan via the Manhattan Bridge, Fort Greene is served by several subway and bus lines and is near a main terminal for the Long Island Railroad.

Brooklyn, in Kings County, is one of the five boroughs of New York City. According to 1990 census figures (1994 County and City Data Book), Brooklyn had a population of 2,524,416 people. The median age was 32, and the median household income was \$25,684. Of those 2.5 million people, 44 percent were white, 36 percent black, 19 percent Hispanic and 1 percent Asian or Pacific Islander. The Fort Greene neighborhood boasts some fine housing stock and is near well-known cultural and shopping areas; however, it continues to be fairly depressed economically.

New York City Health Department

The New York City Health Department consists of a number of facilities throughout the city, including several free and confidential STD clinics. During Battelle's site visit, in addition to visiting the Fort Greene STD clinic, we met with a few key players in the City Health Department to learn more about its organization and concerns. We were particularly interested in the manner in which information systems are utilized.

The Director of Surveillance for the New York City Department of Health (DOH) is responsible for transmitting NETSS data to CDC, managing the data, and giving advice on system configurations. Monthly and annual census data by STD clinic are collected via the District Reporting System. Individual clinics are able to compare their census data with others in the city.

For Pap screening, there is a sizable database that comes from Quest Diagnostics, a local cytopathology laboratory, that can be shared with DOH clinics located throughout NYC. Quest Diagnostics sends a diskette to the Director of Surveillance monthly, using encrypted identifiers for each patient. The encryption, while an appropriate confidentiality measure, presents some difficulties in accessing data and reading the diskette. However, cytopathology lab data are also sent directly to each

respective clinic in the city. The data provide information about the age of the patient, the result of the Pap smear, and the clinic where the Pap was taken.

The STD Surveillance Division tracks cases of disease, but it does not track prevalence. The Division can calculate the number of female patients within a specific age range for the clinic area, zip code, county, and borough. The clinics themselves are not computerized, so they use a paper system for tracking. They have very limited data on human papillomavirus (**HPV**); health department clinics do not conduct HPV DNA testing.

Fort Greene STD Clinic

Description of the Clinic

The Fort Greene STD clinic is located on the fifth floor of a New York City Department of Health building. It is accessible by public transportation. Directly below the STD clinic is a public maternity/family planning clinic with which there is no apparent formal relationship.

The administrator for the Fort Greene clinic also has administrative responsibilities at two other clinics -- Williamsburgh (nearby) and Staten Island (some distance away). Fort Greene is the largest of the three. All STD services are provided free of charge and are delivered on a first-come, first-served (**walk-in**) basis. Cervical cancer screening and anonymous or confidential HIV testing are offered at the STD clinic. Other tests offered to women include gonorrhea, chancroid, herpes, syphilis, chlamydia, trichomonas, monilia, and clue cells. An in-house laboratory performs a number of tests on-site.

The STD clinic waiting room **accommodates** about **35-40** people and has many STD educational brochures, flyers, and posters. There are also STD and HIV prevention posters hung throughout the examination and counseling rooms. There are seven examination rooms, five counseling rooms, and an in-house laboratory in the STD clinic.

Hours of Operation and Staffing

The clinic is open **8:30 am - 5:00 pm**, Monday through Friday, and **8:30 am - 2 pm** on Saturday. Staff report that the clinic is busiest on Mondays. Because the Fort Greene clinic no longer offers evening

hours, many women come in on Saturdays, probably because they work during the week and cannot afford to take time off. Clinic staff report that evening hours were not as successful as weekend hours.

The staffing pattern at the Fort Greene STD clinic is as follows:

- 4 clerical staff
- 3 Public Health Assistants (one works at another clinic two days/week)
- 2 microbiologists
- 2 laboratory technicians
- Several staff who serve in disease intervention capacities:
 - 2 Front-line supervisors
 - 7 DIS (two of whom are senior public health advisors)
 - 3 junior public health advisors
 - 1 CBO liaison (two days/week)
- The health care providers employed at the Fort Greene clinic are:
 - 1 Physician-in-Charge- 35 hours/week (full-time)
 - 1 MD- 35 hours per week
 - 1 MD- 25 hours/week (five hours/day, five days/week)
 - 1 MD- 16 hours/week (four hours/day, four days/week)

The staff is multilingual, accommodating the diverse population that this clinic serves. Clerical staff initiate intake procedures. Public Health Assistants are responsible for (1) assisting the **MDs** during female examinations, (2) assembling the necessary paperwork for specimen collection, (3) labeling all specimens collected during the exams, (4) stocking all examining rooms, and (5) ordering supplies. The microbiologists perform in-house testing of collected specimens, and laboratory technicians draw blood. The DIS mainly work in the clinic, conducting HIV counseling and testing. The junior public health advisors work in the field, following up on syphilis and gonorrhea contacts, and in the clinic, filing the associated paper work. One responsibility of the community based organization (CBO) liaison is to establish contacts with referral sites, such as the relationship recently established with Planned Parenthood for colposcopy services.

Health care providers are available on the basis of 16-23 physician hours on any given day. There are 15 hours of physician time on Saturdays, averaging 2.5 -3 patients per hour. A number of factors influence productivity; for example, examining women takes longer than men, while revisits are likely to be shorter than first-time visits. One physician reported that he sees 16-20 patients daily.

The Physician-in-Charge (PIC) reported that he examines patients 50 percent of his time; he spends the other half of his day reviewing other physicians' charts to ensure that appropriate treatment was conducted. Every two weeks, the PIC reviews charts from the two previous weeks to make sure that appropriate follow-up was conducted.

Clinic Census and Demographics

The overwhelming majority of the clinic's population is black, and 20 percent is Hispanic. Nearly 44 percent of the patient population is female, a proportion that has increased over the years. Staff postulated that more education among women and male partners may have led to an increase in the number of women using the clinic's services.

The Fort Greene clinic collects census data and reports findings to the District Reporting System. It is with this system that staff can distinguish repeat visits from first time visits. Staff are also able to use this system to track the number of clinical visits from non-registered visits. September 1997 census data are presented below.

Male first visit to MD	I	522
Male revisit to MD	I	45
Female first visit to MD		317
Female revisit to MD		61
Total Visits		945
Total non-registered visits		359
Total number of patients turned away		0
Total physician hours		400
Total patients seen per hour		2.36

STD Clinic Flow

Fort Greene is a walk-in clinic. Staff reported that an appointment system does not work in this setting, so Fort Greene has adopted a system of numbers and letters for patient triage. First-time patients are given a number; the Clinic Manager reports setting out 40 numbers per day. Those who are returning for test results, follow up, or partner notification are given a letter. When all of the numbers are given out for the day, the clinic intake process is closed. It is not uncommon for intake to be closed at **8:30** in the

morning. Consequently, patients often line up in front of Fort Greene clinic by **8:00** in the morning to secure a slot to be seen by a provider.

When the clinic officially opens, patients proceed to the intake desk in the waiting room to fill out a form indicating the types of services they are seeking. All of the necessary paperwork for specimen collection is placed into a patient folder and held in a file slot until the patient is called by a physician. As a mechanism for triage, those files with a letter, indicating a follow-up visit or a contact via partner notification, are placed ahead of those with a number.

The physician takes the medical history and logs the information into the medical records. There is no separate medical history form. At that time, each patient is offered an HIV test, either anonymously or confidentially. Once a patient is examined and has had blood drawn, he/she returns to the waiting room until the number or letter is called again. The same doctor who examined the patient also administers medication if indicated.

A patient who is diagnosed with gonorrhea or syphilis must see a DIS to initiate partner notification and contact tracing. DIS conduct morbidity checks on the patients to see if they have been treated in the past and log relevant information into morbidity terminals located in the administrative office area.

Several tests are conducted in the laboratory on site, including **RPRs**, gram stains, and wet preps. Other specimens, such as **GenProbe** CT and Pap smears, are packaged by a PHA so they can be picked up by the reference laboratory daily. All tests conducted that day are noted on the patient's medical chart, and as a cross reference the lab keeps a log of all the tests that have been done that day. When test results return from the reference lab, they are placed inside the medical records.

At the time of the examination, patients are given a call-back slip and are instructed to call back after eight days to receive their results over the phone. These results are given out by staff between **2:00** and **4:00** pm. However, patients seeking HIV results must return to the clinic so that they can also obtain post-test counseling.

Education and Counseling. DIS and physicians have joint responsibility for **STD/HIV** education. DIS conduct an educational presentation about STD prevention and behavioral modification at **9:00** for patients waiting to be seen. Individual counseling sessions with DIS are given for those who have received HIV testing, and for syphilis or gonorrhea partner notification. Physicians report providing STD prevention education while taking the medical history, during the exam, and during any follow-up visits.

Cervical cancer screening in the STD **clinic**. For at least 20 years Pap testing has been offered at the Fort Greene clinic to all sexually active women who are seeking medical attention related to **STDs**. Since no current clinic staff were at this clinic when the service was initiated, no respondents knew why it was added. One staff member postulated that, because most patients coming to the STD clinic view it as their primary source of care, it was seen as a perfect location to provide cervical cancer screening. In addition, there have been no separate budgets developed to support its activities.

The clinic uses a specific protocol for cervical cancer screening procedures, developed by the City of New York Department of Health, Bureau of STD Control. The protocol includes eligibility criteria, Pap smear test procedure, Pap smear follow-up and patient notification procedures, and documentation of procedures and results.

The physician offers each woman a Pap smear, unless there is (1) self-reported evidence that a Pap has been done in the past 12 months, (2) a history of abnormal Pap smear, or (3) the patient is menstruating at the time of the clinic visit. If the patient is menstruating, the physician advises her to return one week after her period ends or to see her primary care physician. Obtaining the Pap smear takes very little time, perhaps a minute, and it is done before cultures are taken. Physicians tell the patients what is being done during the examination. Women deemed eligible to receive the service do not sign informed consent forms for Pap testing at this clinic. One staff member said "as long as we document everything, we can't be held liable." Patients do sign a waiver to release information. Recently, staff began to ask patients for identification or other locating information to facilitate follow-up.

One physician reported taking 6-7 pap smears per day. Pap smear data are not computerized. Although there is a Pap log, which records patient name, date of test, and results, total number of abnormal results stratified by the Bethesda System are not available. To provide us with the total number of abnormal results for one month, the epi clerk did a manual tally from the logs. These results for January 1997 are presented below.

Number of Pap smears done	131
Number of abnormal results	6

Using a procedure similar to that used for STD tests that are sent out of the clinic, the Public Health Assistant collects all Pap smears taken that day, packages them to be sent to Quest Diagnostics, and enters pertinent information in the patient log. Patients are given call-back slips indicating that they should call back in two weeks for Pap results, between 2:00 and 4:00 pm.

On average, it takes **10-12** days to get results for Pap smears. A messenger sends results to the clinic each day, and the epi clerk logs them in. All positive results are held so they can be reviewed by the PIC. This clinic uses the Bethesda system of classification.

Education and Counseling. DIS would like training in the area of cervical cancer and Pap testing so they could provide more education and counseling than they currently do. One DIS reported problems in ‘making patients understand the need for follow-up and repeat smears.’ In her opinion, patients who do not have insurance to pay for colposcopy may put off the procedure, as will younger patients who may not want their parents to know of a problem.

No literature about colposcopy was available at this clinic. One DIS felt that having this type of information on hand would be helpful for staff and patients. At the time of our site visit, the clinic was awaiting a shipment of STD educational material. When available, these pamphlets are in English and Spanish, while educational materials relevant to Pap testing and cervical cancer prevention are in English only.

Follow-up, Tracking, and Referral. As soon as Pap smear results come back to the clinic, the PIC reviews them. If a repeat smear is indicated, the patient will receive a letter to this effect. However, the smear will not be done at the STD clinic unless the repeat smear is needed due to lack of endocervical cells. All abnormal results are followed, and patients needing referral for colposcopy are immediately assigned to a junior Public Health Advisor.

Data are not computerized, and data collection is characterized as time consuming even though record keeping is considered to be quite simple in terms of the procedures used. The manual system is updated monthly. When a woman at the clinic has a Pap smear, the public health assistant fills in her name, the date, and the lab accession number. When results arrive, the epi clerk enters this information.

If the Pap results are satisfactory but show an infection that was not detected at the initial clinic visit, then the patient is sent a letter by regular mail indicating the need for treatment, counseling and/or referral. For abnormal Pap results, the epi clerk assigns a field record and sends a certified letter. A field visit is made within 72 hours and follow-up is to be completed within 14 days. Pap follow-up is now a part of the regular workload for DIS. When patients do not comply, follow-up becomes quite burdensome. According to one DIS, “**STDs** are the more immediate problem for patients, compared to an abnormal Pap smear. ” Also, there are special issues, such as confidentiality, to take into consideration when dealing with young people and others who need follow up but do not have insurance. Despite these problems, the

clinic manager reports a 96-97 percent success rate for the first quarter of 1997 in locating women with abnormal results.

Patients returning to clinic because they were notified of abnormal Pap results receive priority during registration and intake (i.e., they are given a letter instead of a number, and their charts are placed ahead of the numbered ones). A physician speaks with the patient, writes the referral, and gives the woman a copy of her Pap results and a self-addressed envelope so the referral clinic can send her the colposcopy results. The patient is sent to talk to the DIS or to the CBO liaison if she is in that day. At that point, the patient decides where she prefers to have her **colposcopy**. The New York City DOH supplies a long list of providers in all five boroughs, but it appears that Fort Greene prefers to refer women to three sites. Rings **County** Hospital, a municipal hospital with a sliding-fee scale, is suggested as a referral site for women who lack insurance or other means. Women may also be referred to Planned Parenthood, which only recently became a part of the clinic's referral network, or to **Cumberland** Hospital, which not many women choose because it is relatively expensive.

While we were told that Fort Greene STD clinic does not consistently receive notification of whether the patient actually makes it to the referral setting, respondents did characterize Rings County as "very good" about sending a report after a woman is seen there. Also, it is standard procedure for Planned Parenthood to send information to the source of referral.

The STD clinic currently considers its follow-up responsibility to end when a referral for colposcopy is made: "Referral is where our job ends. To find out whether or not patients actually keep those appointments would take major work. However, for HIV-positive patients, we do follow up on the referrals." ...

Family Planning Clinic

Description of the Clinic

Battelle visited one Family Planning or colposcopy clinic at each of the sites in this study. In consultation with staff at Fort Greene clinic, we chose to visit Planned Parenthood of New York City, Inc. Borough Hall Center. This center is located three subway stops from the Fort Greene Clinic in the neighborhood known as Brooklyn Heights, the area contiguous with downtown Brooklyn.

Hours of Operation and Staffing

The Borough Hall Planned Parenthood Center is open Tuesday through Saturday, as follows:

- Tuesday and Thursday, **8:00 am - 5:00 pm**
- Wednesday, **8:00 am - 2:00 pm** and **4:00 - 7:00 pm**
- Friday, **8:00 am - 8:00 pm**
- Saturday, **8:00 am - 4:00 pm**

There are currently 38 people on staff. Providers include a mix of nurse practitioners, physician assistants, and physicians, on full-time, part-time, and hourly statuses.

Clinic Census and Demographics

All demographic data are computerized at New York City's Planned Parenthood headquarters, and the Borough Hall Center is on-line with NYC Planned Parenthood. Between 60 and 100 patients are examined daily at this center. The number of return visits varies from day to day. This clinic aims for a patient load of 20-25 patients per provider each day; for a seven-hour day, each provider sees about 3.1-3.2 patients per hour. Patients need appointments; providers will examine walk-ins, but patients are not encouraged to seek services in this way.

Nearly half (**45-50** percent) of the patients are African American, and 40 percent are Latino. Whites and patients of other races and ethnicities represent the remainder of the patient population. There is a large population of Middle Easterners in this and surrounding communities. About a quarter of the patients are in their teens, with 27 percent between the ages of 16 and 20.

All new patients and all those receiving annual exams are screened for chlamydia, gonorrhea, and cervical cancer. This center sees men only for HIV counseling and testing. Men represent less than one percent of the total monthly census.

Patients are required to pay for services on a sliding-fee scale.

Cervical Cancer Screening

There is a specific protocol for cervical cancer screening procedures that comes from the Planned Parenthood Federation of America. The medical director for New York City Planned Parenthood reviews this protocol and may increase the stringency of some of the requirements. The only exclusion criteria are menstruation and an interval of less than eight weeks since the previous Pap smear.

Nurses, nurse practitioners, and physicians perform Pap tests. The medical director meets annually with those responsible for conducting Pap smears and reviews the process for collecting the smears.

Based on the insurance status of the patient, smears are sent to one of two laboratories for processing and evaluation. It takes about 10 days to get the results back from either laboratory, although one of the laboratories will call sooner if the results show a serious problem. Planned Parenthood receives monthly and annual summary reports from the cytopathology lab, allowing it to determine the total number of abnormal results on a monthly and yearly basis.

Planned Parenthood uses a confidentiality statement that allows a woman to choose how she prefers to be contacted. Staff and patients may establish a code name. Most patients allow Planned Parenthood to mail them letters in a plain envelope or on flowery letterhead -- younger patients prefer the latter.

All results are entered into the patient's chart. Planned Parenthood repeats smears for the following indications:

- unsatisfactory for evaluation
- no name on slide
- not enough cells on the slide
- cannot read the slide
- certain infections

All patients are told to call the clinic to obtain their results. If a woman who has abnormal results fails to call, two letters are sent by regular mail, followed by a certified letter. If there is no response within a six-week period, Planned Parenthood calls the patient, using the agreed-upon code name if necessary. Within the six-week period, there are three attempts to contact a woman before closing the case.

After a woman with abnormal results calls the clinic, she returns to the center for a Pap consult. At this time, the next steps are explained and staff make appointments for colposcopies.

If the Pap smear results indicate ASCUS, CIN I or CIN II, then the patient goes on for diagnostic services. Patients 35 and older must go to the Planned Parenthood Center in Manhattan (the Margaret Sanger clinic), which has no sliding-fee scale. If a woman is referred there from Borough Hall, Margaret Sanger will send information back to Brooklyn.

Colposcopy clinic

Colposcopies are performed at the Borough Hall Center. Staff believe that most of the regular Planned Parenthood patients show up for results, but they lose some people during the time between informing the patient of the abnormal result and the colposcopy or other procedure.

Although not all Planned Parenthood staff were aware that the Fort Greene STD clinic was conducting Pap smears, they reported a very good relationship with the clinic seeing patients referred from the STD clinic for colposcopies. The Center staff send information to Fort Greene as to whether or not a patient shows up for her appointment. Patients who do not show up for scheduled colposcopy are sent a letter.

Planned Parenthood staff reported that the Fort Greene clinic is very good in following patients who were referred to this clinic, yet they cited only four referrals from Fort Greene in the two months that the two clinics had been working together. Of those four, only one woman actually showed up. Women have to wait about one month from the time of referral until being seen. Planned Parenthood will follow up on colposcopy patients referred from the Fort Greene clinic throughout treatment. During the two months since the referral relationship with Fort Greene was initiated by the STD clinic's CBO liaison, there has not yet been much impact on workload. If the volume increases, Planned Parenthood may add more hours to the colposcopy clinic. Currently, colposcopies are performed on Fridays.

Barriers and Facilitators

In this section we summarize infrastructure elements relevant to providing cervical cancer prevention and screening services in the STD clinic.

The Fort Greene clinic collaborates with other public service agencies and hospitals in developing its referral network. This network may also be enhanced by the presence of excellent public transportation in Fort Greene, especially for women who must travel to other clinics for diagnosis and treatment.

An information system is already established that allows staff to distinguish between first-time visits and repeat visits and to track the number of abnormal smears. Most information is kept by hand, though, making tracking a time-consuming process.

A system of follow up is in place. Respondents had varied opinions on the issue of communication between the referral clinic and Fort Greene; some said that Fort Greene often receives information, and others said that this was not usually the case. This discrepancy may be due to the fact that the relationship with one of the colposcopy clinics (at Planned Parenthood) was still new at the time of our site visit. In any event, DIS and Public Health Advisors seem to have a heavy work load even when follow-up is taken only to the point of making the referral for the patient.

All examinations are performed by physicians at the Fort Greene Clinic. They are supervised by a PIC who regularly reviews charts.

There is a contract in place with a reputable cytopathology laboratory. The laboratory provides detailed information on diskette, using encryptors to protect patient confidentiality. Lack of time and staff have precluded using this information fully, but the data are accessible and could be more fully analyzed in the future.

Orange County, California - Site Report

Community Background

Orange County, California covers about 798 square miles and the County Seat is the city of Santa Ana. The county had a 1995 population of 2641,400 people. The ethnic breakdown of Orange County is:

- 64.5 percent white
- 23.4 percent Hispanic
- 10.0 percent Asian/Pacific Islander
- 1.6 percent African American
- 0.5 percent other

The median family income in Orange County is \$55,507 and the median housing cost is \$213,870. The largest source of general purpose revenue in the county is the property tax, 64 percent of which goes directly to the public schools. Approximately 7 percent of the 1995-96 budget was allocated toward health services. Orange County filed for Chapter 9 bankruptcy protection in December 1994, leading to severe reductions in the budget for all programs except debt service, which increased. Approximate budget reductions after the bankruptcy were 40.5 percent of the general **fund**.

Orange County's program under the California Medi-Cal system is called **CalOPTIMA**. People who are not Medi-Cal eligible are often ineligible because they are undocumented or illegal. For **STDs** and any communicable disease, the Health Department has a contract with UC Irvine Medical Center for access to tertiary care. It is mainly used for **TB** or HIV patients. STD patients can utilize it, but that is very rare.

Treatment of cancer for illegal immigrants and the uninsured is difficult. Area hospitals have always had services for the poor. Sisters of Saint Joseph has hospitals in the community and the Health Care Agency has a good relationship with them. Other hospitals will see Health Care Agency patients too, but this occurs on a case by case basis,

Orange County Health Care Agency

Clinical Services

The Orange County Health Care Agency is headquartered in Santa **Ana**, with additional clinics in Costa Mesa, San Juan Capistrano, and Buena Park. Within the public health system, there are three main components – Public Health, Medical Services, and Mental Health/Drug and Alcohol Abuse.

Under Public Health, there are the Divisions of Health Promotion and Disease Control, Adult and Child Health Services, and Environmental Health Services. Within Health Promotion and Disease Control Division there are: the Public Health Laboratory, Epidemiology, Disease Control (including STD, HIV, and TB), and Health Promotion (including Multiethnic/cultural Health, Tobacco Use Prevention Program, Injury Prevention Program, and Employee Health). Within the Adult and Child Health Services Division there are: California Children Services; Maternal, Child, and Adolescent Health Services; Dental Program; Juvenile Health Services; Public Health Field Nurses; and Nutrition Services. Environmental Health Programs cover Community Environmental Management and Quality and Animal Control. Under Medical Services there are: Medical Services for Indigents, Emergency Medical Services, and Correctional Medical Services. Under Mental Health and Drug/Alcohol Abuse there are Adult Inpatient and Special Mental Health services, Child and Youth Mental Health services, Adult Community Mental Health services, and Drug Abuse and Alcohol services.

STD prevention and control falls under the Health Promotion and Disease Control Division. **STDs** and HIV programs are in the Special Diseases Clinic. Family Planning Services are part of the Maternal, Child, and Adolescent Health (MCAH) services within the Adult and Child Health Services Division. There is now a Women's Clinic located in the MCAH clinic in the Santa **Ana** site that offers colposcopy, LEEP, and follow-up services. The Women's Clinic funding is shared by the Disease Control and Adult and Child Health Divisions and staffed by Disease Control.

Colposcopy services were provided in the MCAH clinics prior to the 1994 bankruptcy filing. Follow-up services for colposcopy were also provided in that program. The family planning clinic, including follow-up, was a **capitated** program, but the capitation rates were for uncomplicated family planning and the colposcopy services exceeded that funding. During that time, the Special Diseases Clinic had to refer patients in need of a colposcopy to the MCAH program on an individual basis. We were told

that it was difficult to get the STD patients into the colposcopy program at that time and some were referred to other community resources. There were four MCAH colposcopy sites throughout the county (originally two colposcopes rotated among the four sites but later each site had its own colposcope).

When the county went into bankruptcy protection, the MCAH programs were hit the hardest. At that time, all colposcopy clinics operating in their MCAH clinics were discontinued. Both Disease Control and MCAH felt they needed to continue those services. Disease Control offered to provide the funding and staff if MCAH would supply the medical supervision, clinic space, and supplies. The residency program from UC Irvine Medical Center provides third year resident physicians to conduct the colposcopies, assisted by Disease Control physician and nursing staff and MCAH clerical staff. The joint effort resulted in the Women's Clinic. When Disease Control and MCAH brought together this service, they brought some **STD/HIV** aspects into the clinics that were offered to MCAH patients. In the last two and one-half years, the clinic has identified four HIV positive patients from MCAH. The Deputy Health Director would like to use that collaborative effort to begin new services, such as breast cancer screening.

