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Provision of Hormonal Contraceptives Without a Mandatory Pelvic Examination: The First Stop Demonstration Project

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Context: First Stop, an 18-month demonstration project that operated in 1996-1997, was designed to offer low-income adult women in California hormonal contraceptives without requiring a pelvic examination.

Methods: An evaluation was undertaken to assess the contraceptives adopted by First Stop clients, compare health risks of these women with risks among women using traditional family planning clinics and assess clients' satisfaction. Data on 2,065 First Stop clients and 1,507 women attending traditional clinics were collected through several self- and clinician-administered instruments, including questionnaires, a telephone survey and medical chart abstractions.

Results: After the initial First Stop visit, 38% of women adopted a more effective method than they had used at last sex, 47% remained with the same method, 12% switched to a less-effective method and 3% accepted no method. Of clients who were referred for additional medical care, 73% followed through on their referrals. Compared with clients at traditional clinics, First Stop clients were less likely to have a regular source of health care, but more likely to have made a health care visit in the past year. Most First Stop clients valued the project's services; 76% said it was important to be able to receive pills or injections without a pelvic examination.

Conclusions: Programs that provide hormonal contraceptives without requiring a pelvic examination can expand low-income women's access to these methods and improve the chances that they will obtain other reproductive health services. =paragraph

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More than 20 years ago, the California Office of Family Planning established clinical standards to require physical assessment services, including a pelvic examination and Papanicolaou cytology (Pap smear), for all new family planning clients served at publicly funded clinics. Physical assessment service requirements were similar under the federal Title X family planning program. However, efforts to expand low-income women's access to effective contraceptives and increased attention to women's health care have made innovative family planning service delivery particularly important. Reducing barriers to contraception is critical to improving reproductive health care.¹

For example, the requirement of a pelvic examination may serve as a barrier to clients, particularly adolescents.²

In 1993, a task force reviewing the Title X guidelines recommended that the U.S. Department of Health and Human Services drop the requirement that clients seeking contraceptives first receive certain physical assessment services. For example, the task force recommended deleting the requirement that a pelvic examination be performed before a woman receives a hormonal method, leaving the decision of whether to perform such an examination to the clinician's judgment. The proposed revisions stipulated that clinicians offer a complete physical examination to all clients as an optional service, and that they encourage clients to use health maintenance services.

That same year, the Food and Drug Administration decided to allow women to defer physical examinations when seeking oral contraceptive prescriptions.³ In the mid-1990s, Planned Parenthood revised its guidelines to allow for deferral of the pelvic examination,⁴ and more recently, it has considered removing the requirement of a pelvic examination for oral contraception while encouraging annual examinations for general health care.⁵ Internationally, as well, medical guidelines have changed to allow for the deferral of physical examinations or their unlinking from the provision of hormonal contraceptives.⁶

Although standards have evolved on hormonal contraception and examination requirements, the effects of the revisions on women's access to and use of contraceptives, as well as any health implications, have yet to be fully explored. In one demonstration project, delaying a pelvic examination among adolescent clients did not jeopardize clients' health.⁷ Evidence from overseas suggests that community-based distribution of hormonal contraceptives does not increase risk to clients, but does decrease their risk of unintended pregnancy.⁸

In 1996, the California Office of Family Planning organized a family planning demonstration project called First Stop, which operated at seven nonclinical locations in central and southern California. The project, whose services did not include pelvic examinations, offered women two hormonal methods, oral contraceptives and the injectable depot medroxyprogesterone acetate (DMPA), as well as condoms and other over-the-counter methods. (Other services offered were medical history reviews, blood pressure screening, breast examinations, pregnancy testing and counseling.) Each site was paired with a traditional family planning clinic no more than 10 miles distant, where clients could be referred for follow-up care and receive a physical assessment, cervical cancer screening, diagnosis and treatment of sexually transmitted diseases (STDs), HIV screening and counseling, and other health maintenance services. Links between First Stop and traditional clinic sites were maintained to assist clients in making appointments, to facilitate the tracking of referrals and clients' compliance with referrals, and to help with client follow-up (especially for women with positive medical findings).

