A Strategic Approach to Standard Days Method® Introduction: Expanding Availability and Use of FAM

FINAL STUDY REPORT
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Executive Summary

Despite their efficacy and safety, the availability and use of fertility awareness-based family planning methods (FAM) are low in Title X clinics. The purpose of this project was to test whether integrating the **Standard Days Method® (SDM)**, a FAM that has proven to be both feasible for programs to offer and appealing to providers and clients, into Title X family planning (FP) services would increase use of FAM.

Specifically, this study (1) identified factors which constrain and facilitate FAM availability and use; (2) developed and tested a process to introduce SDM in FP clinics within a framework of expanded choice; and (3) assessed acceptance, correct use and satisfaction among SDM users. It was conducted by Georgetown University's Institute for Reproductive Health (IRH) in partnership with Cardea Services, JSI Research & Training Institute, Inc., and six Title X health centers.

The World Health Organization's Strategic Approach to contraceptive introduction was used both to guide the research and to develop an intervention that had potential for success. This approach calls for the integration process to be need-based and participatory and defines a three-phased framework for introducing a new family planning method: Phase 1: needs assessment; Phase 2; method integration and evaluation; and Phase 3: use of research results for policy and planning. The figure below summarizes the data collection elements of the study as they relate to program activities in the three phases.

Data collection and program activities

	Phase 1 Needs assessment		Phase 2 SDM integration and evaluation				Phase 3
Data elements	Pre SDM integration			Process evaluation		Outcome evaluation	Post integration
Site assessment	√	Tailor SDM integration activities based on needs assessment results	Fully integrate SDM into existing services in participating clinics		Modify integration activities based on results of fidelity research		Use of research results for policy and planning
Provider & staff interviews	√					√	
Client focus groups	√						
Simulated clients				√			
Waiting room questionnaire	√						
Client follow up						√	
Service statistics	→	→	→	→	→	→	

Needs assessment (Phase 1)

Prior to SDM integration, we assessed potential clients' knowledge, needs, and desire for FAM; provider knowledge, skills, attitudes and practices regarding FAM; service delivery systems and outreach activities in the selected clinics to determine how FAM is integrated into the services they offer; individual and institutional barriers that may hinder SDM uptake and use; and opportunities and challenges to adding SDM to the method mix. The needs assessment consisted of the examination of service statistics from the previous year, a site assessment to determine how SDM would fit into clinic systems, interviews with clinic staff, focus groups with potential clients, and waiting room questionnaires.

The results of the needs assessment activities suggested that SDM integration would be feasible at all clinics and accepted by providers and clients. Because FAM was not routinely offered at most study clinics prior to SDM integration, service statistics from the prior year counted only two FAM users reported by the participating clinics. Users were likely underreported, however.

From a systems perspective, discussions with clinic managers as part of a site assessment indicated that there would be no barriers to method integration that could not be resolved with minimal effort for the purposes of the study. However, procurement of CycleBeads®, the visual tool used by most SDM users to track the menstrual cycle, likely would be a challenge in the future as the tool was not on insurance formularies or included in government-sponsored family planning reimbursement programs.

Staff (n=37) from the participating clinics were in favor of expanding options for their clients and open to learning about and offering SDM. While there was some skepticism about the effectiveness of FAM in general among staff, there was also considerable enthusiasm about the ability of SDM to better meet the needs of those clients seeking a non-hormonal or natural method.

Community-based focus group discussions (nine discussions were held with a total of 64 participants) suggested that there was potential demand for a new method – particularly, for a method with no hormones or side effects and one that involved men – among communities served by the clinics. SDM would not meet the needs of all women – for example, those who desired a highly effective (99%+) method or whose partners were not amenable to using such a method. Nevertheless, these results confirmed that SDM integration would be appropriate for and would meet the needs of some women seeking a non-hormonal method.

The waiting room questionnaires (n=594) implemented as part of the needs assessment phase revealed lower satisfaction levels among users of barrier and traditional (such as rhythm and withdrawal) methods compared to users of other methods, suggesting that there were clients who could be better served by an additional non-hormonal method option. The mixed responses to the

question of when a woman is fertile by focus group participants and respondents to the waiting room questionnaires suggested a need for education on fertility awareness, for which CycleBeads would be a useful tool. However, lack of understanding of fertility could cause some potential clients to doubt the effectiveness of the method.