Before the Women's Clinic, STD patients with abnormal Pap results were being referred to outside agencies for colposcopy, or to the MCAH clinics. There was some difficulty because payment was often a problem for patients. Now the STD clinic sends patients to the Women's Clinic and it is a free service. The cost of the Women's Clinic is in the budget of Disease Control and MCAH. Each young person in the Health Department's Juvenile Health Services also receives full medical services, including Pap tests if needed. The number of patient visits through that program has been 50,000 in Juvenile Hall and 45,000 in Orangewood Center. Young women in these programs with abnormal Pap smears can be referred to the Women's Clinic.

Laboratory Services

The Health Care Agency does not process the Pap smear slides internally. They are sent out to a private lab. The lab charges \$6.45 per test.

STD Clinic

Description of Clinic

STD and HIV services are offered in the Special Diseases Clinic. There is no charge for any STD services. There are 2 exam rooms for females and 2 exam rooms for males.

Hours of Operation and Staffing

STD clinic hours are:

- **8:00am to 4:00pm** Monday, Wednesday, Thursday, and Friday
- **8:00am to 5:30pm** Tuesdays.

The clinic is walk-in.

All exams and treatment in the STD clinic are done by physicians. The physicians include a dermatologist, general practitioner, and internist. There are 3 FTE physicians providing clinical services in STD including .25 FTE for the jail. One physician spends half her time as the VD Controller and the other half providing clinical services. In California, each institution can develop standardized procedures and protocols and then train nurses to follow them (e.g., the medical director, program manager, and nurse supervisor would develop the standardized procedures).

Other staff in the clinic include 5 FTE Communicable Disease Investigators (**CDIs**), a supervisor of the **CDIs**, and a public health nurse (PHN). The **CDIs** do not go out into the field. State Disease Investigation Specialist (DIS) do the contact tracing and partner notification. The **CDIs** in the clinic do pre- and post-exam HIV test counseling and education. Reimbursement from the State Office of AIDS for HIV tests provides approximately \$500,000, offsetting **CDI** salaries.

STD Clinic Census and Demographics

Month	Males	Percent	Females	Percent	Total
January	773	55	626	45	1399
February	687	54	590	46	1277
March	731	52	665	48	1396
April	721	52	678	48	1399
May	707	54	609	46	1316
June	691	54	580	46	1271
July	795	55	641	45	1436
August	667	52	615	48	1282
September	681	53	604	47	1285
October	693	52	648	48	1341
November	577	55	466	45	1043
December	614	56	478	44	1092
Totals	8337	54	7200	46	15,537

The ethnic breakdown of the Special Disease Services clientele is:

- 22.7 percent white
- 4.1 percent African American
- 66.4 percent **Latino**
- 0.6 percent Southeast Asian
- 3.0 percent other Asian
- 3.2 percent other/unknown

Of the patients seen in the clinic, approximately 41.4 percent are new patients and 58.6 percent are return patients. The STD clinic administrator call somebody who has not been in the clinic for 90 days a new patient, not a repeat. They have been seeing an increase in the percentage of female patients over time.

The STD clinic averages about 236 Pap smears a month. Pap smear results are classified by Class I through V and Unsatisfactory. In 1997, there were only 18 patients with Class IV result and one patient with Class V result. The test results broke down as follows:

Class I	Class II	Class III	Class IV	Class V	Unsatisfactory
75%	17%	7%	0.6%	0.04%	0.5%

The Health Care Agency administrators we spoke with said that patients do not overlap between the STD and family planning clinics. The explanation was that women who go to the STD clinic do so because they perceive themselves to be at some risk for **STDs**. But those who go to the family planning clinic do not perceive an STD risk. Referral from the family planning clinics to the HIV clinic is unsuccessful because family planning clients do not perceive themselves at risk for any **STDs** including HIV.

STD clinic Flow

Patients come into the STD clinic and check in at the front desk. A chart is made for the patient or the old chart is pulled. Clinic staff do not ask for ID to validate contact or demographic information. There is a computer system that contains: name, first visit, birthday, and chart number, so the information a patient gives can be checked against the chart. There is a form for each visit and it is put with the chart by the intake clerk. The clerk asks if the patient wants STD or HIV services. If the **patient** is only in for HIV, he/she gets called by number. Others get called by first name only. The female intake form asks when she had her last Pap smear.

The patient gets called and talks first to a counselor (CDI). The counselors screen all patients coming into the clinic. The first encounter is a brief screen to see what the clinic can do for the patient that day. The **CDIs** ask about contacts, allergies, last time in clinic, sexual history, behaviors, locating information, and if the patient has not received an HIV test in the last 90 days he or she is offered one. The **CDIs** also look at the intake form to see if the woman had a Pap smear in the last year. They also ask the female patients directly about Paps. If the woman has not had a Pap smear, the **CDI** asks if she would like one. The counselors put the charts in a special rack according to the services the patient will receive. Then it is up to the physician to get more information.

A doctor calls the patient and has an interview focusing on history. The doctor asks even more detailed questions about Pap smears, such as if the results were normal or abnormal. If the patient is sexually active, the doctor recommends an annual Pap test. The patient is brought into an exam room for procedures. Based on the interview, the doctor has checked off which clinical procedures should be done. Each doctor has his/her own protocol he/she follows. One doctor we interviewed does the wet mount first, then the Pap smear, then the **GC/chlamydia** test last. There is not a standard clinical protocol for that. There is, however, a flow chart for Pap screening follow-up that the nurses use.

Cervical Cancer Screening

The STD clinic has been doing Pap smears since the 1960s. The **VD** Controller at the time was very farsighted in seeing the connection between **STDs** and cervical cancer. One STD official told us that the doctor who started Pap screening in the STD clinic did so because he felt that when you are doing a pelvic exam a Pap smear is the right thing to do. Also, the VD Controller felt that if a woman did not get the Pap screening in the STD clinic, she might never get it. There was some resistance from clinic providers at the time it was implemented because they were unsure about giving away Pap smears for free, but this resistance was overcome quickly when the service was implemented.

Pap screening became even more critical when the STD clinic began doing pregnancy testing. In the late **1960s**, the state of California demanded that all public health programs do pregnancy testing. Since the STD clinic was seeing the most young women, Health Care Agency officials felt it was a good place for pregnancy testing. The MCAH clinic was very limited at that time. In 1980, MCAH got a better clinic and expanded services and took on the pregnancy testing. When MCAH took over pregnancy testing, the STD clinic maintained doing Pap testing. Both Special Diseases and MCAH do Pap screening, but they have separate **funding** streams to pay for it.

The Disease Control program brings a doctor to the County Women's Jail two half-days a week and has an STD nurse there full-time. STD services are offered there, especially with the prostitutes. Correctional Services medical personnel do not routinely ask females in jail if they had a Pap test in the last year. Pap smears are done in jail only when the nurse (an NP) thinks it should be done. The medical personnel are seeing approximately 80 women a month in the jail and are only doing around 10 Pap smears a month there. They only see female inmates that ask to be seen.

The HIV Clinic within Special Diseases provides primary HIV-related medical care to approximately 1,100 HIV-positive patients. It does primary care and disease control related to HIV. **The**

HIV clinic does Pap smears for its patients, does its own follow-up of abnormal Pap results, and has its own colposcope in the clinic. An **ob/gyn** comes into the HIV clinic one half-day a month to do colposcopies and treat gynecological problems.

Registration and Intake. The intake form for the STD clinic asks when a woman had her last Pap smear. Also, if there is a history of an abnormal Pap, repeat Paps are recommended every 6 months. If a woman comes in asking just for a Pap smear, she will get referred to the MCAH clinic, Planned Parenthood, or other community clinics. A public health nurse handles that referral.

Pap Smear. A physician does the Pap smear. A nurse is present and helps prepare the slide. The nurse takes the slide, labels it, bags it, and puts it in place for the lab courier. Both the STD clinic and MCAH use the CDC guidelines for Pap screening clinical protocol.

Abnormal Results. It takes about a week to get Pap smear results back from the lab. The clinic tells the patient to call back in eight days for results. There is a chart where a nurse logs all abnormal Pap results. She writes it in the chart and the chart is given to a public health nurse (**PHN**) in the STD clinic to do the follow-up. If a Pap result is abnormal, the STD clinic calls the patient right away. The PHN tells the patient to come back to the STD clinic for a repeat Pap, or if a colposcopy is needed refers the patient to the Women's Clinic. The **CDIs** can also call patients and can even make the colposcopy appointment.

Follow-up, Tracking, Referral. The PHN in charge of abnormal Pap smear results does the follow-up. The PHN who does Pap smear follow-up charges $\frac{1}{2}$ FTE to it, but probably puts in more like $\frac{3}{4}$ FTE for follow-up. She also receives some help from others in the clinic. We were told that thorough follow-up really requires a full-time person.

The process for following up abnormal Pap smear results depends on the degree of severity. Class II abnormalities are followed up with a letter sent to the patient. The letter says to come back in six months for a repeat Pap smear. The patient can get a repeat smear at the STD clinic if she does not have another source of care. If she has a source of care, the PHN in the STD clinic will try to refer her to that provider. After the letter is sent, there is not much additional effort.

Class III results are followed up with a phone call from the PHN. The PHN calls and says she is a friend. Then when she has the patient on the line, she asks the patient's birthday and mother's maiden name to confirm identity. The PHN then gives an explanation over the phone and asks the patient to come

into the clinic for more information. She helps the patient get an appointment and sends out reminder letters about the colposcopy appointment. The case management nurse in the colposcopy clinic (Women's Clinic) also calls the day before the appointment to remind the patient.

When a female patient has a Class III result, or Class II a certain number of times, the PHN in the STD clinic calls the case-management nurse in the Women's Clinic to make a colposcopy appointment. Appointments are based on the patient's menstrual cycle. After the PHN calls the patient to inform her of her results and the need for colposcopy, she sends another letter along with an educational pamphlet on colposcopies (in either English or Spanish).

Once a woman is referred to the Women's Clinic and an appointment is made, care and follow-up is handled by the Women's Clinic. Compliance and follow-through to get women to attend their colposcopy appointment is handled by the case manager in the Women's Clinic. The STD clinic passes the patient's chart to the Women's Clinic before the colposcopy appointment and the chart is sent back to the STD clinic after the procedure with all the necessary information added to it.

Low-income women whose Pap smear results are suspected cancer are referred to a variety of resources for treatment.

We were told that maybe 2 out of 10 women with abnormal Pap results are unreachable. In such cases, the STD clinic sends a public health nurse out to the patient's listed address to try to locate the patient. The STD Clinic will also assist with transportation to the STD Clinic if necessary.

Family Planning Clinic

Description of Clinic

The MCAH Program operates family planning services in four locations. Together they see approximately 2,900 client encounters per month. Of these, about 1,200 are new clients. The MCAH clinic in Santa **Ana** is the largest site and has about 100-200 seats in the waiting room. The clinic is appointment based. The clinic tries to see new clients at least within three weeks. There are ten interview rooms for taking medical histories and initial tests. There are eight exam rooms.

The family planning clinic within the Santa **Ana** clinic sees about 58 percent of the clients. Of these, about 10 to 25 patients a day are new clients. Funding for family planning is fee-for-service, so

they can bill Medicaid or the State Family PACT Program for colposcopy if the patient is enrolled as a family planning client. The family planning clinic uses a sliding fee scale, based on percent of poverty level as follows:

- \$0 for below poverty.
- \$5 for up to 150% of poverty.
- a sliding percentage of the full cost of the service up to 250% of poverty.

If the patient is above 250 percent of poverty, she is charged the full cost of the visit but the clinic collects whatever portion she can pay; no follow-up billing is done. Most patients fall within the \$0 or \$5 charge categories. This cost includes all services, including Pap testing.

The family planning clinic tests for **STDs** based on symptomology. Family planning staff do not regularly screen for gonorrhea because the rates are so low in the county. They screen for syphilis only if the woman is pregnant. They also screen for chlamydia, trichomonas, and herpes and plan to begin HIV testing soon. They are also planning to start providing family planning services for males and will treat **STDs** for those patients if necessary.

Family planning patients get a Pap smear during their initial and annual exam. Family planning clients have usually not had a Pap test somewhere else because family planning is often the only health care they get. Approximately 1,200 Pap smears are performed each month.

Hours of Operation and Staffing

In Santa Ana the family planning clinic hours are:

- Monday - **8am** to 9pm
- Tuesday - 8am to 5pm
- Wednesday - 12pm to **9pm**
- Thursday - **8am** to 12pm
- Friday - 8am to 5pm

There are 4 FTE **NPs** who do the exams. There are 2 contract nurse positions also. There are 4 contract physicians as needed. There is one physician on staff to provide medical supervision of the nurse practitioners, write and review protocols, do record review, and other medical administrative functions. The three satellite family planning clinics are covered by the same staff who rotate among clinics. They do Pap screening at those sites and refer to the Women's Clinic for colposcopy.

Cervical Cancer Screening

Registration and Intake. All new patients must sit through an orientation video about family planning services and then a group discussion. After this, nurses do an individual history with each patient.

Pap Smear. Exams are done by trained **NPs** and physicians. Then the patient receives post-counseling from an RN. The Pap smear, slide, and fixative are done in the exam room. The lab courier comes two times a day.

The person responsible for training and supervising the **NPs** doing Pap smears believes that **RNs** could do Pap smears, but would require certified training in Pap smear techniques. She stated that physicians and **NPs** are already prepared to do Pap smears from their professional training and may just need supervised practice with five patients to feel comfortable. However, since the majority of the Pap smears are done as part of a complete physical assessment, it has not been considered efficient to train the **RNs**.

Abnormal Results. The public health lab does all lab tests except Paps. Paps are contracted out to Westcliff Laboratories. The lab will fax back any abnormal results. It takes less than a week to get Pap results back. Abnormals get phoned or faxed back right away.

Follow-up, Tracking, Referral. Of the 1,200 Pap smears performed each month, about 300 have findings which need follow-up. Family planning nurses told us that their clients are very transient, so it is difficult to contact them. They categorize their follow-up as either “urgent,” which means do it today, or “other,” which means do it within **10-14** days. After an initial phone call, they can then send a letter. After that they can get a county nurse to make a visit to the patient’s home. We were told that on initial calls they can contact up to 50 percent. Overall, they can get around 75 percent by phone eventually. They have a manual tickler system for tracking progress.

Women's Clinic

Description of Clinic

The Women's Clinic is co-located with the family planning clinic in the Santa Ana site, and is jointly funded by the Disease Control and MCAH programs. The Women's Clinic does follow-up of all cervical dysplasia, can do STD and HIV screening, and does all colposcopy and LEEP services (including follow-up). The Women's Clinic serves clients from the family planning and Special Diseases clinics. There is a special book for Women's Clinic appointments to which staff from family planning or STD have access and can make appointments, but the appointments are still coordinated through the case manager in the Women's Clinic.

Patients that come to the Women's Clinic have Class 3 abnormal Pap smear results. The programs have switched to the Bethesda system, so it is anyone with mild dysplasia or greater who is referred to the Women's Clinic. Approximately half of the referrals to the Women's Clinic are from the Santa Ana site (whether STD or MCAH).

The Women's Clinic is open two days a week from 8 am to 5 pm. It was only two weeks before our visit that the Women's Clinic added the second provider to each clinic session. Administrators will also be adding a third day for a limited period of time in order to catch up and shorten the wait for appointments. The wait for colposcopy appointments was up to six months, but they have reduced it to just over three months. The goal of the Disease Control and MCAH administrators for adding a third clinic day is to get the wait to less than one month, after which they plan to return to two days a week with one provider.

The Women's Clinic has two rooms with all the necessary colposcopy equipment. In two rooms they can do 100 colposcopies a month. They do LEEP procedures also. Around 90 percent of Women's Clinic patients are Spanish speaking.

In the past two and one-half years, the Women's Clinic has identified 5 women with cervical cancer, 1 or 2 of whom were from the STD clinic. The others were from family planning.

When a patient has been referred to the Women's Clinic, the first step is for the full-time secretary to retrieve the patient's charts from whichever clinic referred her and to prepare everything for the patient's colposcopy visit. It takes about 1½ people to handle this chart retrieval process and management

of the data on how long it took to get the appointment, the Pap results, any **STD/HIV** findings, and the colposcopy results. The secretary starts collecting charts 2-4 weeks ahead of time. All of those data that are collected in the STD, family planning, and Women's Clinics are available for all patients, but they have not been processed for evaluation purposes.

One reason the Women's Clinic is located in the MCAH clinic is because MCAH has the CAT system (a State mainframe computer system that includes patient information regarding services from MCAH or the Women's Clinic). The CAT system is not a comprehensive information system, but is for simplifying enrollment, so that once women are enrolled in a MCAH program they will not have to re-enroll at every service for which they are eligible. It has yet to be expanded outside of the Santa Ana site. The path a colposcopy client follows when attending the Women's Clinic is as follows:

- Check with the intake clerk first to update the patient's information.
- Come into the clinic and see a nurse for intake. This includes signing consent, making sure the patient is not pregnant, etc. A RN handles this function. There is a draft written protocol for this whole procedure.
- Wait in a room for a physician; then get called for the procedure.
- A nurse and nursing assistant are present in the exam room. The nurse assists the physician and the nursing assistant helps the nurse. It takes about 10 to 20 minutes for the colposcopy process.
- After the procedure, the patient goes into a room to sit and wait to be called. She waits about 15 minutes. One reason for this wait is to make sure the patient is not having medical difficulties resulting from the procedure.
- Then the patient gets called to see the case manager. The case manager tries not to repeat what the doctor has already said. She checks to be sure the patient is stable. She provides education about signs and symptoms, the importance of compliance, family planning, possibly HIV pre-counseling, and information on emergency care if needed. The case manager also answers any questions the patient has.

Hours of Operation and Staffing

The Women's Clinic is held on Wednesdays and Thursdays. The Women's Clinic is staffed by:

- 1 nursing assistant
- **1.5 RN**
- 2 PHN (education and case management)
- 1 office assistant
- 1 resident

Women's Clinic administrators are trying to get a data person and one more PHN. Of the nurses, **RNs** do more clinical care and **PHNs** do more education and counseling for Pap smear and colposcopy follow-up. The PHN who does follow-up and case management in the Women's Clinic is full-time, so is available for clients to call with questions at any time.

Colposcopy

The colposcopy is done by third-year resident physicians from UC Irvine Medical Center. An RN and nursing assistant help the doctor. All Women's Clinic staff are Disease Control staff. MCAH provides the medical supervision, supplies, and clinic space. Pap smear supplies are provided by the lab contract.

When the colposcopies were done in satellite MCAH clinics, the procedure was handled by physicians. One NP was in training to do colposcopies; it was a one-week didactic followed by 100 supervised colposcopy procedures. Resident physicians have taken over the procedure since the Women's Clinic was established post-bankruptcy.

Follow-up, Tracking, Referral

The PHN case manager in the Women's Clinic is responsible for follow-up and communicates that information back to the STD clinic. At a recent internal budget meeting they asked the **county** for additional funding to augment the Pap screening program. In the Women's Clinic the patient load has gone beyond the abilities of one case manager, so additional funding will go for another case manager. The Women's Clinic administrators' argument is that there is now a standard of care established, so it is unethical not to provide proper follow-up when screening. Thus, there is a good chance of getting that additional funding.

So far in 2 ½ years in the Women's Clinic, eight women have been diagnosed with a problem needing additional care. Four were HIV positive and were referred to the HIV clinic. Four needed a hysterectomy, one of whom had Medical and the others needed case-by-case handling. All have received care.

After the colposcopy, the client comes back in two weeks to get the results. If there is a need for a repeat Pap smear, STD clinic patients get a blue card with the appointment on it. The case manager told us that about 85 percent come back for that appointment (15 percent broken-appointment rate). If a patient

breaks the appointment, the case manager will try to call her. There is a broken appointment protocol. It is being updated, but this is the procedure at present:

1. Telephone call in the morning. Another try in the afternoon.
2. Letter with a form saying to please call the clinic (case manager's number) for results and an appointment. They wait 2-3 weeks. If no response, then...
3. Send an appointment letter with an appointment already made for the patient. If no response, then...
4. Send another letter saying "we gave you an appointment and we assume you got other care."

The Women's Clinic has a referral form if the patient needs treatment after the colposcopy. The case manager keeps one copy of the form and makes sure the patient follows through. The patient takes two copies of the form with her, one for the doctor and another to be sent by the doctor back to the case manager with the results on it. If the doctor does not send back the form, the case manager has the patient sign a consent form for release of medical records so she can get that patient's medical records from the physician site.

Choosing a treatment site is done on an individual basis, based on the case manager's experience in the community. Orange County does not have a county hospital, so the case manager must network to get clients services. The case manager considers her role completed when she knows that the patient has gotten the procedure or is connected with a case manager in the referral site. The case manager puts the results of the final disposition in the consult summary form. She then retrieves the patient's chart so she can put that information on it.

Established Infrastructure

All data from the Special Diseases clinic are keyed into a database program. There is no systematic procedure for processing those data currently. However, the Women's Clinic data go back more than two and one-half years and are available for processing and analysis if desired.

The HIV clinic has a data system that does charting, tracks appointments, and results. It is called the IMACS. It is possible that the STD clinic could use the IMACS system.

The MCAH program has been collecting the data for the Women's clinic. The previous summer they had an intern who set up some computer data systems to handle those data, but it "fell apart" when the intern left.

The lab has a computer system also. The lab system contains all test results, including Pap smear results. This system could be used to give reports also.

The Health Care Agency has released an RFP for a vender to design a computerized Public Health Data System. That system will take time to develop, and the first unit to be included in it would be MCAH, but not STD.

Benefits/Disadvantages

The program managers we spoke with are concerned over the quality of care provided in the clinic. There is need for an automated tracking system to improve the follow-up of clients with abnormal results. The current manual system is slow, inefficient, and open to losing the client. Once the tracking system is in place it will provide the means to do the data analysis that is currently missing. They would like to improve the analysis of their data for evaluation purposes, and for that reason would like to be part of the demonstration project.

Wake County, North Carolina - Site Report

Community Background

Wake County is located in the Piedmont of North Carolina and has 12 incorporated cities and towns. The 1996 population of Wake County was approximately 539,288. The largest metropolitan area in the county is Raleigh, which has a population of 259,688. The 1989 median family income for the county was \$44,302, with approximately 8.4 percent of the population living below the poverty line.

Public Health Department

In June 1996, a new state law provided legislative authority for a single state human services agency. Wake County Human Services was established on December 5, 1996, creating a single agency consolidating programs and services previously carried out by six separate departments and offices: Social Services, Health, Mental Health, Job Training, Child Support, and Housing. There is no longer a separate public health agency, as it is now incorporated into the Human Services agency.

An idea currently under consideration is that the \$800,000 paid by the county to the Women's Clinic can be put into an RFP for outside contractors to run. As part of that plan, County administrators believe they can reduce the cost of women's services by one-third and allocate that third to mental health services.

Clinical Services

There are multiple clinics located in the County's "Health Department" building. Clinic A is the STD clinic, and Clinic F is the Women's Clinic (family planning clinic),

Laboratory Services

The STD clinic does not pay for Pap smear lab work. The state lab, just down the street, has a **cytopathologist** and processes Pap smear slides for free.

STD Clinic

Description of Clinic

The STD clinic offers its services, including treatment, free of charge. The clinic is walk-in, with some appointments scheduled throughout the day. Clinic space is used as follows:

- 6 rooms used for STD exams (including Pap smears)
- 2 rooms used for EIP
- 1 room used for mental health
- 2 rooms used for UNC research

Four programs operate out of the STD clinic, including STD services, HIV case management services, mental health services (primarily substance abuse), and University of North Carolina (**UNC**) clinical research. The STD clinic tests and treats for syphilis, gonorrhea, chlamydia, trichomonis, and HIV, but not HPV. Family planning services were integrated with present STD services in September 1994. In this program, female patients who have not previously received family planning services can obtain them as part of their regular care. In October 1996, STD clinic-wide Pap testing services were inaugurated. The STD clinic also functions as a training center for UNC medical students, residents, and public health nurses.

Hours of Operation and Staffing

The STD clinic hours are:

- 8:30 am - 5:15 pm, Monday - Friday
- 8:30 am - 7:30 pm Wednesday

Because the STD clinic is bustling with the activities of several programs, numerous people staff the clinic other than those providing STD services. All staff are presented in Table 1.

STD Services	HIV Services	Mental Health Services	UNC Research Staff
<ul style="list-style-type: none"> ■ 3 Clerical ■ 2 PHIs ■ 3 PHNs ■ ½ PHN (30hrs/wk) ■ 1 NP ■ 1 MD (Infectious Disease Specialist) ■ 1 Med Tech ■ 1 Program Manager 	<ul style="list-style-type: none"> ■ 1RN ■ 1 PA 	<ul style="list-style-type: none"> ■ 1/2 MD (Psychiatrist) ■ Drug Counselors (2 days/wk) 	<ul style="list-style-type: none"> ■ 1 Research Assistant ■ 1 PA ■ 1 PHN ■ ½ Research Assistant

All staff represent 1 FTE unless noted otherwise.