First Stop aimed to extend family planning services to women who are in need of services but may not be attending family planning clinics. Of the seven project sites, four were located within agencies housing the Special Supplemental Food Program for Women, Infants and Children (WIC), and one each in a community center, a housing

project and a social service department. First Stop services were available without an appointment, 12-40 hours per week, depending on the site.

The primary objectives of this study were to measure the adoption of new or more effective contraceptive methods by First Stop clients; to compare the health risks among clients using First Stop services with those among women obtaining traditional clinic services; and to determine women's views on the acceptability of receiving hormonal contraceptives without a mandatory pelvic examination.

METHODS

Data

Several self- and clinician-administered instruments were used to collect data about First Stop clients. At the end of every First Stop visit, the clinician completed an "encounter" form, recording the woman's age and ethnicity and such details of the visit as contraceptive supplies dispensed, the client's primary contraceptive method, whether a referral was made and to what kind of site (i.e., the traditional clinic or another provider), and the reason for the referral. Data from this form were collected on all 2,065 clients and spanned the duration of the project.

At the first visit, prior to receiving services, clients were given a self-administered intake questionnaire that asked about their marital status and education, use of health care services and opinions about the clinic services offered, including the provision of hormonal contraceptives without a pelvic examination. A revised version of the survey included questions regarding clients' contraceptive use at their last sexual encounter, prior acquisition of reproductive health services (including pelvic examinations and Pap smears) and history of STDs. The survey was administered for 13 months, and a total of 1,705 clients (94% of women who visited First Stop during that period) completed the questionnaire—527 the original form and 1,178 the revised form. Because many of the data instruments were administered after the evaluation period commenced, we have a smaller number of observations on some items, including marital status, education, health care received and clients' opinions about the project's services.

We conducted a telephone survey to determine if clients followed up on referrals and what services they received. All 1,241 First Stop clients who received referrals for reproductive health reasons were called approximately six weeks after the referral was made. To verify the telephone responses, we reviewed records at the traditional clinics to determine if First Stop clients who were referred actually followed through with a visit. (Follow-up information was not available for clients referred to other types of facilities.)

Short self-administered certification questionnaires completed by 1,736 First Stop clients and 1,507 traditional clinic clients provided a basis for comparing the two populations with respect to such demographic characteristics as age, ethnicity, income and parity. Additionally, a sample of 400 First Stop clients were matched according to age, race and contraceptive method to 400 clients at the traditional clinics. The medical records of both were reviewed for cancer risk factors and the occurrence of cancer, stroke and cardiovascular disease. Results from the matched sample are presented elsewhere.⁹ An additional assessment questionnaire, completed by 729 First

Stop clients and 1,507 traditional clinic clients, collected information about education, marital status, pregnancy history, general health care access and past health care.

Self-administered forms were written in both Spanish and English at the sixth-grade level. Clinician-administered forms were in English only. The intake and assessment forms were field-tested to determine language difficulty and consistency, and were revised accordingly. All procedures and forms were reviewed and approved by the Human Research Committee, University of California, San Francisco.

The California Office of Family Planning commissioned a telephone survey to assess the potential demand for First Stop services. A probability sample of 800 sexually active women aged 18-44 who lived in low-income areas were questioned on their preferences for contraceptive services of the type provided by First Stop.

Data Analysis

We tested the hypothesis that First Stop could help women adopt more effective methods of contraception than they have been using by comparing the methods that clients had used at their last sexual encounter before attending the project with the primary (i.e., most frequently used) method they reported after their initial visit. Methods were categorized from least to most effective for pregnancy prevention (i.e., no method, nonprescription methods, the pill and DMPA).

To assess possible health risks for clients using First Stop rather than traditional family planning clinics, we determined follow-through rates on referrals for additional medical care among First Stop clients. We then compared characteristics of clients who followed through on their referrals with those of clients who did not, to ascertain whether high-risk clients were less likely to obtain needed care. Additionally, we compared the use of health care services among women who attended First Stop with those among women who visited traditional clinics. Finally, we assessed opinions of First Stop among actual clients at the sites and among potential clients from the telephone survey.

