Acceptability of the Vaginal Diaphragm Among Current Users

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METHODS: In 2001–2002, female members of a managed care organization were interviewed by telephone. The 215 participants, aged 19–49, who reported diaphragm use during the past three months were asked about their experience with the method and background characteristics. Characteristics associated with women's satisfaction with and consistent use of the diaphragm were identified through multiple logistic regression analysis.

RESULTS: Most participants had a low risk for HIV and other STDs. The mean duration of diaphragm use was 8.5 years. Although only 42% of participants reported consistent use in the past three months, most were satisfied with the method (79%) and planned to use it at next vaginal intercourse (85%). Satisfied users had significantly higher diaphragm use self-efficacy and more positive perceptions of the method than those not satisfied. Consistent use was significantly associated with older age and having had some college education rather than none. More than half of women cited dissatisfaction with previous methods (72%) and provider recommendation (61%) as moderately to extremely important in their decision to begin diaphragm use. When asked what they would change about the diaphragm, 32% mentioned concerns related to inserting or removing it.

CONCLUSIONS: From an acceptability point of view, the diaphragm appears to be a viable candidate for a female-controlled method for prevention of HIV and other STDs. Our findings have important implications for the reintroduction of the traditional diaphragm and development of new diaphragm-like products.

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The development of methods that women can use to protect themselves against HIV infection and other sexually transmitted diseases (STDs)* is an emerging public health priority. Despite efforts to develop chemical barrier methods that women can use to protect themselves against STDs (i.e., microbicides), male latex condoms continue to be the cornerstone of STD prevention. However, some men are unwilling to use condoms, and some women cannot negotiate use because of cultural factors such as gender-based power imbalances. Therefore, the availability of methods that women can use without their male partners' knowledge and cooperation is critical.

For several reasons, the traditional diaphragm has emerged as a possible candidate for a female-controlled method that could reduce users' risk of STDs. First, the diaphragm is an internal mechanical barrier device that physically protects the cervix. ⁴ Second, it is approved by the U.S. Food and Drug Administration and is available as a method of contraception. Third, findings from several observational studies suggest that when used with a spermicide, the diaphragm might reduce bacterial STD (mainly gonorrhea)

acquisition and associated long-term sequelae.⁵ This protective effect has important implications for HIV prevention, because untreated STDs can increase HIV infectivity and susceptibility.⁶ Fourth, when microbicides become available, the diaphragm could be used to hold them in place.

However, only 2% of U.S. female contraceptive users aged 15–44 use the diaphragm.⁷ Thus, it is not surprising that U.S. health care providers perceive the diaphragm as having low acceptability.⁸ Because there is a growing momentum of research on and development of the diaphragm and diaphragm-like products,⁹ a thorough understanding of what factors contribute to the acceptability of the diaphragm is critical. Yet to our knowledge, only a few studies have examined diaphragm acceptability, and the majority were conducted in other countries.¹⁰ Research on acceptability is particularly crucial for user-controlled methods such as the diaphragm because acceptability influences the effectiveness of these methods in real life.¹¹

In this article, we document the acceptability of the diaphragm among current users, and associations between user characteristics and diaphragm acceptability. We also describe users' reasons for choosing the method and their suggestions for changes to it.

^{*}Unless otherwise specified, any mention throughout the text of STDs is meant to include HIV.

METHODS

Participants and Procedures

These analyses used telephone interview data from 215 women who reported diaphragm use in the previous three months. Participants were members of Kaiser Permanente Northwest, a nonprofit health maintenance organization serving members in northwestern Oregon and southwestern Washington, and were a subsample of a larger study. Because we could not calculate the response rates separately for this subsample, we briefly describe here the sampling methods used in the larger study, which are reported in greater detail elsewhere. 12

Using existing Kaiser Permanente Northwest databases, we identified all of the 958 women aged 18–50 years who had been members for at least one month in the previous 2.5 years, had received a diaphragm from Kaiser during that period and had an address in the databases. We also selected a random sample of 3,589 women aged 18–50 years who had been members for at least one month in the previous 2.5 years, had not received a diaphragm from Kaiser during that period and had an address in the databases. We sent letters to these 4,547 women inviting them to participate in the larger study.