While the **STD/HIV** Program Manager is responsible for ensuring that all aspects of the STD clinic operate efficiently, the Nurse Practitioner (NP) ensures quality of clinical care. The NP not only directs family planning services in the STD clinic but also is in charge of training and supervising the public health nurses (**PHNs**) on staff. The NP is also responsible for the cervical cancer screening program in the STD clinic, including all aspects of tracking and follow-up. We were told that the Pap screening aspect of the **NP's** job takes about 20 percent of her time.

The physician on staff at the STD clinic is a full-time Assistant Professor of Medicine at University of North Carolina (**UNC**) and is on contract with the county to provide medical expertise for **STDs** and HIV. The former Health Director hired him five years ago in order to broaden collaboration with UNC and because of a need for an HIV expert. He is an infectious disease specialist, provides medical backup in the clinic, runs some clinical trials research, sees STD patients if the clinic is short staffed, supervises the **PHIs**, and is the primary clinical backup in the HIV clinic. He also sees patients and teaches at UNC and is involved in research.

Most STD clinics in North Carolina are staffed by Public Health Nurses (**PHNs**) following specific written protocols. At this STD clinic, they do pelvic exams and take the Pap smears. The clinic is also staffed by a Med Tech who processes the Gram stains, wet preps, and pregnancy tests, spins blood for **RPRs** and HIV tests, and prepares specimens and lab forms to go to the central lab and to the state lab.

The Public Health Investigators (**PHIs**) investigate **STDs** (syphilis, HIV, gonorrhea, and chlamydia). For gonorrhea and chlamydia they make sure people get treated for positive test results. For syphilis they do the contact tracing. Often the **PHIs** get reports from private doctors or Wake Medical

Center about positive gonorrhea and chlamydia cases and will help them contact those patients. For syphilis they handle only cases within Human Services; state **DIS** handle the syphilis cases from private providers. For HIV, the **PHIs** follow patients tested in the STD clinic and provide post-test counseling. The **PHIs** also investigate violators of control measures for HIV. In addition, the **PHIs** facilitate exams under child abuse investigations. The **PHIs** currently have no role relating to Pap screening.

STD Clinic Census and Demographics

From data collected between July and December of 1977, the STD clinic had an average of 795 patient visits per month. During the one evening clinic per week, the STD clinic saw an additional 10-15 patients. Gender breakdown is about 60 percent male and 40 percent female. Between 30 and 40 percent of patients are new to the clinic.

STD Clinic Flow

Patients utilizing the STD clinic go through the following process:

1. The patient is screened by the intake clerk. Patients can make appointments one week in advance, and the clinic has availability for walk-ins for 12 clients at a time. The patient is given a number by the clerk and later is called by that number.
2. Clinic staff get the patient's chart.
3. Nurse calls the patient in by number.
4. Nurse conducts the exam (including Pap smear if indicated).
5. Patient gets next scheduled appointment at front desk before he/she leaves.
6. Clinic gets STD test results back in one week.
7. Patient comes back into the clinic to receive results. HIV patients have to bring back a portion of the encounter form to ensure confidentiality.
8. Patient can go next door to the pharmacy if indicated.

Cervical Cancer Screening

The physician in the STD clinic made the decision about 18 months ago to provide Pap screening for all women seen in the STD clinic. He was looking at expanding services beyond just symptomatic treatment and sees cervical cancer as an infectious disease, especially in light of the high-risk population that frequents this clinic. The physician told us that even if they do not find a lot of cervical cancer, the

testing is important for educational purposes, so that women are informed of the need for screening. He feels that women who attend the STD clinic probably do not get Pap smears anywhere else. In addition to adding Pap screening, they added chlamydia screening and will soon add Hepatitis B screening.

Several important factors converged to facilitate the introduction of Pap testing in the STD clinic. Two years ago, an NP was hired to provide family planning services in the STD clinic. At the same time, Wake County expanded colposcopy services in the family planning clinic. In addition, the county also pays for cervical cancer screening supplies. Most important, the state lab, which is within close proximity to the STD clinic, has a fully operational cytopathology lab. All slides are processed and evaluated there at no charge.

The STD clinic sees an average of 328 women per month (including some who are not examined). The clinic does not have a way to separate female clients examined from the total seen in the clinic. Of the average monthly number of women seen in the STD clinic, cervical cancer screening data from the past eight months are as follows:

Average monthly number of women who got Pap smears	41 (12.5% of female patients)
Total number of women with abnormal results (eight months)	68 (20.7% abnormal rate)
Uninterpretable slides	5
Atypical (including Hyperkeratosis)	41
Mild Dysplasia	18
Moderate Dysplasia	2
Severe Dysplasia	1
Herpes	1
Total number of women referred for colposcopy	124

Registration and Intake. The STD clinic does not routinely screen everyone who walks in. Eligibility is established during registration and intake. Registration for most clinics in the County Health Department (Human Services) building is at the front desk, but for Clinic A (STD clinic), it is done in the clinic. The intake clerk gets the patient’s information and looks in the computer to find any previous lab results or prescriptions. When a client visits any clinic in Human Services, the information is in the

central computer, but only after the lab results have been entered into the computer. In this way, the STD clinic can tell if a woman has had a Pap smear anywhere else in the public health system. The computer shows all the patient's appointments as well. The clerk then gets the patient's chart. They do not routinely ask patients for identification.

After an initial screening at the front desk about any need for family planning services, a nurse can see the patient. If it has been more than a year since the patient's last Pap smear, she will be offered one.

Education and Counseling. The education a patient receives about cervical cancer screening depends on which provider is examining her. The NP in the STD clinic provides education during her exams. We spoke to a PHN in the STD clinic who gives very little education and counseling on Pap smears or cervical cancer, because she feels she would need more extensive training to do so.

Clinic staff told us they would like to have more literature on HPV, cervical cancer, Pap smears, and colposcopies. They would like to have information for the patient on what it is, how the process works, payment, how long she has to wait for specific steps, and how often she might need repeat Pap smears after colposcopy. Clinic administrators told us that they need a health educator to handle some of this. The health educator could do screening and education up front, before the exam, and could also contact a patient who has an abnormal result and bring her back in for education and follow-up. Clinic staff feel unaware of how cervical cancer screening is being done in other places.

Pap Smear. In the STD clinic, nurses follow the Wake County Pap screening protocol, which is based on the CDC protocol. The NP personally trained the **PHNs** to do Pap smears and supervises them. Each PHN has had previous training on doing pelvic and genital exams. Two of the **PHNs** had already done Pap smears in an **ob/gyn** clinic prior to working in the STD clinic. All reports come back to the NP, and she follows a set protocol on what to do for follow-up. When a patient has an abnormal result, the Health Department (Human Services) has responsibility to try everything to get her to further diagnosis or treatment.

The NP has no doubt that **PHNs** can do Pap smears. All **PHNs** in the STD clinic are Category II trained in North Carolina, which means they are certified to conduct both pelvic and genital exams. The NP told us that training to do Pap smears does not take long. A PHN said that after receiving her STD training she worked with the NP in the STD clinic for three weeks on **STDs**. When she started doing Pap smears, the NP checked and supervised her. She also said she had eight years experience watching doctors do Pap smears in private practice.

This same PHN said she sees **10-12** patients a day. She said it takes a little longer to do the Pap smears because one must clean off the cervix to get a good sample. When a patient comes into the exam room the PHN will take an STD history and will do a Pap smear if the patient has not had one in a year or is newly diagnosed with HPV (visual diagnosis) and has not had a recent Pap.

The NP in the STD clinic said that one should not defer taking the Pap smear in the STD clinic, even with the presence of an infection, because you may never get the patient back into the clinic. The only exclusion is heavy menses. However, in the **NP's** opinion the primary objective in the STD clinic is to get a good gonorrhea and chlamydia sample.

After a nurse takes the Pap smear, she takes the slide and lab form to the STD lab. The Lab Tech logs them all in, makes sure they have been labeled correctly and the forms are with the slides, and takes them to the central lab. The Lab Tech told us this does not take much of her time. The state lab comes once a day (mornings) to pick up the slides from the central lab.

The nurse notes on the Pap form whether the patient has Medicaid. If checked "yes," the nurse must get the patient's Medicaid number. If the patient is unable to give a number, the nurse will just check "no." If the patient has Medicaid, then Human Services can bill the costs to Medicaid.

Abnormal Results. When Pap smear results come back from the state lab, they go to the central lab located in the Wake County Human Services building and are distributed to the appropriate clinics from there. One copy of the results goes to the central lab to be entered into the computer system, and the other goes into the patient chart. We were told that it can take up to a month to get back lab results. The lab forms that are sent from the clinics to the lab are labeled as to which clinic they **come from**, which facilitates distribution of results to the appropriate clinic. In the STD clinic, for any patient who is seen as part of the family planning services offered there, the lab form is labeled as though it came from the **family planning clinic**. Thus, the central lab sends those lab results to the family planning clinic, not the STD clinic. It is important to note that the statistics on those patients are not counted in the STD clinic's information. Also, follow-up for those patients is done by family planning, not by the STD clinic.

The NP in the STD clinic does the follow-up on, all other abnormal Pap smear results done in the STD clinic. When a patient has a Pap smear in the STD clinic, the computer produces labels with the patient's information on them. The NP puts one of those labels in a Pap smear follow-up log book. When lab results come back, she matches the results to the labels in the log book. When the result is abnormal, the NP codes it in the log book, copies it, and sends one copy to the central lab to be entered in their computer system. Normal results are also logged, copied, coded, and sent to the lab. The NP in the STD

clinic also keeps a log of family planning patients seen in the STD clinic and tracks to make sure the results came back for them. Once she knows the results came back, the family planning clinic is responsible for follow-up.

Patient charts are kept in a central location in the county building. Therefore, when family planning gets the results from Pap smears done in the STD clinic, they can go to the patient's chart for follow-up. Although follow-up in the STD clinic is done in manual log books, follow-up in the family planning clinic is done with a computer system. All invasive carcinomas are reported to the state.

Follow-up, Tracking, Referral. When a patient gets a Pap smear in the STD clinic, she is told that, in case of an abnormal result, the STD clinic will contact her. It takes about two weeks to get results back from the state lab and can take 1-2 months to contact patients. The NP sends out a letter to each patient who has an abnormal result, asking her to contact the STD clinic. When the patient calls, the NP makes the referral appointment for colposcopy. If a letter does not work, the NP will call the patient.

In more detail, the follow-up process for abnormal results proceeds as follows:

- Send out letter and document it on the log and patient's chart.
- If no response within a month, send second letter.
- If no response after another month, send a certified letter.

Once the STD clinic gets the certified letter notification back, they do not do much more. However, if the result says the patient has dysplasia, the NP will forego the letter and make phone calls right away. If it is severe, she will even make appointments before talking to the patient. On rare occasions, the NP has asked DIS to find the patient.

STD clinic staff told us that their clientele are extremely non-compliant and often do not call back for their Pap smear results. One respondent said that "all the STD patients care about is getting rid of the STD. They are not even scared of AIDS. Many are young teens and have a feeling of invincibility."

For a repeat Pap smear, the patient is told to go to a primary provider. The letter for repeat Pap smear says for the patient to go to her regular doctor or to Clinic F (family planning clinic) if she does not have a regular doctor.

On the phone, the NP finds out if the patient has insurance, verifies prior Pap smear history, and ascertains where she wants to go for colposcopy. The patient can follow-up with a private doctor or go to the family planning clinic for colposcopy (if she is already a family planning patient or wants birth control). If it is a high-grade lesion or white lesion (hyperkeratosis), she can go to Wake Medical Center next door. Approximately half of female STD clinic patients are also family planning clinic patients.

At this time, the STD clinic is not responsible for the patient's colposcopy, but staff there believe that they find out whether if the patient shows up to the appointment. They used to have somebody doing this, but recently lost that person: STD staff do believe, though, that once the person gets to the colposcopy clinic, follow-up can no longer be the STD clinic's responsibility.

Many women with low-grade lesions go to the family planning clinic for colposcopy, but it takes several weeks to get an appointment there. The family planning clinic charges \$100 for a colposcopy. There is funding assistance for women below a certain socio-economic status, but the patients are not always told this over the phone. We were told that many women do not go for their colposcopy appointments because they were told to bring \$100.

At Wake Medical, a woman with severe dysplasia can get a colposcopy appointment for the following week. Wake Medical does not require advance payment and will set up a payment plan for the patient once she is in the system. This was said to be less likely to scare a patient away from going to her colposcopy appointment.

Once a patient has been referred to Wake Medical, she is part of their case management system. If the patient misses her colposcopy appointment, Wake Medical will try to get her back for another appointment. If she misses the second appointment though, they send the referral back to the STD clinic for more follow-up, and the NP at the STD clinic takes up the case again. Wake Medical sends information on the colposcopy back to the STD clinic when completed.

The DIS at the STD clinic in Wake County would rather not be involved in follow-up of abnormal Pap smear results. They feel that the nurses should do the follow-up for Pap smears, because they know more about what it means and what the patient should do. The DIS do not believe they have the time, training, or knowledge to do Pap smear follow-up. The DIS with whom we spoke said that for case management a trained nurse would be the best person, even better than a health educator.

STD clinic staff told us that they would like to have an internal database for logging patient information, maybe computerized. They have a computer with gonorrhea and **chlamydia** results, but they believe that Pap smear results should also be included. They would also like to have one person solely responsible for follow-up.

Family Planning Clinic

Description of Clinic

The official name of the family planning clinic is the Women's Clinic, yet some Human Services staff call it Clinic F. The family planning clinic charges on a sliding-fee scale, based on Medicaid reimbursement rates. Staff from the family planning clinic believe that they see a different patient population than does the STD clinic.

The family planning clinic has a lower incidence of **STDs** than the STD clinic. The staff will treat **STDs** in their patients, but they feel that they should not be treating **STDs** by appearance.

Hours of Operation and Staffing

The family planning clinic is open from **8:30** am to 5: 15 pm, Monday-Friday.

Cervical Cancer Screening

In the family planning clinic, any sexually active female without a recorded Pap smear in the last year will be given one. According to Medicaid, the clinic cannot do a Pap smear less than 365 days from the last one performed.

A physician in the family planning clinic said that a cytopathologist cannot tell the difference between infection and ASCUS but can tell if there is a high grade lesion. Therefore, he believes that the STD clinic should do a repeat smear on any low-grade result, because it could be an infection.

Pap Smear. The State Human Services offers training for **RNs** on how to do Pap smears, but in the family planning clinic, only physicians, **NPs**, or physicians' assistants (PAs) do Pap smears. The physician in the family planning clinic said that it is acceptable for an RN to do Pap smears, as long as he/she is not making clinical decisions **not** do to one based on sight.

Follow-up, Tracking, Referral. When Pap smear results come back to the family planning clinic from the lab, staff first code the results into a computerized system in the clinic. The results are coded first based on the presence of HPV and second based on the level (not the Bethesda system).

Follow-up is a standard letter followed by a certified letter. If the result is low-grade, this is as far as the clinic goes. The letter is generated by the computer and says the patient needs either a repeat Pap smear or colposcopy. A clerical person in the family planning clinic manages the follow-up protocol. She got training by listening to the physician in the clinic talk to patients on the phone and is supervised by the physician. The physician handles any cases where the patient has anxiety. For high-grade results, the clerk calls the patient but then patches in the physician to talk to the patient. For high-grade results, the clinic has actually sent out the Sheriff to find patients.

All tracking in the family planning clinic is handled through their computer system. The STD clinic does not have the same computer system. The clerk does a computer run to determine whether a patient has progressed to the next step. Any patient referred from the STD clinic for a colposcopy in the family planning clinic becomes part of the clinic's follow-up process. If a patient needs follow-up Pap smears after the colposcopy, she automatically becomes a family planning patient from that point on. For women sent to Wake Medical for colposcopy, the family planning clinic requires Wake Medical to send the colposcopy results back to the clinic so the patient can be "plugged back into" the family planning clinic's charts and tracking system.

Wake Medical - Colposcopy Clinic

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Wake Medical accepts STD clinic patients with high-grade abnormal results. Patients with **low**-grade abnormal results go to the colposcopy clinic in the family planning clinic or are referred to private providers. Until 2- 3 years ago, Wake Medical did the majority of Health Department colposcopies. It was at that time that the family planning clinic began doing their own colposcopies. Wake Medical does treatment also.

Wake Medical has two colposcopes. One physician and one nurse do the colposcopy together. Patients can get colposcopy appointments at Wake Medical within 10 days, and a patient with a high-grade abnormal diagnosis can get in the next day. When a patient comes to Wake Medical for a colposcopy, the procedure is as follows:

1. Registration and intake
2. See a financial counselor if she needs funding help

3. Assessment room (done by **RNs**)
4. The RN explains about the Pap smear, the procedure for colposcopy, what is a biopsy, and what will be needed for follow-up
5. Doctor sees the patient for the colposcopy

The doctors at Wake Medical send a referral note with the colposcopy results, information on treatment, and plan or care back to the Human Services clinic that referred the patient. All of this information can be put on the state lab form.

About 50 percent of the women referred to Wake Medical for a colposcopy come when first contacted. Wake Medical does the follow-up to get the patient to come in. However, people we spoke with at Wake Medical expressed the opinion that it should be the responsibility of the place that did the Pap smear to make sure that the patient gets to a colposcopy clinic. Once the colposcopy clinic sees the patient, then it is the colposcopy clinic's responsibility to see that she gets to treatment.

Cost at Wake Medical depends on the number of biopsies necessary. Wake Medical pays \$16 per slide for Pap smear cytology. They have a payment incentive plan for low-income patients. When the patient is screened by a counselor, she may qualify to have her services paid for by the cancer program at Wake Medical. The patients referred to the cancer program funding are those not on Medicaid or uninsured.

Established Infrastructure

Established infrastructure in place in Wake County includes the relationships ~~the~~ **STD** clinic has with both the cytopathology lab and the referral sites for colposcopy . The STD clinic is able to send its Pap smear slides to the State Health Department lab for processing and evaluation free of charge. The STD clinic also has existing relationships **with** the family planning clinic and Wake Medical Center for referring patients for colposcopy .

Benefits/Disadvantages

Staff in the STD clinic identified three main problems they would like to address to improve their cervical cancer screening program. The first problem is their lack of education materials to give to patients. The clinic needs brochures and pamphlets on HPV, cervical cancer, Pap smear screening and

results, colposcopy, and the process of follow-up. The second problem is that the STD clinic, unlike the family planning clinic, relies on a handwritten log book for tracking Pap smear results. STD clinic staff would like to establish a Pap testing database to better track patients. Third, STD clinic staff would like a better method for following-up on difficult patients. This could include a system to validate patients' personal contact information so that follow-up and referral can be easier.



Norfolk, Virginia - Site Report

Community Background

Norfolk is located 91 miles from Richmond, the capital of Virginia. **With** a population of 238,000, Norfolk ranks as the second largest **city** in the state. Norfolk is the business, financial, cultural, educational, and medical center of Hampton Roads, a region comprised of eight cities that surround the natural harbor formed by the Atlantic Ocean and the Chesapeake Bay.

The city of Norfolk provides nearly one-third of the jobs for the region. Major employers in the city include health services, universities such as Old Dominion University (ODU) and Norfolk State University, and the military. The Norfolk metropolitan area has one of the largest concentrations of military activity in the nation, remaining the site of the world's greatest concentration of permanent naval installations. There are several diverse neighborhoods in the city with regard to **socio-economic** status (SES) and race/ethnic@.

Norfolk has several medical facilities, including Virginia's only pediatric hospital, three large **full-**service hospitals, a non-profit community hospital, and a long-term and acute care hospital. There are no public hospitals in Norfolk.

Norfolk Public Health Department

The Norfolk Department of Public Health (NDPH) is one of nine **health** districts in the Eastern Region of Virginia. This health department is located on a large medical complex in the heart of Norfolk, which also includes Eastern Virginia Medical School (**EVMS**), Children's Hospital of the Ring's Daughters, and **Sentara** Norfolk General Hospital. The NDPH operates out of five community clinics, with its headquarters downtown. At the Headquarters are TB, immigration, general medicine, HIV/AIDS, STD clinics, and adult immunizations. Another clinic, Little Creek, provides family planning and colposcopy services. NDPH also operates a school-based clinic in a local high school. In addition to providing primary care and health promotion, NDPH provides environmental laboratory support services.

NDPH is responsible for the city of Norfolk, but patients often come from all around the Hampton Roads area to the Norfolk Health Department clinics. For example, there is quite a bit of crossover with Newport News and Hampton. Approximately 15 percent of patients come from other cities. It must be noted that, despite the large number of military bases in the area, very few military personnel are seen in the public health clinics.

Clinical Services

NDPH promotes integration of all services rendered throughout the community. It is not uncommon to find a clinic located in a building with multiple services. For example, Little Creek clinic is located in a building that houses social services (including WIC), a local police precinct, court services, and mental health service. Furthermore, clinical staff rotate throughout all clinics in the city. The health care providers rotate from clinic to clinic throughout the day. Currently, twelve nurses, three nurse practitioners, and three physicians provide clinical service for all five neighborhood clinics. These staff, nurses in particular, are very well cross-trained and have tackled the issue of missed opportunity on several fronts. For example, they are able to educate patients about birth control methods or HIV, administer pediatric immunizations, and perform pelvic exams, including taking Pap smears. For this reason, when a person is found to have an STD at any of the five clinics, he or she is not referred to the STD clinic but is treated on site.

Cervical Cancer Screening Services. NDPH patients are able to obtain Pap smears at Colley, Little Creek, Berkeley, Huntersville, and Park Place clinics. Lake Taylor high school has a school-based health center where complete physical exams are done by a nurse practitioner. We learned that it is not uncommon to find an abnormal Pap smear at this clinic. In the past, Norfolk Public Health Department operated special Pap clinics, but due to the shortage of staff, this service has been eliminated. Pap tests have never been offered at the STD clinics.

For diagnostic services, there is one publicly funded colposcopy clinic in Norfolk, which began about 10 years ago. Until 1995, there were two colposcopy clinics located at two Health Department sites, but the physician in charge of one clinic left the area. The public colposcopy clinic is only for Norfolk residents. Patients who are not residents but who need this service are referred to another public health clinic, like Virginia Beach Health Department, EVMS, or to a private physician, depending on insurance status.

Community Service-s

Norfolk Department of Public Health provides a variety of community programs to the citizens of Norfolk, including free health screenings, educational classes, and seminars.

Breast and Cervical Cancer Community Services. In collaboration with local private agencies, the health department has established a community program aimed at African American women 50 and older to raise awareness and provide education about early detection of breast and cervical cancer, as part of the Breast and Cervical Cancer Early Detection Program (BCCEDP). A half-time staff person is dedicated to educating the community about BCCEDP screening and to educating providers. BCCEDP education in Norfolk's minority community, provided through churches and other community groups, emphasizes early detection of breast cancer more heavily than screening for cervical cancer.

In the near future, though, the Hampton Roads Region will establish a cervical cancer screening program designed for 650 patients per year, targeted to women 40 and above. Residents at EVMS will perform the Pap screening tests. This new screening program will not affect the STD clinic clientele because most of these patients are under 40 years of age.

Laboratory Services

All five clinics have laboratories that perform moderately complex testing services, such as microbiology, hematology, urinalysis, and chemistry. The state lab is located in Richmond, and relationships are reportedly very good. Norfolk Public Health Department clinic sites do not have an automated system of reporting (on-line reporting), but every site has a printer to receive results from **SmithKline Beecham** (SKB).

Each local clinic is set up to test all gonorrhea smears and vaginal secretions. All cultures, however, must be sent to the laboratory at the Colley clinic (headquarters), where specimens are logged in, processed, and tested. A preliminary chlamydia report is faxed to the local clinic, and a final report is sent within 24 hours. For gonorrhea, a preliminary report is sent within 24 hours, and a final report is sent within 48 hours.

Cervical cancer screening and cytopathology laboratory. In the past, the state was responsible for contracting with a cytopathology lab. Recently, the contracting process was decentralized such that some tests are performed at the clinic itself (e.g., GC smears or vaginal secretions), while others are sent to the central health department laboratory.

The State of Virginia has contracted with **SKB** to perform all special hematological and cytopathologic studies for public health clinics. This contract was determined by volume on a competitive basis. The NDPH Laboratory Director reports a very good working relationship with SKB.

Currently, Pap smears are taken at the local clinics offering this service, and a courier picks up the slides. It takes about two weeks to receive the results, although this time frame varies. The local clinic receives several copies of results for each patient, and another stays in the local laboratory. (There is also a printer for results at the clinic.) As a result, each local clinic has a record of the number of women examined within the last year and the total number of Pap smears at that clinic. All of this information is broken down by age group. The local clinics do not have data on the yield of abnormal tests. This information would have to be obtained directly from SKB.