SDM integration (Phase 2)

Utilizing the results of the needs assessment, Cardea, JSI, and IRH worked with the service delivery agencies to integrate SDM into family planning services. The integration process included three components: (1) integration into clinic systems and establishment of method-related protocols; (2) staff training and support, including provision of SDM counseling aids; and (3) awareness-raising and outreach activities. Due to budget constraints, outreach activities were limited to low-cost efforts including presence at health fairs, community visits by outreach workers, and posting flyers around town.

Once SDM was integrated into clinic services, the fidelity of integration activities was tested to ensure that activities were correctly implemented and to gather information for the clinics to improve their services. We used simulated clients to gauge provider compliance and competence in SDM counseling at least three months after providers were trained in offering SDM.

Simulated client visits revealed strengths and weaknesses pertaining to SDM counseling. A main strength was that the majority of simulated clients received good information on how to use CycleBeads. The main weakness was that some providers did not adequately screen the client, or did not respond appropriately upon hearing the client's response to screening questions. The results of the simulated client visits were shared with each clinic and used to improve services.

Evaluation findings

To evaluate the effect of SDM integration, service statistics were collected each month to evaluate whether SDM integration resulted in an increase in the number of FAM users at each clinic. Post-integration staff interviews were conducted to evaluate provider perspectives following SDM integration and identify barriers to offering FAM. Finally, interviews with SDM clients were conducted to understand method use patterns, continuation, and satisfaction.

Service statistics: During the study, participating clinics reported a total of 198 SDM users, whereas during the year prior to SDM integration, the total number of documented FAM users at all participating study clinics combined was two. This made it clear that the number of FAM users increased after SDM integration.

Staff interviews: A total of 25 clinicians, nurses, medical assistants, and counselors from participating clinics were interviewed about a year after having been trained on SDM and CycleBeads. Some 62.5% said they discussed SDM with clients at least once per week. All of the staff members interviewed stated that they found it easy (either very easy or somewhat easy) to teach women how to use CycleBeads. Staff members generally said that SDM integration had no adverse effect on clinic flow.

All of them believed SDM was effective enough to offer as a birth control method in their clinic and felt that their agency should continue to offer the method after the study was over. The most common reasons staff members gave as to why it was important to offer a FAM such as SDM included the need to offer a wide range of options; the need to provide non-hormonal options for women who desired them; and the need to have a method for women whose religious beliefs left them with few options.

There were four main barriers cited by staff members regarding offering SDM: (1) staff forgetting to offer it because it had not yet been ingrained in them; (2) client preference for other methods; (3) clients not meeting the eligibility criteria; and (4) outreach workers' inability to dispense the method during community talks without a nurse present.

Staff at participating study clinics also identified barriers faced by clients that made it difficult for these clients to choose SDM as their family planning method. The four key barriers cited by staff members are: (1) the client did not meet eligibility criteria; (2) lack of transportation to the clinic, particularly by women in rural areas; (3) lack of confidence in the method or desire for a more effective method, and (4) lack of awareness that the method existed and was available at these clinics. To raise awareness of the method, staff members suggested mass media communications such as television and enhanced community outreach efforts.

Client follow up: Clients who chose SDM were invited to participate in the study by clinic staff immediately after receiving counseling. For clients who agreed to participate, study staff followed them for up to one year of method use, interviewing them at admission (41 clients), then three months (21 clients), six months (12 clients), and 12 months (8 clients) after admission.

Of the 41 clients reached upon admission, 36 were using SDM to prevent pregnancy and met the eligibility criteria for method use. The most common reason for choosing the method, mentioned by 75% of respondents, is that it was non-hormonal with no side effects. Some 93% of respondents said they heard about SDM from the health center.

Of the 21 clients reached after three months, 15 were still using SDM to prevent pregnancy. At six months, 12 clients were reached for interviews, and 10 were still using it to prevent pregnancy. At twelve months, eight clients were reached for interviews, and six were still using SDM to prevent

pregnancy. Reasons for discontinuation included out-of-range menstrual cycles, pregnancy (intended or unintended), end of relationship, and desire to use an IUD.