Interviewers telephoned potential participants and screened them for interest and eligibility. To be eligible, a woman needed to report use of a diaphragm in the previous 2.5 years, or use of a different method in the past three months and never-use of the diaphragm. A woman was ineligible if she did not understand and feel comfortable speaking English; was younger than 18 or older than 50; had not had vaginal intercourse with a male partner in the past three months; had tested positive for HIV; or was pregnant, was trying to get pregnant or suspected she was pregnant.

Of the potential participants selected, interviewers screened 2,717 women (60%) for interest and eligibility.* Among those screened, 571 (21%) declined participation (in all but two cases, before we determined eligibility), and 1,381 (51%) were ineligible. Between July 2001 and March 2002, the remaining 765 women were interviewed by female staff members from the Kaiser Permanente Center for Health Research in Portland, Oregon, by using a computer-assisted telephone interviewing system; interviews took about 30 minutes. Each woman gave oral, informed consent to participate in the study. We mailed a \$25 gift certificate to participants for their time and effort. The institutional review boards of the University of Oregon and the Kaiser Permanente Center for Health Research approved the study.

Of these 765 participants, 215 women reported having used a diaphragm during the previous three months (current diaphragm users), 172 reported having used the diaphragm during the past 2.5 years but not during the past three months (former diaphragm users) and 378 reported having used other contraceptive methods in the past three months but never having used the diaphragm. The present analysis involves only the 215 current diaphragm

users, because we were interested in examining acceptability among current users.

Measures

• Acceptability of the diaphragm. Our measures of acceptability were satisfaction with the diaphragm, consistency and duration of use, and intention to use the diaphragm. Specifically, we asked current users how satisfied or dissatisfied (on a scale ranging from one, "extremely dissatisfied," to five, "extremely satisfied") they were with the diaphragm as a birth control method. Because the distribution of scores was highly skewed and we were primarily interested in the distinction between women who were satisfied and those not satisfied, we used a dichotomous variable for this measure in our analysis: Participants were considered satisfied if they indicated they were "somewhat" or "extremely" satisfied, and were considered not satisfied if they gave any other response (i.e., "neither dissatisfied nor satisfied," "somewhat dissatisfied" or "extremely dissatisfied").

The interviewers also asked the women whether in the past three months (or since they had started using the diaphragm, if that had been during the past three months) they had had vaginal sex at least once without using the diaphragm. Women responding "no" were categorized as having used the diaphragm consistently, and those responding "yes" were considered not to have used it consistently. In addition, the women were asked for how long, in total, they had used the diaphragm.

Last, we asked the women whether they intended to use a diaphragm the next time they had vaginal intercourse. (Participants provided a response on a scale ranging from one, "definitely not," to five, "definitely yes.") The distribution of scores was highly skewed, and our main interest was in the proportion who intended to use the diaphragm; we therefore dichotomized scores into planning to use (based on responses "probably yes" and "definitely yes") or not (based on responses "uncertain," "probably not" or "definitely not").

- Demographic characteristics and STD risk factors. The interview included questions about participants' age, race and ethnicity, education, employment outside the home, marital status, having a main partner, number of children, number of male sex partners in the previous three months, and needle-sharing and STD history in the previous 12 months.
- Perceived risk of and motivation to avoid pregnancy and STDs. Participants were asked to rate how likely or unlikely (on a scale ranging from one, "extremely unlikely," to five, "extremely likely") they were to become pregnant in the next year if they did not use birth control, get HIV in the next year and get an STD other than HIV in the next year.

^{*}The 1,830 unscreened women comprised the following: 29 needing interpretive services; 13 for whom we could not find a valid address by tracing; 236 for whom we could not find a valid telephone number by tracing; nine not successfully reached in at least 20 attempts, 28 who could not be reached; 1,125 whom we were still trying to contact at the termination of data collection; and 390 with incorrect telephone numbers on file that had not yet been traced.