The NDPH Lab Director does not believe it would be an undue burden to add Pap smear testing to the STD clinic. It would be “just one extra slide to send to the cytopathology laboratory.”

Cervical Cancer Supplies. The state currently ships Pap smear supplies directly to the LHD. At this point, there would not be any additional costs of implementing cervical cancer screening in STD clinics for Pap smear supplies. According to the Medical Director, “it will basically be another fiscal transition- cost shifting of funds.”

STD Clinic

Description of Clinic

The Norfolk STD Clinic is located in a building with several other clinics and services, including general medicine, HIV/AIDS, immigration testing and physical exams, tuberculosis, environmental services, and immunizations. STD services are located in a separate wing, the South wing of the building. In a little over a year, all services will be moved to a new building located in the same medical complex.

The clinic is clearly accessible to public transportation, with bus stops right in front of the facility. There is also a parking lot directly in front of the building which is free for patients.

There are two waiting rooms in this clinic. One, which has about 25 chairs, is the area where patients begin the registration/intake process. The other is where the patients await clinical examination. We did not observe the waiting room filled to capacity on either day of our visit. There are educational brochures and posters in both areas. None of the materials we saw were in any language other than English. There is no child care area in this facility. There are three examining rooms -- two for women and one for men -- and several other offices in between the two waiting rooms. At one time, there was a separate entrance for the STD clinic. Now all patients enter the health department building from several entrances.

Hours of Operation and Staffing

STD clinic hours are Monday through Friday, **12:45** through **3:30** pm. It is a walk-in clinic, and appointments are not needed, but there are “expected ins.” The family planning clinic, on the other hand, is not a walk-in clinic. Some people are turned away from the clinic, but only if they present with something that can be handled by another clinic. There is no residency or income requirement for admission into the STD clinic. Some patients do come as referrals from the four major hospitals as well as private physician offices.

STD clinic staff includes three nurse practitioners who rotate among the male and female exam rooms. There are two clerical /registration staff, one doctor on-site, six DIS (usually there are eight), and a lab tech to assist the nurses/nurse practitioners.

The two clerical/registration staff are in charge of registration, inputting data into the computer and pulling charts.

Nurses and **NPs** are cross-trained in STD, general medicine, pediatrics, and family planning. They diagnose and implement treatment for **STDs** using CDC treatment guidelines. An MD signs off on all RN charts, but the **NPs** can sign off on their own charts.

At this clinic, DIS are known as Epidemiology Representatives or “epi reps.” There are eight epi reps and one DIS supervisor, with three DIS in the field and three in the clinic on any given day. In the field, staff are equipped with two-way radios for their protection. At this clinic, the DIS takes the medical history and conducts the exit interview after the patient is treated. DIS initiate lab forms for **CT**, **GC**, and **VDRL** tests.

Generally, patients who test positive for **STDs** (syphilis or gonorrhea) come back to the clinic for treatment. If not, DIS go out to find these individuals and get them in for treatment.

STD Clinic Census and Demographics

Health care providers see 20-40 patients on a typical day, with an average patient load of about 25. There are no particular high-volume days, although the census increases when the local schools are closed and during summer months. The nurses and nurse practitioners estimate that **25-30** percent of the patients are repeaters. NDPH keeps a computerized log of daily census and has the ability to distinguish first-time visitors from repeaters.

There are approximately 7500 yearly individual visits, of which about 6000 are unduplicated visits. A clinician stated that the patient load has decreased significantly in the past year. Sixty-five percent of the clients are male, and 35 percent are female. Ten years ago there were more males attending the clinic. Today more females come in, perhaps due to the reduced stigma of visiting the clinic. Perhaps the clinic has made the process more accommodating to women. In the past, many women went to the ER, but now the NPHD gets fewer women referred from the ER than they did. About 80 percent of the STD clinic's patient population is African American.

STD patients are not asked about their insurance status. According to one respondent, "The fact that these patients are coming to the health department indicates that they do not have private insurance." Some do have Medicaid, however. Some STD-clinic patients may actually have private insurance but are afraid that their employers will learn their tests results. Occasionally, active duty personnel come to the STD clinic who do not want this type of information on their records.

One respondent feels that the huge drop in patient population has been caused primarily by the Medicaid **HMOs**: "These patients now have a set place for their health care. This is a phenomenon experienced all over the state. " In one respondent's opinion, the population coming to STD clinics is different from those attending the family planning clinic.

STD Clinic Flow

Each patient registers with either of the two clerks at the window in the first waiting room. The intake procedure is different at the STD clinic than at other clinics. Basic information is obtained, and a chart is started. Currently, the STD clinic requires a social security number and some sort of identification

card to verify name and address in the event the patient must be tracked down. Taking the medical history is a continuous process. The actual history is taken by one of six epi-reps on staff. The clerk hands the chart to the DIS, who fills out the first part. The DIS then places the chart in a pile for the nurse/nurse practitioner, and the patient waits in the second waiting room. The second part of the medical history form is completed by the **NP/RN** who examines the patient. Most female exams are conducted by nurse practitioners. The physicians provide necessary medical supervision.

While taking the client's medical history, the **NP/RN** asks about Pap testing. Nurse practitioners and nurses are instructed to tell patients that Paps are not done at the STD clinic and that they have only received pelvic exams. Most women at the STD clinic do not have an ongoing source of care. If a woman has not had a Pap test in the past year, she is referred to the family planning clinic.

After the initial visit, patients who test positive for syphilis, gonorrhea, or HIV are put in an "expected in" file. DIS have copies of these files as well. Letters are sent out or patients are phoned, depending on the STD. DIS will go out to find patients who do not return for treatment.

Cervical Cancer Screening in the STD clinic

The Director of Medical Services believes that, "whatever needs to be done to include cervical cancer screening can be incorporated into the current intake process."

The DIS supervisor doesn't see a large impact of adding cervical cancer screening to the STD clinic, other than the possibility that "taking the medical history may take a little longer." The clinic flow would proceed as normal. The patient would go to the DIS, then to the technician, **and finally** to the nurse.

Intake and Registration. All patients are asked to sign an authorization to have an HIV test conducted. If a Pap smear were to be done, this would add about another two minutes to registration.

Education and Counseling. The DIS supervisor feels that cervical cancer education would have to be added to overall patient education in the STD clinic if this service were added.

Pap Tests and Results. In the STD clinic, nurse practitioners do the pelvic exams. In addition, 90 percent of women presenting at the STD clinic are given a chlamydia test via a cervical swab. The Health Director believes that, since staff are well-trained, adding Pap smears would not present a problem.

The nurses we interviewed believed that they would be responsible for carrying out Pap tests in the STD clinic. For **them**, “it is just one more test, no big deal.” Nurses and nurse practitioners currently are responsible for education and counseling of patients. They try to refer patients to the family planning clinic for Paps if they learn from patients’ medical histories that they have not had one in over a year. They believe that they would do more education and counseling on cervical cancer screening if Pap smear screening were implemented into the STD clinic.

Training. The implementation of cervical cancer screening would not require much training for the DIS. The DIS supervisor expects that 95% of all female patients will be educated about this procedure, and the nurses alone may not have the time to do this. It would be necessary to do some minor training for DIS, because they need to know what to do for follow-up.

Follow-up, Tracking and Referral. Follow up is difficult, in part because this is a walk-in clinic. Staff experience a 60-70 percent success rate in finding people with positive cultures. The people who visit the STD clinic have a different agenda than those who go the family planning clinic. Women at family planning clinics take birth control pills, expect to be get a Pap test, and give correct phone numbers and addresses. On the other hand, “10 percent of patients coming into the STD clinic use false names or give false addresses.” There are confidentiality problems. The Director of Medical **Services** believes that the follow-up will not be as good as that observed in the family planning clinic, because of the characteristics of the population; the patients are different than those he finds in the STD clinic.

Time constraints will affect the implementation of Pap testing in the STD clinic. As one respondent said, “If there is an increase in the number requiring follow-up, we don’t know what type of demand this will place on the system. In terms of patient perception and demand of services, that is all speculative at this point. We would probably put Pap follow-up into nursing rather than DIS, because the DIS already have enough to do. There may be a strain on nursing services due to follow-up, although taking the actual test is not a big deal. DIS may only be involved for those patients who are infected with syphilis or other **STDs**.”

The nurses believe that they would need someone to coordinate follow-up and referral. Follow-up is time-consuming under normal circumstances, but the population at the STD clinic is transient, making

follow-up even more difficult. Because these nurses and nurse practitioners also work in the family planning clinics, they are knowledgeable about the cervical cancer screening process. The nurses believe that they will ultimately be responsible for actually doing the referral and follow-up.

The Supervisor of DIS envisions that the follow-up of suspicious Paps may be time consuming. He believes that DIS may be involved in getting patients back for a repeat smear or for referring to another facility. "We would inform patients to return as we do for **STDs** if they were to get an abnormal smear." As previously mentioned, the STD clinic requires social security numbers and identification cards to verify names and addresses.

The DIS Supervisor thinks that ultimately the nurse practitioner or doctor may be responsible for establishing the referral network, but a combination of nurses and DIS will actually conduct follow-up. The nurses will need to set up the tickler system. The nurse will send the letter, and if there is no response, the DIS would make a visit.

"We don't expect any problems with follow-up. There is a procedure for following up with family planning. I suppose that adding Pap smear screening in the STD clinic will follow the same lines." According to the state protocol, the charge nurse in each clinic has to make sure that abnormal Pap smears are followed up. Every three months, a list of abnormal Paps is sent to each site from SKB. The site is supposed to make a statement about follow-up for each one. Also, a notice of abnormal Pap smears goes to the State Health Department, Office of Community Health. The process of follow-up would be the same in the STD clinic as for family planning. Problems may occur with regard to volume, at least in the **near-term**, but nursing staff believe that they could "make adjustments."

According to the DIS Supervisor, most of the follow-up process already exists. "It wouldn't take long to establish a referral system for cervical cancer patients. Follow-up for cervical cancer would probably be very similar to some of the policies that we already have." Because it takes on average two weeks to get Pap results, this coincides with when HIV tests are due back.

If the first Pap is abnormal, the DIS supervisor envisions the patient returning to the STD clinic for the repeat smear, since the abnormality could be due to other inflammatory processes.

Family Planning Clinic

Description of the Clinic

Little Creek family planning clinic sees close to 300 patients monthly. Of those, between one-third and one-half need Paps. Other clinics see about 225 patient numbers monthly. Other sources of care for this patient population are Planned Parenthood or the Nurse Practitioner's Clinic at ODU.

Cervical Cancer Screening

The established protocol used in family planning clinics indicates a Pap smear for women who are 25 years and under or who have had a new sex partner in the past year.

Registration and Intake. The clinic record-keeping system is computerized. There is a manual system in place to record telephone calls and letters to patients. Pap results are not included in the medical records computerized system.

Education and Counseling. Cervical cancer educational materials are available in the waiting rooms of the family plating clinic. There are none in the STD clinic, though they do have educational materials for STDs.

In family planning, cervical cancer education is part of the counseling that the nurses provide. It shouldn't be difficult to add this type of education at the STD clinic.

Pap Test. As a Quality Control measure, the health department tracks efficiencies. All clinical staff are expected to obtain endocervical cells on at least 95 percent of his or her smears.

A medical advisory group for the state health department developed recommendations for follow-up that are not necessarily based on CDC guidelines. There are specific recommendations for repeating Pap smears and for the referral of patients with abnormal Paps.

Abnormal Results. The family planning clinic receives monthly summary reports from the cytopathology lab monthly. The clinic is concerned about atypical squamous, LSIL, HSIL, inconsistent hormonal, repair reactive, and no **endocervical** cells. It was noted that when SKB is asked to do a summary report, **the** response is slow. These slides are sent to a nearby city and then to Philadelphia. The results come over line on a printer everyday. Once a month, FP receives a summary status report from **SKB**.

Protocol. The local clinic nursing staff audit all records that are atypical (LSIL and HSIL). Family planning makes the appointment for follow up with the colposcopy clinic and then faxes patient chart information to the follow-up clinic. If necessary, students can be referred to the University-related center.

Follow-up, Tracking, and Referral. For patients within normal limits, FP doesn't send notification, having told them to assume that everything is fine if they don't hear from the clinic. Each clinic is responsible for initiating follow-up of all abnormal, but one person is responsible for follow up to colposcopy for all clinics in Norfolk. The clinic nurse is responsible for making all referral appointments.

Nurses separate abnormal from normal results. For abnormal, staff pull the relevant files and give them to physicians for review. Using a tickler system, follow-up begins with a telephone call followed by a letter and, if necessary, a certified letter. If all else fails, FP sends a nurse to the patient.

The FP clinic supervisor at the Little Creek facility believes that they do not see the same patients that the STD clinic does.

The staff refer women with abnormal Paps to the Division of Oncology at EVMS, but this service is not available to women with Medicaid. A patient must be indigent and a Norfolk resident to receive colposcopy services. Money is often a barrier to treatment.

The Norfolk clinics institute the state protocol for family planning. If the woman has atypical squamous cells of undetermined significance (ASCUS) or if the woman is HIV-positive, she goes for colposcopy immediately. A gynecologist at the health department does the colposcopy and biopsies for Norfolk residents only. She decides, based on the colposcopy results, whether to proceed with treatment. If treatment is indicated, she either treats patients herself or refers them to the gynecology service next door at EVMS.

At family planning, staff collect **10-30** Pap smears a day, and nurses are assigned to conduct follow-up. In addition, staff report doing about 20 Pap smears a month at the general medicine clinic.

All patients sign a release form at the family planning clinic to send their medical records to EVMS. If they have not received the results after a period of time, family planning writes to EVMS for the records including results of the colposcopy. EVMS sends notification if the patient has not come for treatment. Generally speaking, the family planning clinic knows the results of the colposcopies. This is easy if the referral site is cooperative. EVMS presently sends colposcopy results back to the clinic. Of all of the referral sites for colposcopies listed, the HD is the least expensive alternative. The HD is on a sliding fee scale.

According to the guidelines, results are classified as within normal limits or as atypical. If squamous, the Pap smear needs to be repeated in three months. If glandular or endocervical, a colposcopy is indicated.

Additional checks and balances for follow up are required by the State of Virginia. Clinics have to send reporting forms to the state health departments' Division of Women's Health. This extra reporting might cause a problem if Pap testing were performed at the STD clinic, given the level of confidentiality there. One respondent suggested that Pap tests follow-up procedures would have to be clearly explained to STD patients during the initial visit.

Training Issues. On-site training is used to get nurses up to speed on the follow-up procedures. In addition, physicians and nurses/nurse practitioners meet monthly to discuss issues including training issues.

Benefits/Disadvantages

The Medical Director felt that it would be a wonderful idea to add cervical cancer screening services to the STD clinic. In terms of a budgetary impact, "It is no big deal. It would be cost neutral for us." In her opinion there is a trade-off between repeating smears that have been done in the STD clinic setting or of missing women altogether.

Other questions raised were:

- If a woman comes into the clinic presenting with inflammation, what is gained by doing a Pap test, if it turns out that a repeat smear is necessary?
- Will the percent of HPV change in this clinic population versus another population?

- How long does it take to conduct the test? Will this have an impact on clinic flow or patient volume?
- Will resources allow for follow up through treatment?

The Medical Director felt that the system could handle an increase in volume of patients needing diagnostic services. “ We are more interested that whatever we do has a clinical result that is worthwhile. Then we shift resources to what is important.” In sum, the Director of Medical Services believes that cervical cancer screening is a great idea, especially if there is money there for it. “I would have loved to start this years ago.”

One of the benefits of adding cervical cancer screening at this clinic would be the opportunity to reach underserved populations and those without insurance. An initial disadvantage may be an additional burden on the DIS. “I think that the benefit will outweigh any disadvantages. The STD clinic added HIV services a number of years ago. I don’t foresee adding cervical cancer screening having nearly the impact on clinic workload as HIV did.”

All DIS felt that this added service would be beneficial to the woman and not a burden to them and their workload. Adding this service in Norfolk may increase STD clinic volume. Because of Medicaid managed care, the current clinic volume has been reduced, so the clinic could accommodate the program with current resources.

Established Infrastructure

Other Referral Systems. There is a referral system set up for HIV patients who have abnormal Pap smears.

Women with PID are requested to come back 48-72 hours from the initial visit. The majority of these women do not come back unless they still have symptoms. Patients are given call-back slips with a code that matches the codes on the plate. If they don’t call back, DIS are dispatched to find them.

A referral network is already in place for other clinics in the City. One nurse reported that the EVMS referral system is currently not working -- the waiting time is already 2-3 months. She fears that the wait would increase with the addition of Pap smear services in the STD clinic.

Established Networks. Health Department staff believe that they currently have a very good relationship with the private doctors and hospitals in the area. There is a good network established with the private sector.

Detroit, Michigan – Site Report

Community Background

The City of Detroit, with a population of **1,027,974**, is the largest city in Michigan and the eighth largest city in the United States. The Detroit Metropolitan Area, comprised of three counties (Wayne, Oakland, and **Macomb**), has a population of **4,590,468**; in 1990, that population was approximately 75 percent African American, 21 percent white, three percent Hispanic, and one percent Asian.

The major industry in Detroit is automobile manufacturing. The median household income in metro Detroit is \$34,707 and the median housing value is \$69,260. Approximately 70 percent of housing is owner-occupied (single family), one of the highest rates in the country.

Public Health Department

The Detroit Health Department has over 900 employees in six primary health centers. The headquarters is the Herman Kiefer Health Complex, a large structure that used to be a mental health hospital and TB sanatorium. The STD clinic is located in the Herman Kiefer building. STD services are not routinely provided in any of the six satellite clinics, although staff in the clinics have the ability to test and treat their patients for **STDs**. New patients are referred to the STD clinic at the Herman Kiefer building. Detroit has a limited public transportation system. There is a bus stop near the Health Department building, but it is not clear whether the bus is easily accessible from the neighborhoods from which the clinic draws its clientele.

Laboratory Services

The Health Department central laboratory is located in the Herman Kiefer complex and has eight subdivisions. There are also six satellite labs. Due to CLIA 88 regulations, the Health Department no longer operates a cytopathology lab, because of the expense of having an on-site certified cytopathologist.

women come with any vaginal discharge. Many STD clinic staff said that when women get pelvic exams, they often assume they are getting Pap smears as well.

Hours of Operation and Staffing

STD clinic hours are from **8:30** am to 4:00 pm, but registration begins at 7:00 am. The clinic is closed for **lunch** between noon and 1 pm.

The clinic is staffed by:

- 2 physicians (1 internist, 1 gynecologist)
- 5 Clinic Nurse VD (all can do exams)
- 6 clerical staff (5 staff and 1 supervisor)
- 3 **MLPNs** (Phlebotomists)

The clinic medical director is a gynecologist and primarily works with the female patients. All nurses go through a standard two-week course of STD training and then receive additional training from the clinic's medical director.

There is one nurse supervisor in charge of all Clinic Nurse **VDs** and MLPNs. The nurse supervisor is in charge of training the Clinic Nurse **VDs** and sending them to classes, providing nursing orientation, conducting exams, overseeing clinic flow, and monitoring incidents and complaints. The nurse supervisor also sees the "difficult" patients (patients with whom other nurses are having problems).

There is also a coordinator of clinic operations who develops objectives, coordinates operations, handles budgets, and takes care of administration.

The clinic has a team of 12 disease intervention specialists (DIS). Two are State DIS and 10 are hired from SEMHA (South Eastern Michigan Health Administration) on a contractual basis. They each spend one day in the clinic and the next day in the field following their contacts. The DIS are the last people to talk to the patients before discharge. They discuss the disease process, medications, and prevention.

STD Clinic Census and Demographics

The STD clinic sees 70-90 patients a day, though they have the ability to see up to 100 daily. They stop taking patients when they feel they will not be able to see the patients they already have waiting. The clients are approximately 65 percent male and 35 percent female. The clinic sees patients ages 13-70

Health Department Director know the needs of the clientele?" Decisions on allocation of resources or staff need to be made based on data, such as the number of Pap smear slides processed and their results.

According to the lab director, if the STD clinic were to begin collecting Pap smears, the overall volume would increase. As it is, there is not sufficient staff to handle the current volume. Lab staff would like to shift the staining responsibility to the cytopathology lab.

For Pap smears, the central lab currently pays DMC \$5 a slide, but DMC wants to increase the charge to **\$6.50** a slide. The central lab is considering having DMC perform all phases of the process, instead of just interpretation, and the cost for that would be \$8.50 a slide.

STD Clinic

Description of Clinic

The STD clinic is responsible for prevention, examination, and treatment of **STDs**. At this facility, staff train residents, nurses, and physician assistants. Although the clinic is walk-in, appointments are set up for court-ordered testing and special testing for the Salvation Army and drug treatment programs throughout the city.

The STD clinic is located at one end of the first floor in the Herman Kiefer Health Complex. There is a large open area where clients can fill out forms, check in, and wait to be called. The clinic itself consists of:

- 3 stations for drawing blood
- **9** exam rooms
- Separate male and female waiting rooms (20 seats in female; 15 seats in male)
- A stat lab

All exam rooms in the clinic are set up to do male and female exams. The stat lab in the clinic can handle most STD procedures. The clinic handles all **STDs**, trains residents from Henry Ford Hospital, and serves as the initial contact for HIV patients.

The clinic medical director says that the STD clinic has become as much a triage site as an STD clinic, because it is walk-in, making it relatively easy for people to come in for services. For example,

The central lab has established a unique process whereby cytopathology processing is started on-site and completed by a contracted cytopathology lab. Currently, the Health Department contracts with Detroit Medical Center (DMC) to evaluate slides that have been processed by staff in the central lab. In this arrangement, the central lab does quality control for internal functions and personnel, and DMC is responsible for quality assurance. The Health Department lab director checks the QC sheets quarterly. The contract with the cytopathology lab is for one year and can be renewed for two or three years. The contract is cost-based.

When a Pap smear is fixed, the clinician fills out a Health Department lab form and a **cytopathology/histology** form. The slides are put in a cardboard slide holder and a courier service brings them from the satellite clinics to the central lab two times a day. Slides from the clinics within the Herman Kiefer building are walked down to the lab every day. The slides and the two forms come together. The central lab checks that the slides are properly prepared.

The central lab enters the information from the forms into a computer and prints out a worksheet. Later, the results are entered as well. DMC generates detailed monthly reports of the results.

The central lab stains the slides and puts them in a plastic multi-slide holder, and DMC picks them up 2-3 times a week. Slides get stained at the central lab two times a week because they are short of staff. We were told that if the lab were to need extra help to handle additional Pap smear slides, they would use an agency, because getting the city to hire someone would be very difficult.

The whole process for preparing slides takes about 2½ hours. The lab procedure for the STD clinic would be the same as for the other clinics. It takes 2-4 days to receive slides from the clinics and get the results back from DMC. The courier who picks up the slides also brings the results, which come in duplicate so that the clinics get a copy. Abnormal Pap results go back to the Medical Director. DMC handles all the detailed reports on Pap smear results. The Health Department lab director can call DMC to get special reports on Pap results, such as abnormal, which can be sent right away.

Asked to give advice to Health Department labs that are considering taking on processing of Pap smear slides, the lab director recommended handing off these operations to specialists who know cytopathology (e.g., a subcontractor such as DMC). He said, however, that the Health Department lab should not just turn everything over to a contractor. The Health Department lab needs to make sure to complete reports and be involved in all aspects of the process. Specimens should pass through the Health Department lab so the Health Department can keep up with the status of the slides. If information were to go directly from the clinics to the contract lab (i.e., DMC) and then back to the doctors, “how would the

years, but most are between 16 and 35 years old. Clients are about 95 percent African American, 2-3 percent Hispanic, and the rest are white or Middle Eastern.

The nurse supervisor gets a monthly productivity report that breaks down morbidity statistics and lab results by each examiner. Each examiner sees about 10 patients a day but can see as many as 15.

The clinic sees about 20,000 patients a year, about one-third of whom are females. Most patients come in 5-6 times per year. We were told that the STD clinic clientele are at or close to the poverty level. Many of the women are uninsured. Roughly 30-40 percent of STD clients have some insurance coverage. The STD clinic will begin third-party billing soon. Referral is to Henry Ford or other hospitals.

STD Clinic Flow

A patient walks in to the area by the front desk of the STD clinic, takes a pink number ticket, and fills out a green intake form. The intake form asks the patient's name, contact information, demographic information, health insurance status, reason for visit, and whether he/she has been in the clinic before. A staff person calls the number and goes through the green form with each patient to make sure everything is correct (checks patient ID against the information on the green sheet) and takes insurance information. The staff person signs the green form so the clinic does not have to worry again about the demographic information. The patient is assigned another number and waits in the large waiting area. Early in the morning, the HIV Program staff, comprised mainly of DIS, give an HIV prevention presentation in the waiting area. We observed that educational materials were sparse in the area. The numbers by which patients are called to be seen by a clinician are organized as follows:

- (1-75) Males (numbers start in the single digits)
- (301-335) Females (numbers are the 300s)
- (70 1-7xx) Return patients

A patient who has been to the clinic before and is back for follow-up or treatment gets a 700 number and is seen more quickly. Partner notification generates a PINK SLIP. Patients with pink slips also receive 700 numbers and have some priority.