While all continuing users reported correct knowledge of the meaning of the red, brown, and white beads on CycleBeads, about half of users at three months reported being confused about how to use CycleBeads to track their cycle length each month to ensure that their cycles were not too short or too long to use the method. All users reported being either satisfied or very satisfied with SDM, and nearly all said SDM was easy to use. Some stated that their relationship with their partner had changed for the better since they began using SDM; the rest reported no change.

Because of the small numbers of clients interviewed, these results are informative but not generalizable.

Effect of SDM integration on number of FAM users

While SDM integration increased the number of FAM users at the participating clinics, the overall number of FAM users remained low with respect to the total number of female family planning clients. This was largely due to a lack of awareness among the populations served by the study sites about what CycleBeads were and their availability at the clinics. It was also due to staff forgetting to offer it and the absence of the method from multi-method posters or brochures used as counseling guides.

It became clear that if SDM was integrated at higher levels, including organization-wide (which could have meant method integration into multi-method posters, informational brochures, and counseling guides) and state-wide (which could have impacted the priority given to the method, particularly by managers and clinicians) – the integration process likely would have had greater impact.

Overcoming barriers to offering FAM

Prior to SDM integration, only clinicians were trained to discuss FAM with clients. However, the integration process (specifically, SDM training) enabled non-clinical staff – i.e., medical assistants, counselors, and health educators – to counsel clients on FAM, specifically SDM. However, integration of SDM with CycleBeads into clinic service delivery did not address a major barrier for FAM availability: that many people who needed the method were not reached, for reasons including lack of awareness of the method and lack of transportation to the clinic.

Use of research for policy and planning (Phase 3)

Study staff have engaged in efforts to disseminate and utilize study findings, including presentations at various national conferences. We have developed and are disseminating informational products based on project experience that will assist programs who wish to introduce SDM into their family planning services, including the *CycleBeads® Integration Guide: A Toolkit for Family Planning Programs* (available at http://www.CycleBeadsToolkit.com) and videos that demonstrate counseling scenes that can be used for provider training. Dissemination of these informational materials and study results is ongoing, and opportunities for in-person and online skills sharing and capacity building are being pursued.

Conclusions and recommendations for scale-up

This study demonstrated that SDM can be successfully introduced into family planning service delivery at Title X clinics, from reproductive-health-focused organizations to facilities providing the full range of primary care services. The number of FAM users increased dramatically due to SDM integration. Managers perceived that integrating the method into existing clinic-based systems was relatively simple and straightforward, and providers found that counseling on the method fit within the clinic flow.

Most clients chose the method because it was natural with no side effects and were able to use it successfully and satisfactorily. Staff of service delivery agencies perceived that offering SDM added value to their services because it enabled them to provide more options for their clients and to better meet the needs of clients seeking a non-hormonal method. Health center staff found CycleBeads easy to teach, and clients found the method easy to use.

Larger-scale integration – for example, at the organizational, state, and/or national level – will be required to meet client demand for a method such as this and to reach more women with information and services. Future, larger-scale integration efforts should take the following into consideration:

Utilize mass media campaigns to raise awareness of SDM and CycleBeads among potential clients. Raising awareness of the method through media such as newspapers, magazines, radio, television, or the internet, in a context of informed choice, would increase client knowledge of the method so that clients do not need to rely on the health center as their primary source of information.

Integrate SDM into multi-method counseling materials used by staff. Future integration projects should revise multi-method counseling aids in order to ensure that staff who rely on these

materials do not neglect to mention SDM to clients who may be interested. In addition, managers should remind staff to make the method a regular part of their counseling routines.

Include CycleBeads in reimbursement programs. For this study, CycleBeads were provided by IRH. To ensure that agencies can access the method and that method cost does not make it prohibitive for low-income clients, CycleBeads must be included in reimbursement programs such as California's Family PACT.

Find ways to reach rural areas with services so that lack of transportation to the clinic is not a barrier to access. This is likely an issue for all methods, not only SDM. However, unlike many clinical methods, SDM is an education-based method used with a simple visual tool (CycleBeads) that can easily be offered by non-clinical staff. Therefore, it is well-suited for distribution by outreach workers and *promotoras*.