TABLE 1. Selected characteristics of current diaphragm users in a survey of the method's acceptability, 2001–2002

Characteristic	AII (N=215)
Percentages	
Race/ethnicity	
Non-Hispanic white	90.7
Non-Hispanic black	1.4
Hispanic	4.7
Other	3.3
Education	
<college< td=""><td>12.6</td></college<>	12.6
Some college	25.1
College graduate	62.3
Employed outside home	70.7
Married	72.6
Has a main partner	99.1
Has children	75.3
Had >1 male partner in past three mos.	0.9
Shared needles/had an STD in past 12 mos.	5.1
Means	
Age (yrs.)	36.1 (8.1)
Motivation to avoid STDs*,†	1.8 (1.5)
Perceived risk of pregnancy*	4.1 (1.3)
Motivation to avoid pregnancy*	4.5 (0.9)
Diaphragm use self-efficacy*,†	4.2 (0.5)
Perception of the diaphragm*,†	3.5 (0.4)

*Response options for each item ranged from one to five. The higher the score, the higher the motivation, perceived risk or self-efficacy, or the more positive the perception. †Multi-item scale. Notes: Numbers in parentheses are standard deviations. Data are missing from one woman for race/ethnicity, from one woman for motivation to avoid STDs and from three women for perceived risk of pregnancy.

To measure motivation, we asked participants to rate how important (on a scale ranging from one, "not at all," to five, "extremely") it is to them to keep from getting pregnant now, to do something now to protect against HIV infection during sex and to do something now to protect against other STDs during sex. By averaging the scores for the last two items, we created a measure of motivation to avoid STDs (alpha, 0.98, based on current diaphragm users).

• Diaphragm use self-efficacy. We measured diaphragm use self-efficacy with a nine-item scale adapted from the condom use self-efficacy scale. ¹³ Items assessed how confident (on a scale ranging from one, "not at all," to five, "extremely") participants were that they could insert a diaphragm correctly, remove a diaphragm easily, use a diaphragm correctly, remember to carry a diaphragm with them in case they needed one, use a diaphragm even if they were sexually excited, use a diaphragm without breaking the sexual mood with their partner, use a diaphragm without their partner's knowing, discuss using a diaphragm with their partner and use a diaphragm even if their partner did not like the method.

We created a diaphragm use self-efficacy scale by averaging the scores across the nine items (alpha, 0.80, based on current and former diaphragm users); ¹⁴ higher scores indicate greater confidence in being able to use the diaphragm.

- Perceptions of the diaphragm. We adapted the Contraceptive Attributes Questionnaire from a study of the contraceptive sponge. The agreement section of the questionnaire asked participants to rate the extent to which they agreed (on a five-point scale ranging from one, "strongly disagree," to five, "strongly agree") that each of 18 items was descriptive of the diaphragm.* We created a diaphragm perception scale by averaging the scores from the 18 items (alpha, 0.74, based on current and former diaphragm users); The alpha higher score represents a more positive perception of the diaphragm.
- Reasons for use and recommendations for change. The interview included a question asking women to rate the importance (on a scale ranging from one, "not at all," to five, "extremely") of six reasons in their decision to start using the diaphragm. For ease of interpretation, we dichotomized responses into "moderately, very or extremely important" and "not at all or a little important." Finally, we asked the following open-ended question: "If you could change one thing about the diaphragm, what would it be?"

Analyses

To describe acceptability of the diaphragm, we calculated the proportions of women who reported being satisfied with the diaphragm, using it consistently in the past three months and intending to use it at next vaginal intercourse. We also calculated how long women had used the diaphragm.

We examined associations between user characteristics and two dependent variables-diaphragm satisfaction and consistent diaphragm use. We used simple logistic regression analysis to assess unadjusted associations, and then assessed adjusted associations by fitting multiple logistic regression models that included as independent variables age and all characteristics with significant associations (according to Wald confidence intervals) in the unadjusted analyses. Age was included in these models regardless of its statistical significance because we thought that it could be associated with both acceptability and other independent variables (e.g., self-efficacy). In addition, we assessed the association between diaphragm satisfaction (an independent variable) and consistent use (the dependent variable) by conducting simple and multiple logistic regression analyses.