Differences were measured with t-tests for continuous data and chi-square tests for categorical data; significance is reported at the .05 level. All analyses were performed with SPSS for Windows, version 9.0.

RESULTS

Impact of First Stop on Contraceptive Use

Of the 2,065 clients who visited First Stop sites, 52% made one visit, while the rest returned for additional visits. First Stop clients were primarily women who were income-eligible (i.e., had a family income that was below 200% of poverty), 18-49 years old (mean age, 26) and sexually active. The great majority were Hispanic (77%); the rest were predominantly white (11%) or black (7%), and a small proportion belonged to other racial or ethnic groups. Some 54% of clients did not have a high school degree. The reported median gross monthly family income was \$600. Fifty-five percent of clients had been married at some time, and 44% were currently married. Most (91%) had had at least one live birth, and 31% had had three or more births.

After the initial visit, 94% of First Stop clients reported a primary method of

contraception. Fifty-eight percent said that their primary contraceptive was a hormonal method, 36% a nonprescription method and 6% no method.

Forty-one percent of clients had used a hormonal method at their last sexual encounter before the initial visit to First Stop: 26% the pill and 15% DMPA. Thirty-six percent had used a barrier or natural method: 33% condoms, 1% spermicides and 2% natural methods. Twenty-three percent had used no contraceptive method at all. Thirty-four percent of clients received pregnancy testing at their initial visit.

Of clients who had used no contraceptive at the last sexual encounter before they visited First Stop, 12% chose DMPA, 31% pills and 43% nonprescription methods; 14% left the clinic with no method after their initial visit ([Table 1](#)). Among those who had used a nonprescription method at last sex, 14% chose DMPA and 27% pills; 54% were still using a nonprescription method, and 5% used no method. Most clients who had used the pill before their First Stop visit continued with that method (70%), while 15% switched to DMPA, 14% adopted nonprescription methods and 2% used no method after their visit. Similarly, women who had previously used DMPA largely stayed with that method (59%), whereas 15% subsequently used pills, 22% nonprescription methods and 4% no method.

The use of effective methods improved significantly after women's initial visit to First Stop: Thirty-eight percent of clients adopted a more effective method than they had used at last sex, 47% remained with the same method, 12% switched to a less-effective method and 3% remained with no method ($p < .001$). Additionally, whereas 33% of clients reported having used condoms at their last sexual encounter before visiting First Stop, 66% obtained condoms at their initial visit. Fifty-one percent of those who received condoms at the initial visit also obtained a second form of contraception.

Clients who made at least two visits to a First Stop site were likely to remain with a highly effective method or to adopt a more effective method than they had been using: Fifty-eight percent remained with DMPA or pills from the first visit to the second, 22% changed to a more effective method, 9% remained with a nonprescription method and 10% changed to a less-effective method ($p < .001$). Fewer than 1% reported using no method at both visits.

Health Status of First Stop Clients

In all, 61% of First Stop clients received a referral to a traditional clinic for reproductive health reasons, 16% did not require a referral and 23% declined a referral ([Table 2](#)). Older women were more likely than younger clients to receive referrals (65-70% of clients aged 30 and older, compared with 58-62% of those 29 and younger). Hispanic women were more likely than white or black clients to receive referrals (65% vs. 45-51%); at the same time, they were the least likely to refuse referrals (19% vs. 35-42%). Low educational levels also were associated with an increased likelihood that women would receive referrals.

Fewer than half of clients (46%) reported having a regular physician, but 81% said that they had visited a health care provider within the past year. Clients who did not have a regular physician were more likely to receive referrals for additional care (68%) than were women who had a regular doctor (60%), and those who had not made a health care visit within the past year were more likely than those who had to receive a referral

(77% vs. 61%). Eighty-three percent of clients had had a pelvic examination or Pap smear within the past three years, and these women were less likely than others to receive referrals (56% vs. 71%). Women using a contraceptive method were more likely to be referred to a traditional clinic than were women using no method.