A clerk keys the green sheet information into the computer system and prints out an encounter form. The clerk bubbles in the numbers (patient ID number and clinic call number) from the green sheet onto the encounter form. The STD clinic has a full medical history on each patient that has been seen there before, including all other encounters at the clinic. The patient history prints out at the Epi desk

(where the DIS are located) and is attached to the encounter form and sent back to the clinic. The clinician then has all this information when doing an exam.

Each patient gets a **VDRL** and gonorrhea screening. If the patient wants an HIV test, he/she must request it. The clinician always asks the date of the patient's last Pap smear. Education and counseling are done by the clinicians. The clinicians talk about the disease process, whether it is a virus or bacteria, how it is transmitted, and complications if not treated. They also correlate symptoms with specific diseases, talk about risky lifestyle issues, and give medication information. An exam can be as short as five minutes and as long as **25-30** minutes.

Specimens go to the stat lab in the STD clinic, where wet mounts, smears, **RPRs**, and Darkfields are processed. The central lab is responsible for all cultures. The patient either is treated at the clinic or is sent a letter. The letter is produced by the computer system and is mailed in a city envelope. A patient who tests positive for syphilis is mailed a blue half-sheet asking him/her to return on a specific day for treatment. Clinic staff prefer this system because they do not want patients calling for their results. HIV results are anonymous, but STD is confidential.

Discharge education is provided by the nurse who does the exam. During this part of the clinic visit, STD staff discuss information regarding the patient's STD and complications if not treated, provide STD and HIV literature, provide information about the medication prescribed, and give prescriptions. This educational process varies by person and ranges from five minutes to half an hour (this represents the possible reaction time for bicillin).

After the exam, the patient goes to the Epi desk. The DIS asks about contacts, provides more information (education/counseling), and asks whether the patient has any more questions. **He/she** is given educational materials and condoms and discharged. There is a pharmacy in the basement of the Herman Kiefer building where the patient is referred after the exam.

Lab information is communicated to the STD clinic on sheets that were sent by the clinic to the main lab. The lab fills in the information and sends it back to the STD clinic. (We were told that they are setting up a bar-code system so information will go to the lab with a bar-code and come back that way too.) When positive lab results are entered into the computer system in the STD clinic, a blue sheet is automatically generated with the results. This is sent to the patient as a letter telling him/her to come back. When a patient shows up with the blue letter, he/she can pull the pink number ticket and just fill out the name and address on the green sheet. These patients get 700 numbers and are given priority. The clinic keeps the green sheet and bubble forms but shreds the history printout.

Cervical Cancer Screening

The STD clinic at the Detroit Health Department does not currently conduct cervical cancer screening. Therefore, information regarding the specific steps of cervical cancer screening is prospective, based on the opinions of STD staff.

Registration and Intake. STD clinic staff do not foresee much additional work necessary for registration and intake of female patients if cervical cancer screening is implemented. The computerized system presently in place is sufficient to handle the process. Some items would have to be added to the present intake forms.

Education and Counseling. The opinion of clinicians in the Detroit STD clinic was that registered nurses are well aware of Pap screening and issues of cervical cancer, so not much additional training would be necessary.

Pap Smear. The clinicians with whom we spoke said that Pap smears would not require much extra exam time. Most patients think they are getting Pap smears when they receive pelvic exams, and clinical staff currently have to explain that they are not. The STD clinic medical director believes that if a female patient has a lot of inflammation or trichomonas, they should treat the inflammation and get the woman back in for a Pap smear. Those we spoke with in the STD clinic said that the medical director could train the nurses to conduct Pap smears.

Follow-up, Tracking, Referral. In their current system, if a woman has a positive test result (i.e., an infection), the computer system issues a "blue slip," which means an appointment to come back in for treatment. The same could be done for repeat Paps. The proposed process would be to first send out a letter (as part of the computer system). Clerical staff could handle this part. They would allow five days for a patient to respond. If the patient did not respond to the letter, the clinic would try to call. DIS could go out to find hard-to-reach clients.

On their return, patients would sign a form indicating that they had received the Pap results. Then they would talk with the medical director or nurse supervisor. The patient would be informed of the results and given a referral for colposcopy. The responsibility of the STD clinic would be to make sure the patient goes to the referral site and to make sure the patient maintains that relationship.

The STD clinic medical director would set up the referral network. STD clinicians believe that initially it would take several half-days to set up the referral networks, but once set up, it should not be a problem. There are many hospitals in the area. Many patients have insurance, so the first referral option would be private physicians. The adult health clinic at the Health Department is for uninsured patients and has a contract with the adult health clinic at Henry Ford Hospital. That clinic and St. Johns Hospital have a good relationship with the Health Department. It was also suggested that the STD clinic could utilize the BCCP referral network already in place. The Health Department already has social workers who can help patients develop temporary payment plans.

One respondent said that, the farther the STD clinic goes in following the patient, the better the project. This respondent said that “patients are low employed, not highly literate, and distrustful of the health department. They need shepherding and constant reminding. They need the support.’ Another respondent said that it would be a good idea for the Health Department to know the results of diagnosis or treatment, not to be responsible for the patient at those points, but to get the information back.

We spoke to STD staff about the possibility of DIS carrying out some aspect of cervical cancer follow-up. The only role the DIS may have in referral would be possibly picking up some hard-to-reach patients with abnormal Pap results and getting them to the colposcopy appointment. In the opinion of a DIS supervisor, the DIS have plenty of latitude to take on additional responsibilities. DIS workload is down because disease incidence is down, so DIS could handle the additional responsibilities. For most patients, the computer-generated letters would be sufficient, but according to one DIS, 20-25 percent of patients will “need an extra push,” and DIS could be utilized.

Those in charge of DIS said that training would be necessary for the DIS to be involved in the Pap screening process. Training for DIS would depend on how much information they are asked to deliver. The best estimate was that the training of DIS could be half the staff one day and half another day. Therefore, training would take only two days, but then the DIS would need some practice delivering cervical cancer screening information.

Cost. The STD clinic director believes that the STD clinic should definitely do Pap smears. Women with high sexual activity and who have many **STDs** are at high risk of cervical cancer. STD administration has been trying for 10 years to get Paps in the STD clinics. Money is said not to be the issue. Instead, the reason given for not offering Pap smears in the STD clinic is that it has not caught the attention of higher-level Health Department administrators as an important issue. The actual screening costs are seen as minimal. Physician time is a cost; physicians in the Health Department are on contract

and do not work for the city. Lab costs were identified as a necessary cost. In summary, extra staff time would be the most substantial cost with lab costs as secondary.

Family Planning Clinic

Description of Clinic

There are five family planning clinics throughout the Detroit area, but the program is headquartered in the main Henry Kiefer building. None of the family planning clinics are walk-in; they are all on an appointment basis. They use a sliding-fee scale for payment. The family planning clinic schedules 20 patients per day (six new patients, eight return patients, and six birth control refills). Over 30 percent of family planning clients are adolescents. The family planning clinic sees its patients every six months.

All patients in the family planning clinic get a Pap smear on their original visit and then get an annual Pap smear. The family planning clinic also does VDRL, GC screening, syphilis, and chlamydia. If a patient is an established family planning clinic client and has an STD, the family planning clinic will treat her for it. If she is a new client, family planning will send her to the STD clinic. A family planning patient gets her next appointment before she leaves. She has to remember the appointment, and 95 percent do remember.

In the past, the family planning program had a women's center in the STD clinic and did Pap screening. We were told that this program ended for funding reasons. The family planning program receives money from Title 15 and Title 10 and could make the STD clinic one of its sites under that funding so Pap testing could be done in the STD clinic.

Cervical Cancer Screening

The family planning clinic has 10 sessions a week and six new patients each session, totaling 60 Paps a week total. The family planning program has a Pap smear protocol developed a few years ago, but it is revised annually.

Registration and Intake. If a family planning clinic patient is menstruating, staff give her an appointment to come back for her Pap smear. However, they will do a Pap smear if a patient has an infection.

Follow-up, Tracking, Referral. On average, Pap smear lab results come back in 7-14 days. The lab sends a copy of the report to the clinic. If the results are abnormal, the patient gets a phone call. If there is no response, she gets a letter. If the result is dysplasia, the clinic has the patient come in for a referral to colposcopy. If there is no response from the patient, the clinic sends a certified letter.

For referral, the family planning program has contracts. Where a patient is referred depends on which clinic the patient is from. Family planning calls the referral site and makes the appointment for the woman. They also receive a report from the colposcopy clinic. The results are put on the patient's chart.

In the multi-service clinics, the family planning nurse does the referrals. It can take up to 30 minutes to explain to clients about cervical cancer and colposcopy, but it usually takes about **15-20** minutes. It is mandated that a colposcopy appointment (or some other treatment) must be made within six weeks of receipt of results.

Established Infrastructure

The STD clinic could piggyback on the existing cytopathology lab contract. The STD clinic medical director could read the Pap smear results reports. As another option, the STD clinic could be made a family planning Title 10 site and would then provide family planning services to its clients, including contraceptives, educational materials, and Pap smears.

The STD clinic has an excellent computerized data system. Adding Pap smear information would not consume much time or resources. The clinic's ability to produce the data required for an evaluation is very good.

Benefits/Disadvantages

Some STD staff said that they are somewhat underutilized now. The clinic used to see 100 patients a day but now sees approximately 70-80 patients a day. The clinic has increased the number of

clinicians and could handle a higher patient load. This means that cervical cancer screening would not overtax the current staffing.

Even though doing Pap smears in the STD clinic may not find a lot of cervical cancer, they would find HPV infection and the Pap smears would be a preventive measure. Respondents felt that not doing Pap smears in the STD clinic seems like a missed opportunity.

Possible disadvantages would be the cost of processing and evaluating Pap smear slides and the difficulty of getting patients back into the clinic for follow-up and referral.



Kent County, Michigan – Site Report

Community Background

The population of Kent County is 535,000. The ethnic breakdown of the county is:

- 89 percent white
- 8 percent African American
- 2 percent Hispanic
- 1 percent other

The growing ethnic diversity of Kent County is reflected in the presence of Bosnians, Vietnamese, Mexicans, and others.

The median income in Kent County is higher than that in the rest of the state. According to information from Health Department administrators, only nine percent of people in Kent County report not receiving medical services due to cost. There are four primary hospitals in Kent County, located mostly in Grand Rapids: St. Mary's, Metropolitan, Butterworth and Blodgett Hospitals. The latter two have merged into Spectrum Health Systems.

Public Health Department

The Kent County Health Department has a \$26 million annual operating budget and 349 employees. Health Department facilities include one main building and seven satellite sites. STD services are offered only in the main building in Grand Rapids.

Kent County has privatized many of its public services; twenty percent of the Health Department budget is contracted out. We were told that this is due in part to the conservative nature of western Michigan and the belief in decentralization. For example, family planning and mental health services have been privatized. The Health Department has a contract with Planned Parenthood for providing family planning services at four clinics in the county. The people with whom we spoke in the Health Department were not sure how long Title 10 funding has been passed to Planned Parenthood, but the consensus was that it has been since the 1970s.

There is overlap between the clientele of the STD clinic and Planned Parenthood (PP), but many women who come to the STD clinic would not go to PP. Conservative women will not use PP because it provides abortion referrals. It also was suggested that some women do not go to PP because they do not like to go to new places.

Laboratory Services

The State of Michigan and Counties (Kent, Kalamazoo, etc.) have a regional lab system with one manager overseeing QC and proficiency testing. Clinic-based satellite labs are not full or even stat labs; they provide only limited services. The lab based in Grand Rapids is the headquarters for Region 4, which covers 15 counties in western Michigan. There is also a high-complexity lab located in Grand Rapids that is not considered part of the regional lab.

The Health Department lab performs syphilis, gonorrhea, chlamydia, and HIV testing. The syphilis processing is done for the Health Department and Planned Parenthood, but HIV testing is done for other places as well. The Health Department lab does not do cytopathology; administrators have discussed the matter for at least the past eight years, but they would need a registered **cytotechnologist** to do it.

The Women's Health Network operates a BCCP clinic one day a week, which performs Pap smears. The slides from that program are sent to local hospitals, such as Saint **Mary's** or possibly Blodgett or Butterworth Hospitals, depending on the satellite clinic where they originate. The Pap smear slides are sent directly from the BCCP program to those labs, but the Health Department lab director processes the billing. Pap smear processing costs about \$7 per slide.

The lab has a computer setup for tracking results. The STD clinic does have a computerized database, but access to reports is currently limited to state requirements. Each division within the Health Department has separate data systems, but no other area has access to STD data.

STD Clinic

Description of Clinic

The STD clinic is a walk-in clinic providing free testing and treatment for all except those seeking premarital services. The clinic handles gonorrhea, syphilis, chlamydia, pubic lice, HIV testing, mild PID, HPV for men, Hepatitis B referral, premarital education, court-ordered testing, follow-up, and victim witness. The clinic does not handle gardenerella, trichomonas, herpes, or female HPV; those are referred to Planned Parenthood. Male HPV screening is called “Wart Wednesdays” because that is the day a Nurse Practitioner comes to do the exams for HPV on men. The clinic director does not want to provide HPV services for women because the clinic does not offer Pap screening, fearing that if the STD clinic treated the wart and referred for Pap screening, the client may not get the Pap. Also, clinic administration feel that women should not have to get two separate pelvic exams.

The STD clinic has one waiting room, with about 25 seats, and six exam rooms. All rooms can handle both male and female patients, but one of them is not preferred for women because it is smaller.

Hours of Operation and Staffing

STD clinic hours are weekdays from 8-5, except Thursday hours from 1-7. All patients must be registered by **4:00** pm to be seen that day (except on Thursdays, which require 6 pm registration).

STD clinic staff include:

- 1 part-time RN
- 5 full-time **RNs**
- 1 full-time LPN
- 1 full-time clinic assistant
- 1 full-time clerk
- 3 part-time clerks
- 1 program supervisor
- 1 epidemiologist
- 1 DIS (State-funded)

The DIS in Kent County works for the State Health Department, **HIV/STD** Division, and is assigned to Kent County. He also covers Muskegon, Ottawa, and other counties. He spends about 80 percent of his time in Kent County because he is the only DIS in the county. Muskegon has a County Health Department DIS agent. Other counties have nurses who handle many of the DIS tasks.

The responsibilities of the DIS are to monitor testing, follow-up, and partner notification. He does occasional presentations, but investigation, not education, is the main part of his job. He does the **follow-up** when patients cannot be reached. In terms of workload, syphilis rates are falling significantly, but it is still a full-time job for one DIS. There is a freeze on State employment.

STD Clinic Census and Demographics

The STD clinic sees **25-30** patients a day, about 65 percent male and 35 percent female. The clinic does not have a computer system for reporting on the demographic status of its clientele.

Some patients come in with questions and receive only education, but most are examined. The feeling among staff is that women do not come in for routine visits; they only come in for crises. An STD patient must be at least 13 years of age to be examined. The clientele at the STD clinic includes women 30 and older who have no health insurance. While Planned Parenthood sees many teenagers, the STD clinic sees more college-age and divorced women.

STD Clinic Flow

The clinic intake staff includes a part-time clerk (**8:00** am to **1:00** pm) and a clerk typist in the afternoon. They do registration, prepare the patient charts, and search records. Patients register when they come into the clinic. HIV testing can be confidential or anonymous. For **STDs**, the patient fills out a data information sheet that is later checked against the patient files. Clerks are required to determine whether the patient is a repeat, but some patients use different names.

A clinic assistant brings the patient and chart to the exam room. Exams are done by **RNs**, who also provide education and follow-up. They usually spend 30-40 minutes with female clients and 20 minutes with male clients. The DIS gets involved in education with positive HIV or syphilis cases.

Results come back from the lab in two days, but the nurses tell the patients to check back in three days. All lab results are run by the lab tech and given to the clinic assistant, who logs them into a computer system. Another person puts them into the patient's chart. In this way, two people work with

each result for quality assurance. The forms used in the process include a medical history form, the nurse/medical notes, and the lab results. These forms are kept in the patient charts, which are kept for two years and archived for seven.

If a patient has a positive STD test, the normal notification process is a phone call, followed by a letter, and if those are not successful, referral to the DIS. The clinic nursing staff handle the initial phone calls and letters. Staff try to reach people as quickly and as confidentially as possible. If the patient has not come in for treatment, the nurses pass the case to the DIS. Nurses allow a couple of days for the patient to get back to them, but if she is a teenager or pregnant woman, they may go straight to the DIS without a phone call or letter.

Cervical Cancer Screening

The STD clinic at the Kent County Health Department does not currently conduct cervical cancer screening. Therefore, answers regarding the specific steps of cervical cancer screening are prospective, based on the opinions of STD staff and Health Department administrators.

One Health Department administrator commented that they would need to build quality assurance (QA) into any demonstration project. QA could include chart audits and a patient survey for new female clients. The survey would query whether or not these women knew of the Pap smear testing services in the STD clinic. Another administrator envisions sending feedback cards about the service, to determine whether offering it is a good idea. These cards could be located in the waiting or examining rooms.

Registration and Intake. STD clinic administrators foresee that a number of new forms would have to be developed for cervical cancer screening. These would include a form for the patient to decline further diagnosis. STD clinic staff were adamant about requiring that clients who refuse follow-up services sign such a form.

Education and Counseling. The education and counseling regarding cervical cancer screening would be done by the people conducting the exam, just as it is currently with **STDs**. Since Health Department staff believe that a Nurse Practitioner (**NP**) should conduct the Pap smear, education would also be done by the NP. One clinic administrator suggested that the NP could have an assistant to help with these tasks.

Pap Smear. The STD clinic is currently staffed by **RNs**, but administrators believe that they would need **NPs** to perform Pap smears. The **NPs** who currently work for the Health Department are on contract and paid \$35 per hour, with no benefits. A salaried NP would receive **\$33,000-34,000** annually.

The clinic administrator would prefer not to do Pap smears at the time a woman is infected **with** an STD, but would rather clear up the infection and refer for later Pap screening. This may be due to this person's experience working at Planned Parenthood, where that is the policy.

In the BCCP program, an NP reads the Pap smear results. The Health Department would not consider doing Pap smears in the STD clinic if it were required that a physician read the results. However, they believe there should be a physician available to assist with referrals if necessary. The NP would conduct the Pap smear and label the slide. A clinic assistant would check the labeling and organize the slides. The slides would be packaged and sent to the lab. Results would be logged in and charted.

Follow-up, Tracking, Referral. According to our respondents in Kent County, follow-up includes any energy exerted after lab results come back. They felt that the Health Department is responsible for patients up to the point of follow-up and referral. The prevailing attitude among STD clinic administrators is that clinic staff should do what they can to make it easy for the patient to get to a site for colposcopy and that the STD clinic should receive information back on the colposcopy appointment. The STD clinic's responsibility is to make sure the client understands what needs to be done. The STD clinic can only empower the patient to do the right thing; they cannot force her to do so. But clinic staff stated that with Pap smears, because cancer is involved and there can be tremendous liability, it is important to do full follow-up and have full documentation. One person said that often patients will agree with what they are being told during education because they do not want to look dumb, but that it is important for the nurse to make sure the patient really understands what to do.

While an NP would perform the Pap smear, a contract nurse (RN or LPN) would do the **follow-up**. During the exam, the nurses tell the client to call back three days later for results. When the patient calls, if the person responsible for giving results is comfortable it is the right person, he/she will give the results over the phone. When Pap smear results are abnormal, the patient must come into the clinic for follow-up. According to the clinic administrator, the "no news is good news" method is not acceptable, and they would want to inform all patients of their Pap smear results, whether normal or abnormal. **For STDs**, the clinic does not send letters, but for Pap results they would.

STD clinic staff expressed that it would take approximately one hour or less to follow-up on clients with results of CIN I. For those with results of CIN II or greater, staff envision spending three hours, including using the tickler system.

In summary, for abnormal Pap smear results, they would do the following:

1. Phone contact - clients are more likely to respond to an individual person. Patient feels comfortable when given one person's name to contact.
2. After 48-72 hours, put a letter in the mail indicating to call the STD clinic for information about Pap test results.
3. Tickler system to make sure the patient follows a series of follow-up steps.
4. Certified letter if patient refuses to follow up.
5. If you cannot find the patient, call the emergency contact named by the patient on the registration form.

If cervical cancer screening were implemented, the STD clinic would need a referral list of providers that would see Health Department clients. The clinic administrator has been establishing relationships with providers in the community that could be utilized. Also, residents from local hospitals come through and do hours in the STD clinic. Clinic staff believe that there needs to be a formal referral network and a diverse list in terms of gender and **ethnicity** of doctors.

One possible point of referral would be Planned Parenthood (PP), but at that clinic, a woman must become a family planning client to get a colposcopy. Therefore, she would have to go through the entire sequence of services. Planned Parenthood would not be willing to be used as a colposcopy clinic only. We were told that lesbian clients do not need family planning (birth control) services, so they do not want to go through the entire PP system. However, they are often reluctant to tell Planned Parenthood staff that they are lesbians, so they are not comfortable accessing Planned Parenthood.

When asked about a possible role in follow up of abnormal Pap smears, the DIS agent said that if he just had to deal with Pap screening patients who cannot be found, it would be no problem. However, if he had to knock on doors and go to hangouts regularly, it may be a problem. The one DIS agent is already busy tracking other STD contacts, so most of the people with whom we spoke felt that a nurse should be responsible for follow-up of abnormal Pap smears.

Cost. The only additional costs would be to hire a Nurse Practitioner (NP) to conduct the exam, to initiate the processing and evaluation of Pap smear slides, and to provide staff time to conduct **follow-up, tracking, and referral**. The staff costs are seen as more significant than lab costs, but the program could not be implemented without extra funding for these things. STD administrators said that staff

training would be needed to explain to nurses how Pap testing would fit into existing services. In addition, training would be needed to clarify staff roles, to learn to validate medical histories, and especially to train nurses who have not worked with Pap smears in the past. However, Health Department administrators stated that it would be difficult to get the County commissioners to provide extra money for cervical cancer screening in the STD clinic since it is already provided at Planned Parenthood.

Family Planning Clinic

Description of Clinic (Planned Parenthood)

Planned Parenthood (**PP**) has 11 clinic sites in seven counties of western Michigan. They have 67,000 annual patient visits. There are four PP clinics in Kent County, two of which are in one building in Grand Rapids and share medical records. These two clinics see an annual total of 10,000 patients (27,000 visits). The daily census is around 110. Planned Parenthood clinics are called ‘centers’ because there is a stigma of ‘clinics’ not providing good, quality service.

The demographics of Planned Parenthood clients are as follows:

- Twenty-five percent are 19 years of age and younger.
- The largest percentage are 20-24 years of age, although some are older.
- Breakdown by sex is 94 percent female; 6 percent male.

Racial/ethnic breakdown is:

- 79 percent white
- 11 percent African American
- 4 percent Hispanic
- 6 percent other

Most patients are under-insured or not insured. Approximately one-third have some insurance.

- 80 percent are at or below 150 percent of the poverty level.
- 70 percent of patients come back the next year.
- 90 percent use Planned Parenthood as their only source of health care.

Planned Parenthood handles all **STDs** except HIV treatment. At least 25 percent of patients have an STD. The Health Department lab processes syphilis, gonorrhea, and chlamydia and sends the results

back to Planned Parenthood. The Health Department also helps with contact tracing, partner notification, and tracking patients with syphilis and gonorrhea. Of the 11 counties Planned Parenthood covers, the Health Department only has STD clinics in Kent and Muskegon Counties, so Planned Parenthood is the STD clinic for the other nine counties.

Planned Parenthood provides family planning services for the Kent County Health Department with Title 10 funding. The Title 10 money has been going to Planned Parenthood at least since the 1970s. Planned Parenthood provides birth control, STD testing and treatment, and hormone replacement therapy, and treats urinary tract infections, bronchitis, and strep throat. It also provides smoking cessation services, annual physical exams, premarital education, and counseling.

Planned Parenthood has a computerized system for patient information. Medical information is kept in handwritten charts, but lab results, such as Pap smears, are entered into a computerized system. The computer system has alerts for tracking clients with abnormal Pap smear results.

Hours of Operation and Staffing

Clinic hours are: 8: 15 am to 8:00 pm Monday through Thursday
 8: 15 am to **5:30** p m Friday
 10:00 am to **1:00** pm Saturday

Planned Parenthood is staffed by 15 advanced practice nurses (13 **NPs** and two Nurse midwives) throughout the 11 sites. The medical director sees problem patients, and there is a **contractual** arrangement with another doctor one night a week (**ob/gyn**). However, 99.9 percent of care is given by nurses. All PP clinics do Pap smears as routine. They conduct 16,000 Pap smears a year.