We calculated the proportion of women who reported selected reasons as being important in their decision to use the diaphragm. The qualitative data from the open-ended question about recommended changes for the diaphragm were assessed by content analysis. To code responses, three members of the research team read the text and then developed a coding scheme (content coding) to capture the themes, or sentiments, of responses. Next, two researchers read and coded all the text according to the established themes. They then compared their coding of the text to as-

^{*}These were the 18 items: "does not require you to touch your genitals"; "is not messy to use"; "does not have to be washed or stored"; "can be used without your partner knowing"; "can be bought without seeing a health care provider or getting a prescription"; "does not require you to take natural or artificial hormones"; "only needs to be used when you have sex"; "reduces your chance of getting HIV"; "reduces your chance of getting STDs other than HIV"; "will not cause side effects like bleeding, cramps, weight gain or changes in mood"; "will not cause pain or irritation"; "will not decrease sexual pleasure for you or your partner"; "is effective in preventing pregnancy"; "is inexpensive"; "is easy to use"; "has been around a long time"; "is a method you can control"; and "is a method your partner likes."

sess agreement; any differences in coding were discussed, and consensus was reached.

In all analyses, we treated responses of "don't know" and declined responses as missing data. We analyzed the data by using SPSS software, version 10.1, and we set the level of significance at 5%.

RESULTS Descriptive Data

Some characteristics of current diaphragm users in this sample have been described elsewhere. These participants ages ranged from 19 to 49 and averaged 36 years (Table 1). Most women (91%) were non-Hispanic white. Participants were generally well educated—62% were college graduates—and 71% were employed outside the home. Seventy-three percent were married, and a majority (75%) had children. Because all but two women had a main partner, we did not use this measure in subsequent analyses.

Women in this study appeared to have a low risk of STDs. Only 1% reported having had more than one male sex partner in the past three months, and 5% reported having shared needles or having had an STD in the previous year. Only three women thought they were somewhat or extremely likely to get HIV or other STDs in the next year (not shown). Because the measures related to STD risk lacked variability among the responses, we did not use them in subsequent analyses. We did, however, use scores for motivation to avoid STDs, which varied across the five-point range. The mean score for motivation to avoid STDs was low (1.8); 72% of women thought it was not at all important to take precautions to keep from getting STDs when having sex.

The average score for perceived risk of pregnancy was 4.1, and 55% of women perceived conception in the next year as extremely likely in the absence of birth control. The mean score for motivation to avoid pregnancy was 4.5, and 66% of women reported it was extremely important to keep from getting pregnant now. Scores for these measures also ranged across the five-point scale.

Average scores for self-efficacy in diaphragm use and perception of the diaphragm were high—4.2 and 3.5, respectively (ranges, 2.8–5.0 and 2.4–4.6). When we looked at the 18 individual items comprising the diaphragm perception score (not shown), only 2% of women somewhat or strongly disagreed that the diaphragm protects against pregnancy; in contrast, 76% somewhat or strongly disagreed that it reduces the risk of HIV (152 of 201 women) or other STDs (151 of 200 women).

Acceptability of the Vaginal Diaphragm

Overall, 79% of participants were satisfied with the diaphragm (38% were extremely satisfied, 41% somewhat satisfied). Although fewer than half (42%) had used the diaphragm consistently in the past three months, most women (85%) planned to use it the next time they had vaginal sex. According to responses from all but one woman, total duration of diaphragm use ranged from about one day to 30 years; the average was 8.5 years (standard deviation, 8.6).