Most referrals (93%) were for reproductive health maintenance services—usually a pelvic examination (89%) or a Pap test (91%), but also HIV screening and counseling (9%), screening for chlamydia or other STDs (37%), or other reproductive health services (6%). Seven percent of all referrals were for problems that might be related to the use of hormonal contraceptives. Among clients who sought a method not available through First Stop (10% of all clients), the most common method sought was the IUD, which accounted for 6% of referrals.

The majority of clients who were referred to the traditional clinics (73%) kept their appointments. Women who received referrals for a Pap smear or pelvic examination were significantly more likely to follow through on their care (82-83%) than were women with other types of referrals (38%; $p=.000$). We compared the characteristics of clients who went to their appointments with those of clients who did not and found no differences except by race or ethnicity ([Table 3](#)): Hispanic women were significantly more likely to follow through on the referral appointment (74%) than were white or black clients (58-66%).

Compared with clients at traditional clinics, First Stop participants differed on several characteristics ([Table 4](#)). According to the certification forms that all clients at both clinic types filled out, women attending First Stop had a younger age distribution than those at traditional clinics, were slightly more likely to belong to minority racial or ethnic groups (90% vs. 84%) and were more likely to have already had a live birth (91% vs. 81%). Results from the optional questionnaire suggest that First Stop clients had lower educational levels than clients at traditional facilities and were less likely than others to have more than a high school education (20% vs. 27%). First Stop participants were more likely to be currently married (44% vs. 40%) and to report having made a health care visit in the past year (81% vs. 76%) but less likely to have a regular source of care (46% vs. 60%).

Results from the matched comparison of medical chart abstractions of the two groups show that except for having a higher parity, First Stop clients were no more likely than traditional clinic clients to have risk factors for cervical cancer (abnormal Pap smears, a history of STDs, early age at first intercourse, multiple partners and smoking).¹⁰

Opinions of First Stop Services

First Stop clients reported that they placed a high value on their ability to obtain the project's services. Of those who were asked their opinions about the project's providing pills or DMPA without a pelvic examination or Pap test, 76% replied that this was an important service, 13% said it was not important and 11% were not sure ([Table 5](#)). The pattern was similar regardless of women's characteristics, but the proportion who considered this service important increased as women's age rose and decreased as their educational level rose. It was elevated among Hispanic women, clients who were using a contraceptive (particularly a hormonal method) and those who had had a pelvic examination or a Pap smear within the previous three years.

Among clients interviewed about their satisfaction with services at the First Stop site, 92% said they would recommend the service to their families and friends (not shown).

According to the community telephone survey of women who could potentially be First Stop clients, 86% responded favorably to the idea of obtaining a hormonal contraceptive without receiving a pelvic examination. Eighty-nine percent reported having had a pelvic examination including a Pap smear within the past three years. Nevertheless, 75% associated pelvic examinations with fear and embarrassment, and 31% said these feelings had prevented them from getting a pelvic examination at some point. Women of Hispanic origin, particularly those with a low level of education, were significantly more likely than other women to say they had avoided going to a physician at some point because of a pelvic examination.

DISCUSSION

Since the advent of hormonal contraceptives 40 years ago, much has been learned about their safety, efficacy and acceptability. The amount of epidemiologic and physiologic information about contraceptives has grown enormously, and the methods have evolved toward safer formulations; today's oral contraceptives, for example, contain much lower doses of contraceptive hormones than did earlier versions. Although international medical guidelines support the safety of providing hormonal contraception without a concurrent pelvic or breast examination, only a few studies have directly examined the issue outside the developing world, where community-based distribution has long been an acceptable norm.

One purpose of the First Stop demonstration project was to increase access to effective contraception for low-income women. Our results show that women who used First Stop services were less likely than clients of traditional clinics to have a regular source of care. These women were, nevertheless, more likely to have had some kind of health care visit in the past year than traditional clinic clients. Thus, the First Stop service delivery model is an effective channel for reaching women who need care and are motivated to seek it out, but do not have a regular source of care.