Cervical Cancer Screening

Planned Parenthood in western Michigan uses the Pap screening protocol from the National Federation of Planned Parenthood. The director of the Planned Parenthood there questions the ability of **RNs** to carry out Pap screening. **NPs** are the preferred level of expertise for doing Pap smears at Planned Parenthood. The NP must have a microscope available, must check for and clear other infections before taking the Pap smear, or must at least be able to decide whether to do the Pap smear or chlamydia swab first, based on the presence of other infections. The training for whichever clinician will do the Pap

smears is very important. There must also be a medical director available with a strong background in gynecology for evaluation purposes.

If the STD clinic adds cervical cancer screening to its services, the director of Planned Parenthood could be the person to train the clinic staff, establish follow-up protocol, and possibly provide some level of supervision. The PP director approves the Pap screening protocols for all the Health Departments in Michigan.

Registration and Intake. Many different staff members do intake in the Planned Parenthood clinic. Criteria for who does or does not receive a Pap smear depend on the judgement of the clinician. Patient charts are not computerized, but there is a computerized information management system that alerts staff to the extent of follow-up needed and/or completed. The lab results are not entered into this system.

Education and Counseling. The clinician educates the patients on what a Pap smear is and how the procedure works. Patients are told that a negative result is good. If a patient gets an abnormal result, Planned Parenthood sends her information, and her charts are heavily flagged.

Pap Smear. The Pap smear is done by the NP during the course of the patient's exam. At Planned Parenthood, only advanced practice nurses can examine patients.

Pap smear slides are sent to International Cancer Screening for processing. They are picked up daily by Airport Express. Planned Parenthood has a contract with the lab, and the **same lab** also processes the colposcopies. The lab provides all of the necessary supplies for Pap screening. There is a 2-3 week turnaround time for results. The results are mailed, but the lab also calls Planned Parenthood with results of HSIL or higher.

Abnormal Results. Anything not negative is an abnormal result. The **cytopathology** lab sends PP a list of abnormal results monthly. If the result is definitely suspected cancer, Planned Parenthood will refer the patient right away to a setting where treatment is possible. A large percentage of patients choose Planned Parenthood for **the** colposcopy. Planned Parenthood has two nurse colposcopists. There is a 3-4 week wait for colposcopy once the referral is made.

Follow-up, Tracking, Referral. Planned Parenthood staff work on follow-up daily. An RN is in charge of notifying women of abnormal Pap smear results, and other staff are responsible for logging all normal results. Finally, a person with more advanced credentials (such as NP) is responsible for reviewing and initialing charts with abnormal test results.

The Planned Parenthood clinic in Wyoming, Michigan does the colposcopies. The colposcope was put in the Wyoming clinic because of available space. The Planned Parenthood clinic is part of a referral list given to patients for colposcopy. An administrator at Planned Parenthood said that colposcopies in the area are normally \$600, including lab costs and physician fees. By comparison, at the Wyoming Planned Parenthood clinic a colposcopy costs only \$260.

Women in need of diagnostic services are given a list of referral sites from which to choose. Most choose the Planned Parenthood colposcopy clinic because of cost, but a small number go to their own private provider or somewhere else.

Established Infrastructure

The BCCP program at the Health Department does Pap smears for older women, and it is possible they could provide services for younger women. The laboratory contract and referral network from the BCCP program could be utilized by the STD clinic as a start. Because the family planning program in Kent County is not internal to the Health Department, there is no existing infrastructure from that program that could be utilized by the STD clinic.

The head of Planned Parenthood of Western Michigan is a consultant to the State Health Department on Pap screening protocols. She would be available to help develop the County Health Department's Pap screening program, to train staff in proper clinical and follow-up procedures, and to provide some level of supervision and QA.

Benefits/Disadvantages

Benefits

Health Department administrators in Kent County believe that convenience is a good reason for offering Pap smears in the STD clinic. They feel there are a number of women in STD clinics who are probably at risk for cervical cancer. The addition of Pap smears to the STD clinic could also allow them to start a female HPV screening program. Further, women who do not go to Planned Parenthood should have the choice of getting Pap smears at the STD clinic. It was a common statement among our respondents that women in the STD clinic often assume that they are getting Pap smears when they get pelvic exams.

Disadvantages

One issue that would need to be addressed is clinic staffing. For example, only **NPs** would do Pap smears, but most female patients are currently examined by **RNs**. Would the NP have to move from room to room, conducting a Pap smear at the end of the exam given by the RN? Would it be possible for the NP to be available at the end of each exam without making the patient wait with her legs in stirrups? Would it require a second exam after the STD exam, thus putting female patients into the position of being on the exam table twice? Administrators told us that a systems approach would be used to incorporate the NP role into STD clinic operations. Also, the clinic would explore special training for **RNs** to perform Pap smears.

Finally, if Pap smears are not given when an infection is present, what is the likelihood of getting the patient back in for a Pap smear once the STD is cleared up? Planned Parenthood has this policy, but PP also has consistency of care with its patients and can deny birth control if a patient does not comply. An STD clinic does not have these options.

The biggest difficulty expressed by those in the Health Department was the ability to get women back into the clinic for follow-up. One idea is to use staff from the Women's Health Network to develop follow-up protocols and procedures for referral. Also, STD clinics are operating at full capacity, and HIV

services have already cut into STD resources. Pap testing and follow-up would be an additional burden. Additionally, the extra time needed for Pap screening could limit the number of people who can be seen who may have an STD. The Health Department is struggling with the idea of providing comprehensive care but not becoming a primary provider.

Another difficulty would be the space available in the clinic. There could be a need for extra exam rooms or an office for the follow-up person. Clinic staff told us an additional office can be located. Last, the very experienced nursing staff in the clinic could be wary of either the possibility of more work being added to their present workload, the presence of short-term nursing staff coming into the clinic for a demonstration project, or that the addition of Pap screening could detract from the focus on **STDs**.

A Planned Parenthood administrator told us that the more screening in Kent County, the better. The issue is the need to have trained personnel to conduct the exams. At the PP clinic, **RNs** and **NPs** go through training, evaluations, and quality assurance.



Memphis/Shelby County, Tennessee - Site Report

Community Background

Shelby County, home to the city of Memphis, is in the southwestern corner of Tennessee, bordered by the Mississippi River to the west and the Mississippi state border to the south. In the city of Memphis, African Americans make up 55 percent of the population, and whites make up 44 percent. Asians and Pacific Islanders constitute almost one percent, and Hispanics, another one percent. Memphis is central to the southern region of the country as an active transportation and distribution hub. The Federal Express Corporation has its central operation based in Memphis and is the area's largest employer, with 23,000 workers. Other large employers include educational institutions and area hospitals. About 35 percent of the African-American households have median incomes below the poverty level, compared with only seven percent of the white households.

In addition to the Health Department, Memphis has five major hospitals. There is one public hospital in Memphis, and this is the facility most used by low-income patients. The working poor in Memphis can access health services at the Church Health Center (CHC), which is funded by individual donations from over 150 church congregations in the Memphis area.

Memphis/Shelby County Health Department

The Memphis/Shelby County Health Department is organized into three major bureaus, each directed by an Administrator: the Bureau of Administrative Services, the Bureau of Environmental Services, and the Bureau of Personal Health Services, which includes Infectious Disease, Clinical Services, and Community Services branches. The Health Department is also one administrative unit under the Tennessee Department of Health. As such, it operates an STD clinic out of the main building in Memphis. The Health Department STD clinic is located in the city center, with all STD and HIV services offered in the same location. The Health Department operates six Primary Health Care Clinics: Bisson Clinic, Cathron Clinic, Guthrie Clinic, Hollywood Clinic, South Memphis Clinic, and Wellington Clinic. In addition, the Health Department operates two school-based clinics, four WIC clinics, and several

satellite/specialty clinics throughout Memphis and Shelby County. Almost all of the specialty clinics are located at the main Health Department location.

Clinical Services

Memphis/Shelby County residents are able to receive the following services on a sliding-fee scale: family planning, nutritional services, pregnancy testing, routine child care, immunizations, primary care, and routine care for stabilized chronic disease conditions (high blood pressure, diabetes, arthritis, and seizures). Routine dental care for children up to 17 is provided at one of the primary health care clinics. All satellite clinics offer family planning and STD testing and treatment. All six primary care clinics, located within Memphis city limits, are open Monday through Friday. Some clinics offer evening hours one night a week. The satellite clinics, on the other hand, are open part time and are located further out in Shelby County. Physicians are on site at all clinics.

Cervical Cancer Screening Services

Cervical cancer screening is offered in all of the primary care centers in the city. There is only one Nurse Practitioner (NP) per site, who usually conducts the Pap smears. In family planning, the provider who conducts the Pap smear is responsible for follow-up. Each clinic develops its own system to track and follow up abnormal Pap smear results. In all instances, these systems are not computerized. The systems vary from clinic to clinic; some use a tickler system, others do not. The clinical protocol is clearly defined, but the means of following the protocol is up to the clinician's discretion. Currently, the cost of processing Pap smear slides is \$7.25 per slide at Memphis Pathology Lab and is expected to increase to \$8 per slide. Colposcopies done at the Health Department cost \$175.

Laboratory Services

The Memphis/Shelby County Health Department laboratory system consists of the central laboratory, Memphis branch laboratory, six primary health care clinic laboratories, 10 satellite testing sites, and four WIC sites. There are two people in each primary health care clinic who provide laboratory support. The Central lab is very modern. The laboratory is certified under CLIA-88 and provides clinical and environmental testing support to the 842,500 citizens of Shelby County through Personal Health

Services and Environmental Health Services. When **TennCare** began and the Health Department became a primary provider for some managed care organizations (**MCOs**), the central lab had to become a full medical lab.

There is no in-house cytopathology lab at the Health Department because it is outside of the scope of most of the Health Department functions. Furthermore, there are no in-house cytotechnologists or board-certified pathologists. The Health Department contracts out to **SmithKline Beecham** and Medical Pathology Labs (MPL) for processing and evaluation of Pap smears. **SmithKline Beecham** has a collection station in the Health Department building in Memphis and sends its slides to its central lab in Nashville by Federal Express. For patients who have chosen Access Med Plus as their managed care organization, 45 percent of whom are seen at the Health Department, their slides must be sent to **SmithKline Beecham**. All others patients' slides can be sent to MPL. Neither lab sends statistics of the test results back to the Health Department. One Health Department administrator commented: "If we were willing to pay those labs, then we could probably get that type of information back from them."

Community Services

Managed Care. Memphis is in the midst of a full transition to Medicaid managed care. Since 1994, Tennessee has received a 1915 waiver to enroll all Medicaid-eligible people into their Medicaid managed care program, called **TennCare**. Initially, 700,000 Medicaid-eligible people converted to **TennCare** and an additional 400,000 uninsured people enrolled. Converting 1.1 million people throughout the state to **TennCare** was not error-free. In fact, in some cases when incomes were compared to Social Security numbers and did not match, these applications were put on hold, and the applicants were without health care. **TennCare** has opened up to include the uninsurable, such as people who have cancer or are diabetic, and children. If a resident is above the poverty level, he or she will have to pay, based on a sliding-fee scale. The state plans to conduct re-verification of eligibility soon, which may purge the rolls of some people and open up eligibility for others.

About 12 **MCOs** are enrolled in the **TennCare** system to provide care throughout the state of Tennessee. When enrollment was opened, these organizations actively marketed for the Medicaid population. Of the 12 **MCOs**, two are statewide, providing care for Medicaid populations and those who pay privately: **BlueCare** and Access Med Plus. As with conventional managed care organizations, certain

physicians, pharmacies, and hospitals have contracted with certain **MCOs**. Eligible residents have a choice of any of the **MCOs** available in their area. In Tennessee, once a patient is assigned to a primary provider, the patient must go to that provider for all services. Over 20,000 people have been assigned to the Memphis/Shelby County Health Department as their primary provider.

There are seven **TennCare MCOs** in Shelby County, including TLC Family Care Healthplan, Access Med Plus, Phoenix Healthcare of Tennessee, **OmniCare** Health Plan, PHP **TennCare**, Prudential **HealthCare** Community Plan, and **BlueCare**. About half of the Health Department STD patients have **TennCare**. One person we interviewed characterized **TennCare** as “a bureaucratic quagmire.” We were told that there is a lack of data from **TennCare** and that it is difficult to know who is getting what care under the system. An interesting comment from one Health Department administrator was: “If I were doing the study, I would want to get Tennessee involved because of the managed care situation, especially since this is going to be the situation in other parts of the country soon.”

STD Clinic

Description of the Clinic

The STD clinic, also known as the Packer Clinic, is a specialty clinic housed in the main Memphis/Shelby County Health Department building. Signs posted at the entrance to the building provide directions to the clinic. The clinic is accessible by bus, though relying on a bus system as the sole means for transportation can be inefficient. There are **35-40** chairs in the waiting room. This facility has 12 exam rooms, all of which can handle female exams. However, providers opt not to use two of these rooms, because they are a bit small to examine women.

The Health Department STD clinic charges \$8 for testing and treatment. We were told that no patient is sent away if he or she cannot pay. One DIS reported that STD services used to be free but that the clinic started charging clients several years ago. In recent months the charge for services increased.

Clinicians routinely test for and treat syphilis, gonorrhea, and chlamydia; HIV is optional. Forty to 50 percent of all patients request an HIV test. Staff do not screen for HPV. Gram stains are processed for males and wet-preps are completed on women who have a discharge. Chancroid cultures are also taken. The STD clinic operates a stat lab for **RPRs** and gram stains. Nurses send all Gen Probes,

gonorrhea, chlamydia, HIV, and chancroid testing to the Health Department central lab. There is an area within the STD clinic where nurses read wet preps and Darkfields. Upon testing, the nurses treat and educate the patients about **STDs and** how to prevent them.

The STD clinic appointment system is not computerized, but there is a computerized list of patients that contains demographic information. This system contains only the patient's name, date of birth, and medical file record number and is used by the clerical staff to facilitate pulling patients' medical records. The medical records are handwritten. The clinic has devised another system to facilitate the patient flow. There is a "colored dot system" used to quickly inform the nurses what services the patient is seeking:

- blue - volunteer (self-initiated STD visit)
- red - HIV testing only
- green - follow-up visit
- yellow - DIS referral

At present, the Packer Clinic does not have **MediFax**, the computerized system to check patients' **TennCare** status. Nevertheless, the clinic collects insurance status information from the intake forms and keeps a **TennCare** log. The log's purpose is to validate education/prevention expense to **TennCare**.

Hours of Operation and Staffing

The Packer Clinic is open from **7:30** am to **7:00** pm on Monday and **7:30** am to **4:30** pm Tuesday through Friday. Appointments are scheduled from **7:45** am to **5:45** pm on Mondays **and** **7:45** am to **2:45** pm all other days of the week. The STD clinic moved to an appointment system because there were **100-120** walk-in patients on any given day. Since all of these people showed up early in the morning, the clinic had to cut off intake and people had to come back the next day.

When fully staffed, clinic personnel include:

- 1 part-time physician
- 1 nurse supervisor
- 6 nurses
- 3 medical lab assistants
- 1 administrative tech
- 5 clerical staff
- 15 DIS

Nurses conduct all of the exams at the STD clinic. These staff attend a two-week STD training session in either Atlanta or Birmingham before they are allowed to examine any patients. For that reason, the Health Department feels that **these** providers are well-trained. Clinic nurses have the opportunity to receive update training; however, the Health Department can only send one nurse at a time, and at most only two nurses can attend each year. Presently there are five **RNs**, while in the past there were seven. As a result the clinic is a bit short-staffed. The Health Department was filling these positions, as well as three MLA positions, at the time of our site visit.

In 1991, the Health Department had 31 DIS rotating through five teams. Now the staff has been reduced to 12, who rotate through only two teams. Currently, DIS conduct field investigation on cases of syphilis and on gonorrhea for males. They also educate patients about **STDs**, discuss sexual partners if applicable, and educate regarding test results and follow-up treatment if necessary. **DIS** also provide pre-test HIV counseling for patients opting to take an HIV test. Two case managers were hired just after our site visit.

In addition, DIS in this site are participating in a CDC-sponsored survey to elicit risk factor information from HIV-positive patients. CDC sends the Health Department a list of new HIV-positive patients in the area. DIS locate these individuals to bring them into the clinic. As another part of their field work, DIS go into the community to do HIV counseling and get patients into care. One DIS representative estimates that 60-70 percent of their time is consumed by HIV questions and concerns.

STD Clinic Census and Demographics

Total number of patients registered per month	1929
Total number of patient examined per month	1517
Number of male patients per month	750-900
Number of female patients per month	450-600
Average age of patients	20-24
Percent African American	70
Percent White	27
Percent other	T 3

The STD clinic's daily census by sex is 60 percent male and 40 percent female. The STD clinic sees 68-110 patients per day. Of those, according to one administrator, 20-30 want only an HIV test. The number of nurses available on a particular day determines how many appointments are scheduled. Each nurse sees 13-15 patients daily. Although there are no hard data to support this claim, staff believe that most of the patients that come into the clinic are not repeaters.

STD clinic Flow

Patients are greeted by a receptionist, who is often the same person with whom they made the appointment. Walk-in patients are triaged by nurses. When DIS refer people to the STD clinic, they encourage the patients to first make an appointment. Nevertheless, if the clinic workload allows, the nursing staff will work walk-in patients into the schedule.

Each patient signs in and fills out one of several color-coded intake forms. The receptionist assigns him or her a number. If the patient is not a referral, he/she pays \$8 and takes a seat in the waiting area. Patients do not pay if they have been referred. One of the intake clerks then either pulls the patient's medical record or types up a new record and initiates a lab slip. The clerk places the records, depending on services requested, in either the nursing slot or the HIV slot in the hanging file folder.

When a patient's number is called by either a nurse or an MLA, the patient proceeds to an examination room. The intake process, including wait time, can take 5-30 minutes, depending on the mix of services requested. Patients who want **only** HIV testing speak to a DIS and sign a release form before getting tested. Then these patients are sent to have blood drawn for HIV testing. In the examination room, the **MLA** draws blood, then the patient gets undressed for the exam. There is some education given during the examination. After the examination and the patient is dressed, the nurse returns to provide STD prevention education. The patient is sent back to the waiting room for about 10 minutes to await test results and then called back in to receive treatment if indicated. At this point, depending on the results of the tests, the patient is routed to the DIS. Specifically, if a woman is tested positive for syphilis or is a contact of someone who has syphilis, then she goes directly to DIS. If a man is tested positive for syphilis, is a contact for syphilis, or has gonorrhea and is between ages 16 and 29, then he is sent to DIS for further counseling and partner notification.

All patients are all told to call back within seven days to obtain the results of the lab tests. For positive gonorrhea tests, a clerical staff person produces a "white epi slip." **If** the patient does not come back within three days of notification, the clerical staff person seeks DIS support; the slip goes to **the DIS**

supervisor, who assigns the case to a DIS. In the past it took two weeks to get HIV results, and the number of patients who called back was very small. One DIS told us that if the patients were told to call back in one week, that number would be larger.

Clerical staff receive the results for **STDs** and enter the information into the information systems. For example, if a gonorrhea culture is positive, they put the information into the computer; for negative results, the information goes into the patient's chart. There is a reactor system for syphilis at this clinic.

Cervical Cancer Screening

The STD clinic at the Memphis/Shelby County Health Department does not currently conduct cervical cancer screening. Therefore, answers regarding the specific steps of cervical cancer screening are prospective, based on the opinions of STD staff and Health Department administrators.

Registration and Intake. No changes to the intake process are envisioned in order to include Pap testing.

Education and Counseling. We were told that nurses would need additional training to provide education and counseling on cervical cancer and Pap screening. As previously mentioned, all STD nurses attend an intensive two-week training course. We were told that these nurses have periodic update training, but one nurse reported, "I have never been to an update, and I have been here for 13 years." The Director of Nursing suggested that the STD nurses could be trained to do Pap smears through two half-day training courses.

Pap Smear. We discussed the idea of a nurse practitioner (NP) staffing model for conducting the Pap smears in the STD clinic. Under that model, the NP would do all Pap smears, provide patient education regarding cervical cancer and Pap testing, and conduct the follow-up for abnormal results. If that model were followed, the STD clinic would have to hire an NP to do Pap screening. In Tennessee, for an NP to do advanced practice, he/she must be trained (Masters level and certification is required) and thus commands a **\$45,000-\$60,000** annual salary. Even if the clinic were to use a contracting service, an NP would cost approximately \$35 per hour.

The Director of Nursing felt that the staff nurses at the STD clinic could take the smears but would require additional training to do so. The Director of Nursing did not think that it would be wise to have

first a nurse and then an NP examine the patient. She would not want to have to use the speculum twice on a patient in one visit. Also, she did not like the idea of having only one provider on staff capable of doing the Pap smears, because women coming into the clinic would have a longer wait time. Instead, all STD clinic nurses would need to be trained to do Pap smears.

Follow-up, Tracking, and Referral. The nursing supervisor foresees that the same follow-up that occurs for positive gonorrhea results would be used for cervical cancer screening follow-up. In her view, a nurse would conduct follow-up on abnormal Pap results instead of DIS. She is concerned that women who receive notice of an abnormal Pap smear would have questions that the DIS could not answer. She thinks that the follow-up should be conducted by personnel who have some familiarity with Pap smears and cervical cancer. The same clerical person who “cuts white slips” for positive gonorrhea results would “cut a slip” for abnormal Pap smear results and give it to the nurse for follow-up.

One DIS respondent suggested that DIS could be tied into the follow-up process, but they would require additional training as to how to talk to women with abnormal Paps. Another DIS representative felt that follow-up would be strictly a nursing and clerical function, with no great impact on current DIS workload. This DIS suggested that both nurses and clerks would need additional training.

DIS respondents raised several questions. What would their level of responsibility and/or liability be if a patient refuses to come back for follow-up on abnormal results? Would they have to do a “one-time shot” to find a patient with abnormal Pap smear results, or would they go to the same length as with other **STDs**? According to one DIS, if they have to make more than one visit, there is a lot of time and effort involved. Also, the DIS question what the priority would be for getting women back ~~into the~~ clinic for abnormal Pap smear results, compared to other **STDs**.

Family Planning Clinic

Description of the Clinic

Memphis/Shelby County has a large family planning program, with aggressive testing and **follow-up** for HPV. Family planning clinic hours are **8:00** am to 11:00 am and **1:00** pm to 3:00 pm, Monday through Friday. There is a night clinic on Thursdays.

The Health Department offers a colposcopy clinic in the Hollywood Primary Care Center. In the family planning clinics, providers test and treat for all **STDs**, except syphilis patients are referred to the STD clinic for treatment. Staff involve DIS only for syphilis and for men aged 16-29 who are infected with gonorrhea. Title 10 funding allows family planning clinics to examine women 10 years of age and above. In Tennessee, many clients are assigned to the Health Department as their primary provider. TennCare pays for one Pap test a year, and there must be authorization to refer for colposcopy. When the patient is assigned to the Health Department as her primary provider, there is no problem in getting the authorization. However, when a woman comes in and is not assigned to the Health Department, she cannot be as easily referred for a colposcopy because of the regulations surrounding **TennCare**.

Cervical Cancer Screening

Registration and Intake. For identification, patients are required to show Social Security cards.

Pap test. At the Hollywood Clinic, the nurse practitioner (NP) is responsible for taking Pap smears and for educating patients about cervical cancer. The NP also initiates follow-up on all abnormal Pap smears and then delegates the rest of the process to an LPN.

Two different procedures are used to prepare the Pap smear slides for the cytopathology lab. **SmithKline Beecham** picks up the slides daily. For slides that must be sent to Medical Pathology Labs (MPL), the Health Department picks up the slides on a daily basis from the clinic. It is interesting to note that if **SmithKline Beecham** is too busy, the lab sends the slides to another affiliated lab in Florida.

Abnormal Results. On average, it takes 3-6 weeks for the Hollywood Clinic to get Pap smear results back from the Health Department. Abnormal results are usually obtained more quickly.

SmithKline Beecham will fax abnormal results directly to the Hollywood Clinic if they are high-grade. Otherwise, Health Department clerical staff report a two-day turnaround time for returning Pap smear results to the Hollywood Clinic and other neighborhood clinics.

Follow-up, Tracking, and Referral. There are three steps for contacting patients with abnormal Pap smear results: (1) telephone call, (2) letter, and (3) certified letter.

A tickler system is set up. A nurse at the Hollywood Clinic told us that if a patient does not come in after the certified letter, the case is closed. However, as a last resort with patients with high-grade results, staff at the Hollywood Clinic send a District public health nurse to find the patient.