TABLE 2. Selected characteristics of diaphragm users, by satisfaction with the method, and odds ratios (and 95% confidence intervals) from logistic regression analysis assessing associations between users' characteristics and satisfaction

Characteristic	Diaphragm users				Odds ratio	
	Satisfied (N=169)		Not satisfied (N=46)		Unadjusted	Adjusted*
	%	Mean	%	Mean		
Age (yrs.)	na	36.4	na	35.1	1.2 (0.9–1.6)†	0.9 (0.6–1.4)†
Non-Hispanic white	89.3	na	95.6	na	0.4 (0.1-1.7)	na
Education						
<college< td=""><td>11.2</td><td>na</td><td>17.4</td><td>na</td><td>1.0 (ref)</td><td>na</td></college<>	11.2	na	17.4	na	1.0 (ref)	na
Some college	25.4	na	23.9	na	1.6 (0.6-4.7)	na
College graduate	63.3	na	58.7	na	1.7 (0.7-4.2)	na
Employed outside home	70.4	na	71.7	na	0.9 (0.5-1.9)	na
Married	71.6	na	76.1	na	0.8 (0.4-1.7)	na
Has children	74.6	na	78.3	na	0.8 (0.4-1.8)	na
Motivation to avoid STDs‡	na	1.9	na	1.6	1.2 (0.8-1.8)†	na
Perceived risk of pregnancy‡	na	4.1	na	4.0	1.1 (0.8–1.5)†	na
Motivation to avoid pregnancy‡	na	4.5	na	4.3	1.2 (0.9–1.7)†	na
Diaphragm use self-efficacy‡	na	4.3	na	3.8	2.3 (1.6-3.3)†	1.8 (1.2–2.7)†
Perception of the diaphragm‡	na	3.6	na	3.2	5.1 (3.0-8.5)†	4.4 (2.6–7.5)†

*The following independent variables were used in the model: age, diaphragm use self-efficacy and perception of the diaphragm. †Odds ratios and 95% confidence intervals are for an increase in one standard deviation (see Table 1). ‡For an explanation of scores, see Table 1. *Notes*: Participants were considered satisfied if they indicated being "somewhat" or "extremely" satisfied. na=not applicable. ref=reference category.

Satisfaction with the Method

In the unadjusted analyses (Table 2), having higher diaphragm use self-efficacy and having a more positive perception of the diaphragm were significantly associated with being satisfied with the method. Age, race and ethnicity, education, employment outside the home, marital status, having children, motivation to avoid STDs, perceived risk of pregnancy and motivation to avoid pregnancy were not.

Six of the nine items making up the diaphragm use self-efficacy score were significantly associated with diaphragm satisfaction (not shown). Specifically, women satisfied with the diaphragm were more confident about inserting it correctly, removing it easily, using it correctly, remembering to carry one in case of need, using a diaphragm despite sexual excitement and using a diaphragm without breaking the sexual mood with their partner.

Eleven of the 18 scale items for perception of the diaphragm were significantly associated with diaphragm satisfaction (not shown). In particular, women satisfied with the diaphragm more strongly agreed that the diaphragm is easy to use; will not cause side effects; will not cause pain or irritation; will not decrease sexual pleasure; is a method they can control; is effective in preventing pregnancy; reduces their risk of HIV; needs to be used only when they have sex; is not messy to use; can be used without a partner's knowing; and is a method their partner likes.

We fitted a multiple logistic regression model to assess the adjusted associations between diaphragm satisfaction and age, diaphragm use self-efficacy and perception of the diaphragm. In this model (Table 2), having higher diaphragm use self-efficacy and having a more positive perception of the diaphragm were significantly associated with satisfaction (odds ratios, 1.8 and 4.4, respectively, for an increase of one standard deviation), but age was not.