First Stop clients were younger and less educated than clients at traditional clinics. Fourteen percent had not used a contraceptive method at last sex, and 38% switched from an over-the-counter method to a more effective one when they came to First Stop. Hispanic women were the most likely to benefit from the First Stop services, since they reported a greater reluctance to see a physician because of a pelvic examination. They were less likely to refuse their referrals and more likely to follow through and seek additional care when needed than non-Hispanic women. They also reported significantly higher satisfaction levels.

Many women who came to First Stop were introduced to more effective contraception, and three-fifths were referred to preventive and screening reproductive health services. First Stop clients were not at greater risk of reproductive health problems than women who visited traditional clinics during the same time period. Most, although not all, of the women whom First Stop providers judged to need a visit to a traditional clinic (usually for a pelvic examination in conjunction with a Pap test) made that visit.

Some weaknesses of this evaluation deserve attention. Because the duration of the demonstration project was only 18 months, the average client made only 2.5 visits to a

First Stop site. Those who enrolled early made more, but late enrollers may not have had an opportunity to make more than one visit. The short duration of program participation and, consequently, the few visits made by a typical client do not permit evaluation of contraceptive continuation—a generally accepted index for measuring the success of a family planning program.

Furthermore, the nonexperimental, comparison-group design used to answer the health status questions in this evaluation provides limited evidence of the health status of First Stop versus traditional clinic clients. However, since 76% of those who used First Stop said that obtaining a hormonal contraceptive without undergoing a pelvic examination was important to them, it seems likely that some might have delayed visiting a provider for contraception if they had to undergo a pelvic examination. It also seems likely that some would have relied on less-effective methods or would have missed an opportunity for health screening and possible referral.

Some data were difficult to interpret because they were collected from a number of instruments over different time periods. Because the First Stop sites inaugurated services at various times, some sites had a longer duration of evaluation than others. To compensate for these variations, we analyzed only data collected within the 18-month period when all sites were running simultaneously. Second, site staff were instructed to telephone clients six weeks after a referral was given to determine whether the women had kept their appointments. This time frame was too short to allow us to gather complete information, especially if clients had to reschedule their appointments beyond the six weeks. Our evaluation of STD risks is compromised because First Stop did not offer urine-based testing for chlamydial and gonococcal infections. We were, therefore, not able to obtain an accurate account of undetected infections in First Stop clients.

Despite its weaknesses, this evaluation provides support for offering hormonal contraception without a pelvic examination and guidance for planners and other personnel contemplating such programs. The availability of urine-based testing for chlamydial and gonococcal infections will make it possible to provide these tests even in programs where pelvic examinations are not performed. Given that only 37% of project clients were judged by their clinicians to need STD testing, it would not have been cost-effective to screen everyone visiting First Stop. However, women who needed testing might have benefited from a urine test administered at the project site.

Another potential addition to First Stop services would be the provision of emergency contraception. A sizable proportion of First Stop clients (23%) were not using any method at all when they made their first visit, and many clients (34%) received pregnancy testing. In addition to the women without a method, those relying on barrier methods or oral contraception could benefit from learning about emergency contraception and having it available if needed.

Only 7% of all referrals were for problems that might be related to the use of hormonal contraceptives, demonstrating that for most women, First Stop personnel were able to provide effective methods without a pelvic examination and without deferring the contraceptive decision until after a referral visit. For women judged by their clinicians to be at risk if they used a hormonal contraceptive, the decision was delayed and a temporary method (usually condoms) was provided. Results from this project may

inform the debate on over-the-counter distribution of oral contraceptives. Although First Stop clients were seen by trained health professionals before receiving a hormonal method, the screening that they received could be completed by women themselves, particularly if they had detailed instructions for taking their own medical history and blood pressure (at a pharmacy, for example).

In summary, First Stop participants valued the program's services, many chose to use more effective contraceptives than they had previously used and most kept referral appointments that introduced them to preventive reproductive health care. Future programs of the First Stop type should take advantage of the usefulness of providing a hormonal method without requiring a pelvic examination and should introduce urine-based STD testing (but not universal screening) as well as emergency contraception.

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