The Hollywood Clinic is the Health Department site that offers colposcopy services. The clinic is staffed by three nurse colposcopists. Patients with abnormal Pap smear results can be diagnosed either at the Hollywood Clinic or can go to a private provider. The staff at the clinic request the results of a colposcopy in the event that the patient seeks diagnostic services elsewhere. For patients who stay in the Health Department system, the Hollywood Clinic obtains their results all the way through treatment.

Past Experience of Cervical Cancer Screening in the STD Clinic

In 1994, the Memphis/Shelby County Health Department decided to enhance women's health services by providing initiation and referral services for family planning in the Packer Clinic for sexually transmitted diseases. This decision was made in part due to a survey that was conducted in the STD clinic in 1992. Results indicated that 47 percent of women attending the clinic at that time did not receive family planning counseling from a physician, Planned Parenthood, or from their neighborhood clinic. A Title 10 Special Initiative Grant was awarded for a 2-3 year period to provide Pap screening in the STD clinic.

The Health Department implemented a component of family planning in the STD clinic for the period from January 4, 1994 through October 2, 1995. Because only one treatment room was available for family planning services at that time, only initial screening and family planning counseling, with referral for continuing care, were offered. The project was staffed with an NP and a health aide and was budgeted for \$185,638.

Due to lack of interest on the part of the clients, this service was discontinued six months earlier than scheduled. The STD clinic stopped offering Pap smears in the STD clinic because they were not seeing enough interested women: Asked why the introduction of this service was not successful, one staff member pointed out that “generally speaking, people come to the STD clinic for **STDs**, not for a doctor.” The service was offered to all women in the STD clinic, but most were reportedly not interested. In fact, the clinic publicized quite heavily to get women into the clinic.

We were told that there is a great deal of overlap between family planning and STD. The NP identified a significant number of women who were coming in for STD services who were already regularly seen by a provider at one of the neighborhood clinics, where they receive an annual Pap smear as part of normal practice. The nurse who staffed this pilot program believes that the women who came into the STD clinic knew where to get Pap smears.

Another reason given for the failure of the effort was that the intake process was a bit cumbersome. The nurse had to get the patient’s Social Security number to see what **MCO** she was assigned to. Women could not participate in the program if they were not assigned to the Health Department as their primary provider or if they had been to a public primary health care center within the past year. Presently, all of this information on **TennCare** status is available via **MediFax**. However, at that time the nurse had to call the Ten&are hotline to verify a woman’s eligibility and then would have to call the **MCO** to identify the provider that the patient could go to within the system. When women were not assigned to the Health Department as their primary provider, the nurse would encourage them to go to their assigned provider or suggest that they change their primary provider to the Health Department (a process that takes 45 days).

The following table contains data from the pilot project:

Total number of patients requesting FP services	427
Total number with Paps	349
Total with abnormal results	47
Moderate dysplasia	1
Mild dysplasia	5
Atypical	20
HPV	21
Unsatisfactory	14

Training Issues. The nurses at the Hollywood Clinic voiced concern about doing Pap smears in the STD clinic. They expressed that getting the patient back to the STD clinic for a repeat smear would be difficult. This is especially true since one must wait 1-3 months before taking a repeat smear. These nurses were also concerned about the likelihood of duplicating the Pap smears, because they believe that most of these women already have a regular place of care. One nurse remarked that she was concerned that many women believe that they are having a Pap smear during a pelvic exam and thus may be giving incorrect medical histories. Nevertheless, family planning staff felt that the **RNs** at the STD clinic could do the Paps and read the results if needed.

Facilitators and Liitations. The laboratory director would like to see Pap testing added to the STD clinic because in his opinion “it is good health care.” The nursing supervisor felt that it was a good idea to add cervical cancer screening to the STD clinic because, in her opinion, “STD testing and treatment is often the only health care people get.” Furthermore, she stated that many of the female patients she sees report not ever having had a Pap smear.

One difficulty is that if an adolescent who comes into the STD clinic wants a Pap smear, the clinic may have to get parental consent, which undermines the confidentiality of the STD clinic. The clinic can see patients as young as age 13, but Pap smears are not considered “usual and customary” in an STD clinic and thus would not be covered under that confidentiality arrangement.

Feasibility Issues. Both clinical and administrative staff in the STD clinic (in contrast to the opinion of a nurse we spoke with in family planning) felt that there was not much overlap between those patients who go to the family planning clinic and those who seek services at the STD clinic. Some staff were concerned about the STD clinic population, especially in regard to the impression that STD patients do not come back in **unless** they have an obvious STD. Therefore, it would be very difficult to get them to come back in for Pap smear results and follow-up.

Some staff expressed concern about starting a project and providing a service to the community and then not continuing it at the end of the demonstration project. While they agreed that in the short term it may be a good idea, in the long term they do not want to offer a service and then take it away.

Managed care may pose an additional problem for establishing Pap testing in the STD clinic in Tennessee. First, the STD clinic staff will need access to **MediFax** and will need to be trained about **TennCare**. More important, for an STD patient who is in **TennCare** and for whom the Health Department is not the primary care provider, the STD clinic would have to go through the patient's primary care provider to get a referral for colposcopy. This raises questions as to what to do with female clients for whom the Health Department is not the primary provider, such as what to do if she presents with an abnormal Pap smear result.

Clark County, Nevada ▪ Site Report

Community Background

Clark County is one of 17 counties in Nevada. Comprised of 7,927 square miles, it includes five incorporated cities: Las Vegas, Henderson, North Las Vegas, Boulder City, and Mesquite. The county seat of government is Las Vegas. Clark County is the most populous of Nevada's counties (population 1,040,688), with over 60 percent of Nevada's population residing there. The city of Las Vegas is Nevada's and Clark County's largest city. Demographically, Clark County is the fastest-growing county in the United States, with 6,000-7,000 new residents moving there monthly.

The **race/ethnicity** of the population of Clark County is:

- 75.4 percent white
- 11.2 percent Hispanic
- 9.3 percent African American
- 3.3 percent Asian/Pacific Islander
- 0.7 percent American Indian
- 0.1 percent other

The median household income in Clark County is \$30,746, with 10.5 percent of persons living below the poverty level. The labor force in Clark County is about 449,215 persons, categorized as follows:

- 53.6 percent Services [hotel and motel workers comprise 30.1 percent of total labor force]
- 17.9 percent Retail Trade
- 9.6 percent Construction
- 5.9 percent Finance, Insurance, and Real Estate
- 5.1 percent Transportation and Utilities
- 3.5 percent Wholesale Trade
- 3.4 percent Manufacturing
- 0.75 percent Agriculture

In Nevada, prostitution is legal in counties with less than 100,000 population. Prostitution is not legal in Clark County because of the population size, but there are well-known brothels in neighboring Nye

County, just 60 minutes from Las Vegas. Illegal prostitution thrives in Las Vegas, as demonstrated by hundreds of full-page advertisements for “entertainment” in the Yellow Pages.

Public Health District

The Clark County Health District is governed by an 11-member Board of Health, with two representatives from each of Boulder City, Las Vegas, North Las Vegas, Henderson, and Clark County, and one member-at-large. This board identifies public health needs for local taxpayers, residents, tourists, visitors, and the commercial service industry. The goal of the Board of Health is to “establish and conduct a comprehensive program of health to prolong life and promote the well-being of the people of Clark County” (County Ordinance 163: subsection b of Section 6).

Public health services are available to all residents of Clark County, regardless of income. The Clark County Health District is one of the largest health districts in the country, serving a population of **1,132,805** (66 percent of the state population) with a staff of about 320 employees working in four divisions. The Health District offers no primary care. There are case management services available for women and children in the HIV program.

Since 1986, all legally registered prostitutes in Nevada are required to have pre-employment HIV and STD testing. In addition, they are required to receive weekly testing for gonorrhea and chlamydia and monthly repeat testing for syphilis and HIV. These legal prostitutes must carry a registration card that shows they have gotten their testing and have negative results. If a prostitute tests positive for any STD, she is forbidden to work in the brothels. There is also a condom law for sex industry workers, under which prostitutes are required to have clients wear condoms. We were told that some brothels are so strict that if a sex worker is caught not using a condom with a client, she loses her job on the spot.

Many brothels have a physician come weekly to provide testing, but if the brothel wishes to have the Clark County Health District provide the testing, the women are usually brought to the STD clinic in a company van or by airplane. The Health District also provides information for prostitutes on how to identify **STDs** on male clients. In all licensed brothels, a male client goes through a specific series of steps:

- Line-up (available female sex workers line up so the client can choose which one he wants)
- Woman takes customer to a room

- Woman performs a physical inspection on the client (using training from the Health District to identify possible **STDs**). The woman can decide to turn away the client if there is any suspicion of an STD.
- Services are chosen from a menu and prices are negotiated.

Approximately 40,000 HIV tests have been performed by the Clark County Health District on legally registered prostitutes. Of these, only 25 have been found positive on pre-employment HIV tests. In these cases, the women were not allowed to work as legal prostitutes in Nevada. By contrast, around 5,000 HIV tests have been done on illegal male and female sex workers (volunteers in the STD clinic, picked up on the streets, or tested in jail), 215 of which were found to be positive for HIV. Three-fourths of the HIV-positive individuals from this cohort were males.

The Clark County Health District also has a ‘food handlers’ program in which every person employed in the hotels, restaurants, and casinos must go through a series of tests in order to receive a Health Card. This program is the largest service the Health District provides, with 600-700 people coming through the Health District each day for Health Cards. The program processes approximately 120,000 Health Cards per year. To receive a Health Card, a client must fully register with the Health District and pay a \$10 fee, receive a skin test or x-ray to check for tuberculosis, and attend a **90-minute** class and movie. Health Cards must be renewed every two years.

The food handlers program in Clark County is interesting because of the number of people who are processed through the program each year. In many localities, most people do not go to the Health District, but in Las Vegas up to 120,000 people become acquainted with Health District services each year. This would provide a good opportunity to educate people about cervical cancer screening if this service were added to the STD clinic.

Clinical Services

Clinics in the Clark County Health District include the following:

- Immunization
- AIDS Service Clinic
- STD Clinic
- Family Planning Clinic
- WIC Clinic
- Tuberculosis Clinic
- Opiate Addiction Treatment Clinic

Laboratory Services

The Health District lab does all STD testing except HIV, which is sent out to a contract lab. We were told that STD tests comprise 75 percent of tests processed by the Health District. The lab was originally established mainly to handle **STDs**. There is not a cytopathology lab in the Health District. The family planning program sends its Pap smear slides to Associated Pathology Laboratories, Inc. (APL). A regional family planning grant provides funding for those services. APL has a monopoly on cytopathology in the Las Vegas, Clark County area. APL charges the Health District \$10.20 per slide.

The contract with APL is not on a clinic-by-clinic basis but is for the entire Health District. APL offers discounted rates for the Health District. All slides sent to APL are funnelled by the family planning clinic to a local courier who delivers them daily.

STD Clinic

Description of Clinic

The STD clinic provides testing for syphilis, gonorrhea, chlamydia, HIV, trichomonas, yeast infection, and bacterial vaginosis. Chlamydia testing is routinely performed for females age 25 and under. They do not test for herpes or HPV. The STD clinic charges \$10 per visit, which covers examination, testing, and treatment. If a person is not able to pay the \$10, the clinic will provide services anyway. We were told that no patient is turned away for not being able to pay.

The STD clinic is walk-in, with no appointments necessary. Staff told us that this system worked well in the past when they tested only for syphilis and HIV, but with the addition of other **STDs** it is somewhat problematic. The clinic has two exam rooms, each of which can handle female patients.

The communicable disease investigators (**CDIs**) from the STD clinic have collaborated with community health agencies in low-income areas and set up health fairs offering numerous services (including syphilis and HIV testing and counseling). If a person tested at the community based organizations is positive for syphilis or HIV, **CDIs** make every attempt to locate him or her and provide necessary and appropriate services or referrals.

Hours of Operation and Staffing

STD clinic hours are **8:00** am to **4:30** pm, Monday-Friday. Mondays are the busiest day in the STD clinic, with about 60 patients seen. Often Monday mornings begin slowly, but there is a rush of patients around noon to **2:00** pm.

STD clinic staff include:

- 2 full-time **RNs**
- 2 full-time clerks
- 3 **CDIs** (communicable disease investigators) and 1 Federal advisor
- 1 part-time PA (physician assistant)

Two **RNs** work in the STD clinic each day, providing all STD services. The PA who presently works part-time in the STD clinic will move to full-time in the near future. Clinic administrators are advertising for and interviewing candidates for an NP in the STD **clinic**. The RN model will be replaced by the PA and NP in the STD clinic.

A family practice physician from the community comes to the STD clinic on Tuesday afternoons to process patient charts and help with exams. Another physician, a dermatologist, sees referrals for skin rashes on Wednesday afternoons and Friday mornings. This physician occasionally performs male STD exams.

STD Clinic Census and Demographics

The STD clinic saw 4,558 female patients in 1997 (**350-400** clients per month). STD clinic staff told us that the average age of STD clients has gone up over the last couple of years. Teenagers used to be the majority, but most patients now are in their mid-20s and 30s. The STD clinic clientele is approximately 50 percent male and 50 percent female. The STD clinic does not have the information systems necessary to differentiate repeat visits from first-time patients. ID numbers for brothel workers can be tracked because legal prostitutes are all tracked separately from all other clients.

STD clinic Flow

The intake form for the STD clinic contains the client's name, address, age, birth date, social security number, marital status, employer, next of kin, allergies, and a place to sign for consent to test. The clerk asks the patient whether she has been to the clinic before, and if so the clerk finds the patient's chart. Demographic information in the chart is checked against the intake form and corrected if necessary. Patients are not asked for any form of ID to verify identity. The clinic asks for ID only when a patient returns for HIV test results and does not have the card given to him/her when the HIV test was taken.

The intake form is given to the nurse, who also fills out a medical history form. The medical history includes previous health care, description of current symptoms, and information about sex partners. Those forms become part of the patient's chart.

RNs perform the exams and tests in the STD clinic. They take gonorrhea and chlamydia specimens, draw blood for syphilis, and encourage the patient to get an HIV test. If the patient has asked for an HIV test, the nurse will draw two specimens of blood, one for syphilis and the other for HIV. After the exam, patients sit in the waiting room for some results that can be done within 20 minutes (such as trichomonas and bacterial vaginosis). Gonorrhea cultures take 72 hours to process, but the nurses often treat presumptively and use the results for confirmation. Syphilis takes 24 hours to process, but if there are visible symptoms such as chancres or rash, the clinic can do a stat blood test that takes 35 minutes and treat as indicated.

The nurses then provide education to patients on the importance of condoms **and risk** of multiple sexual partners, give the patients educational brochures, and ask them to bring in sexual partners for an exam. If a patient tests positive for syphilis, gonorrhea, or chlamydia, additional education and counseling is provided by the **CDIs**. **CDIs** do all contact tracing and partner notification for syphilis, gonorrhea, and chlamydia. When a person comes in for HIV test results, a nurse or counselor from the HIV program comes to give results and do the post-test counseling. To protect confidentiality, **CDIs** do not give test results over the telephone.

Cervical Cancer Screening

Only 65 percent of women in Nevada who make under \$10,000 a year get Pap screening. The Healthy People Year 2000 goal is 85 percent. Health District officials told us that the STD clinic may be

one place to reach those women and improve the rates of Pap screening. Currently, if a female patient comes into the STD clinic and wants a Pap smear, the clinic staff will give her a list of providers, including the family planning clinic.

Education and Counseling. CDIs told us that they would need more education on cervical cancer, Pap smear screening, and the meaning of Pap smear results to be able to do patient education. They attended a two-week course on **STDs** and go to conferences in order to stay current on that knowledge. CDIs said that they would need two days of didactic training on Pap screening and a few days of on-the-job mentoring in order to become comfortable with delivering these messages.

Pap Smear. The State of Nevada Board of Nursing precludes **RNs** from conducting Pap smears. If Pap smears were implemented in the STD clinic, the PA and NP would do the exams and Pap smears in the clinic.

An expert from the Cancer Division in the State Health Department told us that even with the presence of an infection, the Pap smear should always be done first. Otherwise, if the clinician takes a GC swab first, the epithelial cells needed for an accurate Pap smear get disturbed. However, an STD administrator with whom we spoke did not necessarily agree with this idea. This issue may not be as important in the Clark County STD clinic because it has very low rates of positive STD infections among its clientele. Unlike some other STD clinics, a portion of the clientele in Clark County are there because of legal requirements. Because of condoms laws and standard practices, they do not become infected with **STDs** very often. For example, in December 1997, among patients under 25 years old **there** was a 17 percent positivity rate for Chlamydia. Only 25 female patients tested positive for gonorrhea, and the most frequent diagnosis was bacterial vaginosis.

Abnormal Results. The BCCP program used the Bethesda system for diagnosis.

Follow-up, Tracking, Referral. A clinician in the STD clinic told us that someone other than the examining nurses should do follow-up for Pap screening, because the clinic is walk-in and nurses are too busy. This clinician said that **CDIs** could do follow-up, with additional training, but that a clinical professional would still need to read the results and make decisions on what should be done.

CDIs said that tracking for follow up is based on the information provided by clients on the intake form. They noted that, even if the client provides incorrect information, *usually something* on the form is

correct, because it is difficult for people to lie about everything. The **CDIs** can track a client based on that one correct piece of information. For example, the client may have gotten a Health Card from the Health District at some time.

CDIs told us that the addition of chlamydia screening added paperwork to their workload and that they are currently overwhelmed by paperwork responsibilities. However, they said that the STD clinic is fairly slow now, so they believe they could handle the addition of Pap smear result tracking. **CDIs** expressed the opinion that the referral of patients for colposcopy or further treatment should be done by clinicians, not **CDIs**.

Multiple respondents in the STD clinic told us that, for comprehensive follow up and referral of patients with abnormal Pap smear results, a case manager should be hired. The case manager could establish the referral networks, handle the process of informing the patient of results and need for further diagnosis, walk the patient through the referral process (including making appointments), and receive and track information on the progress of the patient after referral.

A State Health Department official told us that, for reasons of effective public health, the clinic should get reports on whether a referred patient got to treatment beyond the colposcopy. A clinician in the STD clinic said that they make referrals to the University Medical Center for herpes and other services, and the clinic sends a triplicate copy form with the patient so that one copy can be returned to the STD clinic. However, this clinician also said that UMC never returns the form.

Family Planning Clinic

The family planning clinic offers complete physical exams, pregnancy testing, education about contraceptives, mammography, and cervical cancer screening, and men can get testicular exams. Prenatal care is not available.

Description of Clinic

The family planning clinic provides STD testing for its female clients, including syphilis, gonorrhea, and chlamydia.

Hours of Operation and Staffing

The family planning clinic has one full-time advanced practice nurse (APN), equivalent to an NP or PA, and it will add two more **APNs** in the near future. Each **APN** can see 21 patients per day. The clinic has two full-time **RNs** and a third who comes on “pill refill day” each week. There is also clerical help, but it is not clear how many clerks are on staff.

Cervical Cancer Screening

An administrator in the family planning clinic said that doing the Pap smears is the easy part of the process. The counseling and referral is more important, and a public health nurse with specific training should do that part. She said that a clerical support person is also needed to assist the nurse.

The Health District recently contracted with Health Plan of Nevada (**HPN**), a managed care organization, so that Pap smears and other family planning services can be done for HPN clients in the family planning clinic, and HPN will pay.

Registration and Intake . The family planning clinic does not check patients’ insurance status on intake. Nurses will find out about insurance status only if necessary for referral, such as if a patient has high-grade abnormal Pap smear results and needs a colposcopy.

Education and Counseling. Education on Pap smear screening is done by nurses in the family planning clinic.

Pap Smear . The exam and Pap smear are performed by an advanced practice nurse (APN) who also does the education, fills in the forms, preps the slides, and handles all follow-up. The family planning clinic handles the same **STDs** as the STD clinic, including doing its own wet mounts. Staff always do the Pap smear first, even if the patient has an obvious STD infection. The director of the family planning clinic said that **RNs** should not do the Pap smears because they do not have the ability to interpret results and do not have knowledge of pathophysiology.

All Pap smears are sent to APL, a statewide reference lab that has five offices in Las Vegas. There are few, if any, other options in the area. The family planning clinic pays \$9 per Pap smear slide

for processing. Results are sent back to the clinic within 2-10 days, with the average said to be about seven days. If the results are high-grade, the patient is informed within 1-2 days.

Abnormal Results . All Pap smear results come back to the clinic, and an RN sorts them. The nurse highlights the abnormalities and sets them aside. They are then given to a clerk who files the normal results and gives the abnormalities to a clinician for further evaluation. The clinician whose patient it is gets the abnormal result and does all the follow up for that patient.

In family planning, all patients with low-grade abnormal results are brought back into the clinic in three months for a repeat smear before getting referred for further diagnosis. For ASCUS, the family planning clinic will sometimes perform repeat Pap smears up to three times to see if it reverts to normal before referring for colposcopy. For high-grade abnormal results, the clinic calls the patient (see **follow-up, tracking, referral**).

The cytopathology lab (APL) sends a monthly report of results to the clinic, and family planning staff check the results against their own records for quality control.

Follow-up, Tracking, Referral . In family planning, each woman is told as part of the education and counseling procedure that she will hear from the clinic if her Pap smear result is abnormal. If she does not hear from the clinic, she may assume that she is all right, but she can call the clinic if she is worried.

If a patient has high-grade abnormal results, the family planning clinic will call her and say that there were “changes on the Pap” and she should come in for follow-up. If clinic staff cannot locate the patient, they will send a **CDI** to bring her in to the clinic. The **CDI** does not tell the patient about the nature of the problem. At the clinic, the nurses counsel the patient about high-grade Pap smear results and explain about colposcopy and possible biopsy. They explain that the abnormal result, while serious, is not necessarily cancer. Clinic staff use a picture book to help explain the whole process.

If the patient has a primary provider, the nurses will refer her there. If the patient does not have a primary provider, clinic staff will determine whether she is eligible for Clark County social services, to see who will pick up the bill for the one-time service at the University Medical Center (UMC). Patients with high-grade abnormal results will get colposcopy services at UMC no matter their ability to pay. Other options for referral include the Economic Opportunity Board or Planned Parenthood, although it is rare for referrals to be made to Planned Parenthood, because women there have to pay in advance. If the

patient's results are high-grade, the family planning clinic will call the referral site to make the colposcopy appointment. If the results are not high-grade, the clinic will give the patient a list of possible providers.

The family planning clinic has a referral form that is sent with the patient. The patient is supposed to get the clinician at the referral site to fill out the form and give her a copy to bring back to the family planning clinic. This is for verification that the service has been performed. Family planning gets feedback from the physician in the referral site until the clinic is told to resume regular Pap smears. The family planning clinic is able to tell patients that if they do not bring back the information from the referral site, they will not get their birth control pills. The family planning director said that it would be more difficult in the STD clinic, because they would not have this leverage with patients.

Planned Parenthood

There is a Planned Parenthood (**PP**) clinic in **Las Vegas** that is an affiliate of Planned Parenthood of the Rocky Mountains (**PPRM**). The headquarters of PPRM is in Denver, Colorado. PPRM has 46 clinics in six states. All lab work for the Planned Parenthood clinic is done in Denver at two labs. Pap smear and colposcopy cytopathology are done at the PPRM lab. All STD processing is done at the Colorado Department of Health lab. The only lab work done locally is HIV test processing, which is done at the Clark County Health **District** lab.

Planned Parenthood offers all gynecological services, including STD testing and treatment, Pap smears, breast exams, and pelvic exams. If a female patient tests positive for an STD, PP will provide her with medicine for her sexual partner.

PPRM has its own set of clinical protocols, tailored from the Planned Parenthood Federation of America protocols.

The Planned Parenthood clinic processes about 1,200 Pap smears per month. Approximately 10 percent have abnormal results that need either a repeat Pap smear or colposcopy.

clinic Flow

When a patient comes into the clinic, a medical assistant (MA) does education and counseling. The MA does the intake, goes over the patient's chart and vital signs, counsels on **STDs** and pregnancy prevention, and writes up the subjective report of symptoms. A nurse practitioner (NP) does the physical

exam, including STD cultures, Pap smear, heart and lung exam, breast exam, pelvic exam, and dispensing of birth control. The clinicians at PP do the Pap smear first, then do the swab for gonorrhea or chlamydia and a wet mount if there is a discharge. The clinicians draw blood for syphilis or HIV only if indicated. If the clinician does a Pap smear along with STD treatment, repeat Pap smear for that patient is done only after the infection is cleared up. Under the PP protocol, patients are automatically referred for colposcopy after two abnormal results, so waiting for STD infections to clear avoids unnecessary colposcopies.

The PP clinic gets lab results within a week. For moderate dysplasia or above, the lab calls within **2-3** days. Lab results are entered into a computer system that prints out a letter with the actual lab readings and follow-up procedures. If a colposcopy is needed, a pamphlet is mailed with the letter, with information on colposcopies. The patient must then call the clinic for follow-up. The NP will call to follow-up on the letter. With two abnormal results or high-grade results, the next step is to send a certified letter to the patient.