TABLE 3. Selected characteristics of diaphragm users, by consistency of use, and odds ratios (and 95% confidence intervals) from logistic regression analysis assessing associations between users' characteristics and consistent use

Characteristic	Diaphra	Diaphragm users				Odds ratio	
	Used consistently Used inconsistently (N=90) (N=125)		,	Unadjusted	Adjusted*		
	%	Mean	%	Mean			
Age (yrs.)	na	38.4	na	34.5	1.7 (1.2–2.2)†	1.5 (1.1–2.1)†	
Non-Hispanic white Education	92.2	na	89.5	na	1.4 (0.5–3.6)	na	
<college< td=""><td>6.7</td><td>na</td><td>16.8</td><td>na</td><td>1.0 (ref)</td><td>1.0 (ref)</td></college<>	6.7	na	16.8	na	1.0 (ref)	1.0 (ref)	
Some college	26.7	na	24.0	na	2.8 (1.0-8.0)	3.1 (1.02-9.4)	
College graduate	66.7	na	59.2	na	2.8 (1.1-7.5)	2.6 (0.9-7.0)	
Employed outside							
home	74.4	na	68.0	na	1.4 (0.7-2.5)	na	
Married	74.4	na	71.2	na	1.2 (0.6-2.2)	na	
Has children	74.4	na	76.0	na	0.9 (0.5-1.7)	na	
Motivation to avoid							
STDs‡	na	1.9	na	1.8	1.1 (0.8–1.4)†	na	
Perceived risk of							
pregnancy‡	na	4.1	na	4.1	1.0 (0.8–1.3)†	na	
Motivation to avoid							
pregnancy‡	na	4.6	na	4.4	1.4 (1.01-1.9)†	1.2 (0.9-1.7)†	
Diaphragm use							
self-efficacy‡	na	4.3	na	4.1	1.4 (1.1–1.9)†	1.3 (0.9-1.7)†	
Perception of the							
diaphragm‡	na	3.6	na	3.5	1.4 (1.03–1.8)†	1.2 (0.8–1.6)†	

*The following independent variables were used in the model: age, educational level, motivation to avoid pregnancy, diaphragm use self-efficacy and perception of the diaphragm. †Odds ratios and 95% confidence intervals are for an increase in one standard deviation (see Table 1, page 66). ‡For an explanation of scores, see Table 1. Notes: Participants were considered to have used the method consistently if they reported never having had vaginal intercourse without diaphragm use during the previous three months (or since they had started using the diaphragm, if that had been during the past three months). na=not applicable. ref=reference category.

Consistency of Use

In the unadjusted analysis, older age and higher scores for motivation to avoid pregnancy, diaphragm use self-efficacy and perception of the diaphragm were significantly associated with consistent use (Table 3). In addition, compared with women who had no college education, college graduates were significantly more likely to have used the diaphragm consistently. No other variable was significantly associated with consistent use.

Four of the nine items on the diaphragm use self-efficacy scale were significantly associated with consistent use (not shown): Consistent users reported being more confident about removing a diaphragm easily, using a diaphragm correctly, remembering to carry one in case of need and using

TABLE 4. Percentage of diaphragm users reporting that selected reasons were moderately to extremely important in their decision to use the method

Reason	%
Dissatisfied with previous method	72.3
Health care provider recommended the diaphragm	61.3
Medical problems with previous method	47.9
Wanted a method that provides dual protection	
against both pregnancy and some STDs	23.3
Partner didn't like previous method	20.1
Wanted to get pregnant, and decided to use the	
diaphragm while a hormonal method wore off	9.3

Notes: Data are missing from two women for dissatisfied with previous method, three for health care provider recommended the diaphragm, and one for wanted to get pregnant and decided to use the diaphragm while a hormonal method wore off, all because they responded don't know. For partner didn't like previous method, data are missing for one woman, who declined to respond.

a diaphragm despite sexual excitement.

Three of the 18 items constituting the diaphragm perception scale were significantly associated with consistent use (not shown). Specifically, women who had used the diaphragm consistently more strongly agreed that the diaphragm is easy to use, will not cause pain or irritation, and is effective in preventing pregnancy.

We fitted a multiple logistic regression model to assess adjusted associations between consistency of diaphragm use and age, education, motivation to avoid pregnancy, diaphragm use self-efficacy and perception of the diaphragm. In this model (Table 3), consistent use was significantly associated only with being older (odds ratio, 1.5, for a one standard deviation increase in age) and having some rather than no college education (3.1).

Association Between Satisfaction and Consistency of Use

Being satisfied with the diaphragm was significantly associated with consistent use (unadjusted odds ratio, 2.4; 95% confidence interval, 1.2–5.0). Twenty-six percent of those not satisfied with the diaphragm and 46% of satisfied participants had used the diaphragm consistently. We fitted a multiple logistic regression model with consistent use as the dependent variable and with the following independent variables: satisfaction with the diaphragm, age, education and motivation to avoid pregnancy. We did not include diaphragm use self-efficacy and perception of the diaphragm as independent variables, because these variables were strongly associated with satisfaction. In this model, being satisfied with the diaphragm remained significantly associated with consistent use (odds ratio, 2.2; 95% confidence interval, 1.1–4.7).

Reasons for Using and Suggested Changes

Women rated the importance of six reasons for deciding to use the diaphragm. The reasons most commonly reported as being moderately to extremely important (Table 4) were dissatisfaction with a previous method (cited by 72% of women), provider recommendation (61%) and medical problems with a previous method (48%). In addition, one-fifth or more of women reported wanting a method that provides dual protection against both pregnancy and some STDs (23%) and a partner's not liking their previous method (20%) as moderately to extremely important reasons.

When we asked women an open-ended question regarding what they would change about the diaphragm, these were the issues reported most often (Table 5): concerns about insertion of the diaphragm, removal of the diaphragm or both (32%); concerns about spermicide use (21%); and concerns about the physical characteristics of the diaphragm (12%). Twelve percent suggested no changes or said they did not know.

DISCUSSION

Is the diaphragm an acceptable contraceptive method? In this study of current users, participants had used the diaphragm for an average of 8.5 years. The majority were sat-

TABLE 5. Percentage of diaphragm users, by issues raised in response to an open-ended question asking what one thing they would change about the method

Issue	%
Concern about insertion/removal*	32.1
Concern about spermicide use†	21.4
Concern about its physical characteristics‡	11.6
Don't want to leave it in for such a long time	10.7
Fitting issues§	4.2
Concern about effectiveness in preventing pregnancy**	2.8
Partner concerns††	2.3
Dislike that a prescription is required	1.9
Would like it to protect against HIV/STDs	0.9
Other‡‡	4.2
Nothing	5.6
Don't know	6.0
Vague/unclear response	3.7

*For example, not wanting to insert and remove it, wanting it to be easier to insert, wanting to leave it in longer, wishing it would not interfere with the moment. †For example, spermicide side effects, messiness, need to reapply spermicide. ‡For example, material, cleaning/maintenance requirements. §For example, concerns about improper fit or discomfort. **For example, not knowing its effectiveness, wanting it to be more effective. †For example, wishing partner would not feel it. ‡For example, cost, increased risk of bladder infections/health problems. *Note:* Percentages add to more than 100% because 16 participants each contributed two responses.

isfied with the method, and 85% intended to use it at next vaginal intercourse. Taken together, these data indicate that in this sample, the diaphragm was highly acceptable. Moreover, women's reported use of the diaphragm in this study meets Severy and Newcomer's criterion of acceptability, which is "the voluntary sustained use of a method in the context of alternatives." ¹⁸

In contrast, fewer than half of the women had recently used the diaphragm consistently. However, our definition of consistent use was conservative, denoting use for every occasion of vaginal intercourse during the prior three months. Furthermore, even if a woman is highly satisfied with the diaphragm, various factors may influence whether she uses it for every sexual encounter. Because this method does not require continuous use over long periods of time but rather is used only in conjunction with occasions of sexual intercourse, women and couples have the option of alternating between this and other barrier methods (e.g., condoms). For example, more than one-quarter of current users in our study reported recently using condoms. ¹⁹ The option of alternating use of the diaphragm with use of other methods may even add to the acceptability of the diaphragm and may help explain why many satisfied users in our analysis had used it inconsistently. Women may use different methods at different times (e.g., depending on phase of the menstrual cycle) or in different situations. Clearly, further research is needed to elucidate women's alternating use of different methods, including the diaphragm, and how that is related to acceptability of specific methods.