The patient can come into the PP clinic for colposcopy within one or two days. Any patient who does not want to get her colposcopy at PP gets a written referral to another provider. The referral has three copies: one goes in the patient's chart, the patient keeps one, and the referral site is supposed to return one to the PP clinic with results. When a patient comes back for family **planning**, the clinician can see the referral for colposcopy in the patient's chart and check with the patient about the procedure, the results, and any forms that need tracking.

When a patient comes in for colposcopy, she receives detailed education again. The education can be done by the MA or NP. Often it is done by the MA first and then repeated by the NP.

At \$270, colposcopies at PP are less expensive than anywhere else in Las Vegas. The clinic director said that the Health District can refer to PP for colposcopy. PP offers a payment plan for anyone who cannot afford the full amount. UMC offers minimal monthly payments, as does PP.

Established Infrastructure

Established infrastructure includes the existing Health District contract with APL for cytopathology processing. The family planning clinic is adjacent to the STD clinic, and Pap smear slide collection and courier service could be easily coordinated.

Benefits/Disadvantages

A state-level public health official told us that STD administrators would very much like to be part of the demonstration project because it will provide an important service. If the service is offered, and if the funding stops at the end of the demonstration project, this respondent said that the service could be continued, because another source of funding would fill the gap.

The nursing supervisor told us that each new service added to the STD clinic adds more time to each visit. For example, the addition of testing for chlamydia and bacterial vaginosis has already added time to each exam. The STD clinic is also being asked to provide Hepatitis B services for Health District clients 12-19 years of age. Clinic staff feel that the STD clinic is continually being asked to add more services but is not being given additional staff to handle them.

A difference between an STD clinic's ability to follow up on abnormal Pap smear results and a family planning clinic's ability is the leverage the family planning clinic has over the patient's birth control. In the family planning clinic, they give only a three-month supply of birth control pills on the first visit. That way, if the Pap smear result is abnormal they know the patient will be coming back into the clinic, and they can either do a repeat Pap smear or refer for colposcopy.



Norwalk, Connecticut - Site Report

Community Background

The population of Norwalk, Connecticut, located 45 minutes from New York City, has been steadily growing over the past 10 years and now reaches 78,670. Norwalk is the sixth largest city in Connecticut and is surrounded by several wealthy communities. The primary users of the Health Department are Norwalk residents. In order to address issues of access to health care, the Health Department conducted a study to determine medically underserved areas in town. As a result the Health Department has taken a lead role in establishing a Federally Qualified Health Center (FQHC) scheduled to open by the end of 1998.¹ The Primary Health Care Center at the Norwalk Hospital, which includes pediatrics, **ob/gyn**, and adult medicine, is scheduled to move to the new FQHC site early next year. Norwalk Hospital clinics provide immunizations, STD care, prenatal care, and family planning services, largely to low-income residents. Norwalk Hospital is also a provider for the state's Breast and Cervical Cancer Early Detection Program (BCCEDP).

There are 169 cities and towns throughout Connecticut, all of which operate city-level government. Family Planning services are not offered in several cities and towns in the state. Residents are referred to Planned Parenthood and/or to gynecology clinics in local hospitals. **The state** is now moving toward a system whereby local STD services will be housed in Planned Parenthood. This arrangement has been established in Meriden and Manchester and is being considered in Willimantic. The state would cover the cost of STD care including medication and laboratory work. Patients pay a flat fee (\$10) for STD services at Planned Parenthood. The state lab processes all Planned Parenthood tests including gonorrhea, chlamydia, syphilis, and herpes. The State Health Department is in the process of developing a protocol to outline the duties and responsibilities of Planned Parenthood in providing STD services.

¹ **Changes in the health care marketplace delayed establishment of the FQHC. At one point, the state halted cost-based reimbursement, but has since reinstated it, allowing for the continuation of plans to open the FQHC.**

Norwalk Health Department

In Norwalk, the Board of Health sets policy for the Health Department, which is funded through local tax dollars, state and federal grant monies, and revenue generated by some of the services it provides, particularly travel immunizations. Providers are well paid and some are unionized. The addition of services must be approved by the Board, which approved the initial investigation for the cervical cancer screening project. The mayor is the only person who can sign a contract for the city.

Connecticut is in its second year of Medicaid managed care, but this change in the health care system does not affect STD clinic services because both STD testing and treatment are provided **free-of-charge**. STD care is described as episodic and not comprehensive. Even so, we were told that the Health Department would like to try an added service because it would be 'unique, different, [and] on the cutting edge.'

The Health Department has changed greatly over the past year. For example, it laid off 200 people due to the sale of the home health care component. A benefit of this process is that it has allowed Health Department staff to focus on core public health services. The Health Department earns revenue through its travel and immunization clinic, which operates on a fee-for-service basis. Revenue is also generated from fees for licenses and permits from the housing and environmental services and by fees for laboratory services.

Clinical and Community Services

The City of Norwalk Department of Health offers several different services and programs for preventable diseases, environmental health, housing code enforcement, laboratory services, and health education. It also operates four clinics: Well Child, Childhood Immunizations, Sexually Transmitted Diseases (including HIV and AIDS counseling and testing), and Travel and Immunization. In addition, the Health Department offers other programs, such as smoking cessation; Women, Infants, and Children (WIC); chest consultation for tuberculosis infection; hypertension screening; case management for the elderly; and HIV counseling, testing, and education. All of the clinics and programs are by appointment except the STD clinic. The state initiated HIV testing in STD clinics about a year ago, along with Hepatitis B vaccinations for those under 20 years of age.

The Health Department does not operate as a fiduciary agent for Title X funds and does not offer family planning services. Patients in need of this type of care who have little or no insurance are referred either to Planned Parenthood or to the gynecology clinic at the Norwalk Hospital Primary Health Care Center. Patients who have insurance are referred to private providers.

Laboratory Services

Health Department laboratory services include STD testing, potable water testing, environmental services, parasitology, Lyme disease testing, and throat cultures. Lab staff report spending half of their day on STD testing. Specifically, RPR, gonorrhea smears, wet preps, gram stains, and premarital testing (syphilis and rubella) are conducted locally. Presently there are two lab staff - one full-time employee and a half-time lab assistant. All lab reports are computerized. **GenProbe** specimens for gonorrhea and chlamydia are sent to the state laboratory daily.

Physical Description of the Clinic

There is a large parking lot behind the Health Department and a bus stop directly in front of the building. A new waiting area, currently under construction, is scheduled to be completed in February. In the meantime, patients seeking services for WIC, pediatric immunizations, and STD services all wait in the same room, which has about 20 chairs. In the event of an overflow in the waiting room, patients are able to sit in the adjacent staff lounge area. Due to construction, **STD/HIV** prevention educational materials were sparse in the waiting room, but available in exam rooms and in the lobby. There are plans to install a television with **STD/HIV** prevention videos in the new waiting room.

Educational materials, both CDC-standard and Norwalk-specific, are displayed on racks in each examination room. All educational materials are in both English and Spanish. In general the clinicians only use one exam room at a time, because there is only one clinician providing STD services at a time,

Hours of Operation and Staffing

The STD clinic is open 9:00 am - 11:30 am, Monday through Friday. On Wednesday evening, the health department is open 3:00 pm - 6:30 pm, providing several services including STD screening and treatment. STD services are provided on a walk-in basis.

The Medical Director reviews all charts at the Health Department and oversees all services. A part-time contract physician provides direct STD services on Mondays. There are four nurses on staff, including a part-time nurse practitioner who works two days a week. One RN at a time is responsible for providing STD services, typically seeing five or six STD patients for each session.

One DIS is assigned to the area of the state that includes the Norwalk Health Department. Although he is not assigned to this site specifically, he is based in nearby Bridgeport. The role of DIS at this site includes providing post-test counseling for positive HIV and contact tracing for positive syphilis cases. In the event that a person who was determined to have syphilis does not come in for medication, the Health Department will send out DIS to retrieve the patient. The DIS also provides follow-up for clients who do not return for the second or third Hepatitis B test.

Currently there are a total of 10 DIS, including four Public Health Advisors (three field staff and one supervisor), five state DIS, and one DIS from the city of Hartford. However, the DIS staff is in flux due to maternity leave and sick leave. Since STD morbidity is currently low, CDC will not replace assignees in the state. DIS use all the demographic information obtained during the assessment to find patients. Some DIS can draw blood while out in the field so that contacts will not have to come into the clinic. This is especially the case with women named as contacts through partner notification. On average it takes DIS up to two weeks to locate a person. The supervisor, located in Hartford, ultimately decides when to close out a case.

STD Clinic Demographics

Patient load varies depending on the time of year. The clinic sees 3-8 people per session. Only about 85 people come into the clinic per month, and on some days the STD clinic sees no patients at all. Approximately 65 percent of the STD clinic census is male. The average age of the women who come into the clinic is between 20 and 29. STD nursing staff said that many of these women have not had Pap smears done, probably because they lack health insurance, education, money, or time to obtain adequate health care. Clinic staff said that many of these women, do not think about prevention. Many of the STD patients coming into the clinic are thought to be hourly workers, unemployed, or students. The number of younger patients in their teens and twenties has remained constant in the past few years, despite the presence of two school-based health centers. All local STD Health Department statistical information is aggregated into the monthly report that is sent to the state.

STD clinic Flow

When patients enter the building, they go to the information desk where a clerk asks the reason for the visit. Then they are directed to the waiting room until it is their turn to be seen. Clinicians do not call the patients by name, but simply ask who is next. This system works, apparently because the STD clinic deals with very small numbers. At one point, staff attempted a number system during evening hours, giving patients who were there for **STDs** one color slip and those for other services another color. Staff found this process much too cumbersome, given the number of people they see. At **9:30** am on the day of the Battelle site visit, there were only three people in the waiting room (for all Health Department services).

All STD records are computerized at the Norwalk clinic, but each patient also has a written chart.

A clinician greets the patient and ushers him/her into the examination room, where the clinical assessment begins. The nurse first conducts an assessment and then performs the exam. From the assessment, the nurse determines whether the patient is at high risk for HIV infection. If so, the patient is counseled and blood is drawn for analysis. If the patient has extensive counseling needs, an on-site HIV counselor is available for assistance.

After the examination, the patient goes back to the waiting room with educational material to read while awaiting initial lab results. Waiting time is **5-10** minutes. When the results arrive, the patient is brought back to the examination room for treatment and for more education if necessary.

People who come to the clinic only for HIV testing are referred to the AIDS counseling and testing program. All STD patients who receive HIV tests are given appointment cards indicating when to return for the results. STD clinic staff do not provide post-test counseling for patients who receive positive HIV tests. Instead, DIS from the state come to Norwalk to conduct this consultation, which takes **45-60** minutes. For **STDs**, however, patients have the option to call for their results or return to the clinic.

The clinic adheres to CDC and State protocols for follow-up of patients with positive STD results. The provider calls the patient "**as** many times [as necessary] without hounding them," until the patient is reached by phone. A registered letter is sent if contact has not been made after many efforts. As the last resort, the nurse may refer the case to the DIS. Nursing staff report that very few patients give false names, addresses, or telephone numbers.

Nurses report that they conduct patient education throughout the clinical process. This begins when the patient walks into the examination room where the initial medical history is taken and continues during the exam and treatment. Staff often spend time correcting patient misinformation.

Cervical Cancer Screening

The Norwalk Health Department does not conduct cervical cancer screening. Most nursing staff would like to see this service instituted in the STD clinic, as noted by the clinic supervisor. According to STD nursing staff, many of the women who frequent the STD clinic have not had Pap smears as often or recently as they should, except perhaps those who are postpartum.

Asked whether patients would take advantage of cervical cancer screening services if they were offered at the STD clinic, the nursing staff reported that some women have already asked for the services. However, nurses felt that difficulties may arise in determining eligibility criteria.

Nursing staff speculated about what would happen if Pap testing were added to the STD clinic services, based on what happened when the clinic initiated evening hours. They said, “the community response was phenomenal. If word gets out that women can now receive a free Pap smear in the STD clinic, there would be a flood of patients coming in.” One way to control this influx would be to require that, when patients come in for Pap smears, they must receive complete STD care. Even so, based on experience with HIV testing, women may come for free Pap smears without considering themselves to be STD patients. A benefit of this scenario is that it could present a good opportunity for finding undiagnosed **STDs**. On the other hand, they did not want this clinic to become a primary care facility, worrying that if it is advertised that women can get a free Pap smear, the clinic census will increase dramatically. According to the nurses, adding cervical cancer screening would increase the scope of care.

It was emphasized in our interviews that doing the Pap smear is the easy part, compared with such issues as determining whether the patient has had a Pap smear already. One nurse said that, ideally, patients should see private doctors and that the STD clinic should be the provider of last resort. Asked why women are not getting the care that they need, nurses perceive that some patients “lack skills and do not recognize the benefit of preventive care.” The general perception of staff is that the patients seen in the STD clinic come back only when they are in need of immediate service.

Registration and Intake. Nursing staff in the Health Department clinic suggested that the current computerized data form could be modified to add cervical cancer screening.

Education and Counseling. Nursing staff envision that education and counseling should be done from the beginning of the exam, including a discussion of what an abnormal test means. Nurses said that people need to be advised that an abnormal result is a serious matter and that a letter will be sent or someone will come to the patient's house in the event that the test result is abnormal.

Pap Smear. The nursing staff believed that **RNs** with training would be responsible for carrying out Pap smears in this clinic. All nurses at this clinic received, at a minimum, a three-day intensive course in **STDs**.

Follow-up, Tracking, and Referral. **Nurses** in the clinic thought that they would be the ones to make appointments for patients in need of diagnostic services, with patient permission. Nurses stated that follow-up includes making sure that the patient has a good understanding of what the test means. Furthermore, nurses said that **DIS** could be involved in finding hard-to-locate patients with abnormal results.

Nurses talked about the need to refer patients to a primary care provider but said that they do not think that they could follow the patients to see if they made an appointment for their next Pap smear and kept it the following year. The nurses felt that they have to give the patients someplace to go. The Community Health Center (FQHC) scheduled to open in the autumn of 1998 may fulfill this role.

Follow-up was a major issue of concern for the nurses, who wanted to know who would be ultimately responsible for abnormal Pap smears. They stated that conducting the test is not a problem, but defining the extent of their responsibility to the patient is important. The nurses give the findings to **DIS** for follow-up if a positive syphilis case does not return for treatment..

The **DIS** supervisor said that Pap testing in the **STD** clinic is a good idea. In her opinion, the majority of Pap tests done in the **STD** clinic are likely to be abnormal, and it will be the **STD** clinic's responsibility to make sure that the referral for diagnosis is actually made. Currently, there is a Hepatitis I3 program that has follow-up procedures that could be used as a model for a Pap screening program'. For women who do not call back for their results, **DIS** expressed that they could inform patients that their Pap results were abnormal and impress upon them the need to return to the clinic.

¹ **Local health departments offer Hepatitis B vaccines to patients. When the patient receives the first injection, a demographic form is filled out. A reminder letter is sent for the second injection. If the patient does not return within a week of the scheduled appointment, a delinquent letter is sent. Then, a field record is drafted and a DIS is dispatched to conduct follow-up.**

DIS state that once the patient is referred for colposcopy, the STD clinic's responsibility ends. DIS staff would need training about cervical cancer, Pap smears, abnormal results, and possibly other issues. Despite their own enthusiasm, the two DIS supervisors whom we interviewed were unsure if other DIS would be interested in being a part of this effort. One of these supervisors thinks they would be, because "it would be something different." If cervical cancer screening were to be implemented in STD clinics, supervisors believe that another DIS would need to be hired. According to the DIS supervisor, she would prefer that the new hire be female and Spanish-speaking.

In terms of record-keeping, DIS believe that the person who currently oversees the data for the Hepatitis B and chlamydia projects could be responsible for the abnormal Pap test data. State DIS also envision that the Pap data would be centrally located in Hartford. (The Norwalk staff has experience sending data to the state.) The DIS supervisor said that more of the burden of this added service should be shouldered by the central office in Hartford, given the current workload at the Norwalk clinic.

In terms of costs, DIS envision that, including data entry and follow-up through the initial referral, staff time would be one-half FTE. If the DIS were to follow each patient with abnormal results through treatment, total DIS time may be one FTE.

The Norwalk Health Department STD clinic would need to establish a contract and negotiate a price with a cytopathology lab. Staff in the Health Department lab did not know where they would establish this contract. In the past, the Health Department lab has established contracts with a private reference lab and with the Norwalk Hospital lab. The school-based clinic presently sends slides to Norwalk Hospital.

Prior to the Battelle team arriving in Norwalk, the Health Department Administrator took the concept of adding Pap testing in the STD clinic to the Norwalk Board of Health, which consists of two **MDs**, a nurse case manager, a pharmacist, and an attorney. The Board agreed that they would be interested in such an effort. Under this Administrator's leadership, the Health Department has informally attempted to assess client satisfaction. For example, an outcome of an initiative to improve customer services was the implementation of evening clinic hours. The overall philosophy of the Health Department is to be service oriented.

Family Planning Clinic

Description of the Clinic

Battelle visited the gynecology clinic at the Norwalk Hospital Primary Health Care Center as a part of this site visit. The Primary Health Care Center has a large waiting area with signs in Spanish and English. This appointment-based clinic is open Monday through Friday, 8:00 am to 6:30 pm. Although most patients make appointments, the Primary Health Care Center also operates as an ER follow-up center and accepts some walk-in clients. The clinic functions as a primary provider for patients enrolled in Medicaid managed care. Five different managed care organizations (MCOs) have contracts with this health care center. Fee-for-service patients pay according to a sliding scale directly related to poverty level and the number of people in the patient's family. The lowest fee for an office visit is \$35 and includes up to \$300 worth of lab tests; beyond that, the patient is required to pay 15 percent of the total bill. Fifty percent of the clinic population is enrolled in Medicaid.

The Primary Care Center is divided into a medical section and an obstetrics and gynecology section. The gynecology clinic has a special colposcopy clinic once a week, and twice a month there is a procedure day for LEEP or insertion or removal of Norplant. Pap smears are done in both the gynecology and medical clinics. The State BCCEDP operates from the Medical clinic. The Hospital has specific guidelines for cervical cancer screening. There is no minimum age for birth control and STD treatment; however, if a minor patient wanted just a Pap smear, the clinic would most likely require parental consent. The clinic does not screen specifically for HPV, but uses the results of the Pap smear as a proxy.

Cervical Cancer Screening

Education and Counseling. Educational materials are in English and in Spanish, and a translator is available to the clinic.

Pap Smear. The Primary Care Center has a full-time attending gynecologist who does all of the Pap smears at the gynecology clinic. She sees 5-12 patients in any given morning, including walk-ins that need to be seen that day. She prefers to take the Pap smear before she takes another type of culture and generally performs Pap smears on all women, with the only criterion for exclusion being heavy menses. However, if a woman has a yeast infection, the gynecologist prefers to treat the infection rather than do the Pap smear.

Pap management guidelines are based on the Bethesda system. Nurses keep a Pap log by hand, which contains unit number, date, and name of patient. When the results come back, the nurse initials the result and then puts the result in the log. A second copy of the result is made to ensure that proper **follow-up** is made.

Laboratory processing begins as soon as the specimens are taken and corresponding information is entered into the computer and into the log. All Pap smears are processed and evaluated in the lab at the hospital.

Abnormal Results. The attending gynecologist reviews all Pap smears done anywhere in the Primary Care Center. She initials the lab reports and then reviews the charts in order to make a decision on follow-up based on the patient's medical history. At that point, the clinic contacts all patients with abnormal results. It takes about two weeks for Pap results to come back to the clinic, but if there is a rush, staff can access that information sooner through the computer system.

Follow-up, Tracking, and Referral. The clinic contacts all patients with abnormal Pap smear results. The last step in contacting patients is to send a registered letter. If the clinic is still unsuccessful after all steps, they close out the case. As a part of standard hospital procedure, all patients sign a form that protects the clinic should the patient refuse treatment, even if due to the inability of the clinic to locate

the patient. The follow-up time was characterized as “not too bad now, [but] the clinic has some problems pulling records because all of the medical records are in a central location [away from the clinic **itself**].”

The wait time for getting a colposcopy depends on the degree of abnormality of the Pap smear result. Staff at the Primary Care Center try to fit patients in within a couple of weeks.

The gynecology clinic receives referrals from Planned Parenthood, the Springwood clinic (a small clinic in South Norwalk), and from the adolescent center at Norwalk High School. The clinic also gets a lot of referrals from the Medical clinic within the Primary Care Center and from BCCEDP, which has a separate follow-up component. Information is shared between BCCEDP and the gynecology clinic.

Planned Parenthood does Pap smears and refers patients to Norwalk Hospital for colposcopy. The nurse manager at the gynecology clinic reported that sometimes Planned Parenthood will call to make the appointment for women in need of a colposcopy and other times the patients themselves will call for the appointment. Sometimes the physician at the gynecology clinic repeats the Pap smear for patients referred from another clinic when the original Pap smear was taken three months or more prior to the colposcopy. If the Pap smear was done within three months, the physician usually opts not to do the repeat smear. Staff at the gynecology clinic reported that many patients who come to the clinic get Pap smears every year.

Feasibility Issues in Cervical Cancer Screening at the STD Clinic

The Medical Director at the Norwalk Health Department does not believe that STD clinics should add cervical cancer screening services. He stated that “it has no place in the STD clinic.” He told us that “it is feasible but not indicated.” However, despite this belief, he said that if it were mandated, he would do the best that he could to implement such a service.

The Medical Director said that the provider who examines the patient should collect the Pap smear specimen, but in his opinion he would limit the staff allowed to conduct the screening to himself or possibly the nurse-practitioner (NP). He does not envision **RNs** taking Pap smears, a potential problem since the clinic is staffed mainly by **RNs**. The Medical Director does not believe that the presence of infection would mean that a Pap smear is contraindicated, only that it may make it more difficult to do. The Health Department would have to contract with an outside lab for processing and evaluation of the Pap smear slides. The Medical Director would interpret results and make all decisions, since he would be the person responsible for medical issues. He did not express any concerns about liability.

In the Medical Director's opinion, "we have a good clinic, and we do a good job. It is a very important service to provide STD care, because these people may not have anywhere else to go." However, he does not believe it is a part of public health to provide primary care. The Medical Director was also quite concerned about the issue of follow-up. Questions included: "How far do you go? What do you do when you find it? When do you quit? Repeat the smear ? Treat for cervicitis? Now you are doing primary care. "

We asked the gynecologist at the Norwalk Hospital Primary Health Care Center a number of questions concerning the needs of a new program, based on her experience. In her opinion, the Pap smear and the colposcopy results should come from the same lab if possible. She believes that an RN with specific training can do Pap smears and that a colposcopy could be done by a nurse practitioner with special training, because there are well-established protocols that are not difficult to follow. The basic requirement for a good program is "meticulous follow-up."

This gynecologist said that it is necessary to consider what is entailed in a release of records. For a patient with an abnormal Pap smear result, an effort must be made to get her previous medical history. Also, if the index of suspicion is high, you need to have someone on board who has clinical judgment. The gynecologist added that it is important that the person devoted to follow-up have a relationship with the patient. The patient needs to know this person, and a clinic needs to have qualified nurses do the **follow-up**. The greatest challenge in adding Pap smears to the STD clinic would be avoiding loss in follow-up and lack of continuity. In sum, for a cervical cancer screening program to be successful, a site would need doctors and nurses working together as a team.

Information Systems

The data management system at the Norwalk Health Department is excellent. All computers in the facility are networked to a common server. All staff have access to information in the system, but with constraints for the sake of confidentiality (the entire computer system is password-protected). When a patient comes in, the nurse fills out a medical history form and enters that data into the computer system. A form is sent to the laboratory that identifies all of the specimens scheduled to be obtained during the examination. Once the specimens are taken and analyzed, lab personnel enter the results into the computer system. A completed specimen sheet is then sent back to the nurse so that she can give the appropriate treatment.

Norwalk Health Department administrative staff create monthly reports for the data collected and maintained in the information systems. For example, all laboratory specimens are tracked, the number of women who have been **examined** can be queried, and number of women who were examined and had positive tests can be obtained.

If changes to the data system are needed in order to facilitate cervical cancer screening, the administrative staff do not feel that this would be a problem. The Health Department director envisions assembling a group of potential users to help the programmers design the system so that it would meet their needs.

Existing Infrastructure

The new Community Health Center (FQHC) will absorb the Primary Care Center at the Norwalk Hospital. A relationship with the new FQHC could create a referral site for the STD clinic for colposcopies. We were told by the gynecology clinic staff there that they do not perceive any burden if the STD clinic added cervical cancer screening. The Health Department could fax all necessary information when referring patients to them, initiating a procedure for colposcopy or treatment.