Our finding that women reporting consistent use were older and appeared better educated than others has several possible explanations. Older women tend to be in more stable situations (e.g., living arrangements), which could make consistent use of one method easier than it would be for other women. In contrast, younger women may find

that alternating methods better fits their lifestyle. In addition, an international study found that typical diaphragm users were older and better educated than women who chose other methods, and the authors suggest that older women may have traits that facilitate successful diaphragm use; in particular, they may have a broader range of experience with various birth control methods, and they may feel more comfortable with their bodies.²⁰

Unlike consistent use, satisfaction with the diaphragm was not significantly associated with age, education or other demographic factors. This finding may indicate that satisfaction is more closely linked to method experience than to demographic characteristics. In our analysis, women with higher diaphragm use self-efficacy and a more positive perception of the diaphragm were more likely to be satisfied with the method than were women with lower scores on these measures. Although this finding is not surprising, it has important implications for the reintroduction of the traditional diaphragm into the compendium of methods currently available for women, and for the development of new diaphragm-like products. More specifically, women need to be instructed in correct diaphragm use, including proper insertion and removal techniques, and they need to have the opportunity to develop their skills and increase their comfort with using it. Indeed, when asked what they would change about the diaphragm, one-third of participants expressed concerns about insertion or removal. Furthermore, three in five indicated that a health care provider's recommendation was a moderately to extremely important factor in their decision to begin diaphragm use. Thus, providers could play a major role in increasing diaphragm acceptability and introducing new diaphragm-like products, even over-the-counter ones. If the diaphragm is found to effectively prevent HIV infection, providers' attitudes toward the diaphragm, and their educating women about it, will be essential for increasing the use of this method.

Of note, nearly three-fourths of the women indicated that dissatisfaction with their previous method was an important factor in their decision to use the diaphragm. Another study found that overall rates of method switching are high among married and unmarried women. ²¹ Severy and Silver argue that contraceptive choice is extremely "unstable"; they posit that when deciding among contraceptive options, users will choose the "least bad alternative." ²² Together, these findings indicate that women need contraceptive options, and that for some women, the diaphragm may be the most acceptable option.

Women's responses to our open-ended question asking what they would change about the diaphragm have implications for the development of new female-controlled barrier methods that are similar to the diaphragm. For example, one-fifth of participants indicated that they were concerned about spermicide use. Some women wished that they could insert the diaphragm further in advance or leave it in longer; others wanted to be able to remove it sooner after intercourse. These results suggest that products that are used without spermicides and that allow greater flexi-

bility in the timing of insertion and removal might be more acceptable to some women.

Several limitations of this study warrant mention. First, although our analysis showed associations between variables, temporal sequence and causality could not be established, because cross-sectional data were used. Second, because certain analyses involved relatively small response groups, some odds ratios had fairly wide 95% confidence intervals. Third, the data are retrospective self-reports; women who had been using the diaphragm for several years may not have accurately remembered the importance of various factors in their decision to begin using it. Fourth, because we studied current users, satisfaction among these participants was probably greater than it would be in a population of new users. Fifth, the findings could differ for current users who were not reached or who declined to participate: Although a fairly low proportion of the women contacted declined to participate in the larger study (21%), we reached only 60% of the selected women. Furthermore, our findings may have limited generalizability because our sample was selected from a health maintenance organization in the Pacific Northwest. Most respondents were well-educated, white and married, had a low risk for STDs and had access to medical care. Acceptability of the diaphragm may differ particularly among young women at greatest risk of STDs. Accordingly, we are conducting a study of the acceptability of the diaphragm among an ethnically diverse sample of young women at risk for STDs who have never used the diaphragm.²³

The diaphragm was a very popular contraceptive method at one time, but it has fallen out of favor with U.S. women in the past 30 years. ²⁴ This study shows that there are current users who consider this method highly acceptable. Thus, from an acceptability point of view, the diaphragm seems a viable candidate for a female-controlled method of STD prevention. We believe that the diaphragm could make a dramatic comeback if randomized, controlled trials show that it reduces the risk of STDs, and if health care providers promote its use.

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