In summary, this experience suggests that it is feasible and beneficial to offer SDM in Title X clinics. Integration of this method enables clinics to offer a simple fertility awareness-based method and therefore to better achieve their mission of offering a wide range of options to meet their patients' needs. However, sustainable, widespread integration of SDM in the United States likely will not occur until the method is included in state and national family planning norms and until the broader family planning community takes action to ensure that this method option is accessible to all.

I. Introduction and Purpose

Despite their efficacy and safety, the availability and use of fertility awareness-based family planning methods (FAM)[1] are low in Title X clinics. According to national level data, less than one percent of female family planning users at Title X clinics use a FAM (Fowler, 2011). Possible reasons for low use of FAM include a lack of availability through many family planning (FP) programs and the fact that people who might be interested in using them are unaware that these methods exist, lack information about how to use them, are concerned about efficacy, or find them difficult to learn and use (Mikolajczyk, 2003; Díaz, 1997; Vernon, 1987; Gribble, 2003). Suggested reasons for limited availability include lack of trained providers, the perceived time and effort required for counseling, and the perception of many programs managers and providers that these methods are unreliable and will not be chosen by their clients (Arevalo, 1997; Snowden, 1988; Stanford, 1999; Fehring, 2001; Silvonek, 2004).

The purpose of this project was to test whether integrating the **Standard Days Method® (SDM)**, a FAM that has proven to be both feasible for programs to offer and appealing to providers and clients (Gribble 2003; Gribble, 2008), into Title X FP services will increase use of FAM. We suggest that offering SDM – a FAM that is effective, feasible for programs to offer, and easy for clients to learn and use – while also engaging stakeholders (including decision-makers, program managers, providers, and clients) in developing and implementing a strategy to offer a FAM, will improve both availability and use.

SDM was integrated into services of selected Title X clinics through a participatory, **Strategic Approach** in an effort to increase programs' and providers' willingness and ability to offer a FAM as part of their routine services. It was conducted by Georgetown University's Institute for Reproductive Health (IRH) in partnership with the Cardea Services, JSI Research & Training Institute, Inc., and selected Title X service delivery agencies in their regions. Together, these organizations conducted a study to: (1) identify factors which constrain and facilitate FAM availability and use; (2) develop and test a process to introduce SDM in FP clinics within a framework of expanded choice; and (3) assess acceptance, correct use and satisfaction among SDM users.

[1] "Fertility Awareness-Based (FAB) methods" is the language used in WHO's "Medical Eligibility for Contraceptive Use" (2004) and "Contraceptive Technology", 18th Edition (2004), among others. Others use the term "Fertility Awareness Methods" (FAM). These terms are sometimes used interchangeably with "natural family planning" (NFP), although the intention of the WHO, et al, language is to acknowledge that alternative methods may be used on fertile days. Despite some controversy over the use of the terms FAB, FAM and NFP, we use FAM throughout this proposal, acknowledging that some may equate it with NFP while others do not.

This study contributes to the small body of knowledge regarding strategies to increase the use of FAM in the U.S. It also provides important information on program, provider and client factors that constrain or facilitate FAM availability and use. An effective, feasible and replicable strategy to increase availability and use of FAM, if scaled-up widely, could help organizations throughout the U.S. interested in including FAM in their programs to better meet the needs of the populations they serve. Implementation of such a strategy could play a role in decreasing unintended pregnancies, especially among groups not currently using FP services.

II. Background on SDM

A number of effective FAM have existed for several decades, including Cervical Mucus and Symptothermal methods. These methods have been offered successfully in private sector (often faith-based) programs in the U.S. and around the world. Highly-skilled individuals and dedicated organizations support programs to provide these methods. IRH has engaged in a comprehensive research program focusing on FAM for more than 20 years, with funding from the U.S. Agency for International Development (USAID) and, more recently, the Office of Population Affairs (OPA). During the early years of IRH's work in developing countries, we worked with faith-based, non-governmental, and public-sector programs to expand availability and use of these methods.

Despite this work and the efforts of other national and international organizations that focus on natural methods, both in the U.S. and elsewhere, use of these methods remains low.[2] Other studies indicated potential interest in a natural method that is effective but requires less time to train providers and counsel clients (Vernon, 1987; Díaz, 1997; Jennings, 2006). Thus, in the late 1990s, IRH decided to develop a method – SDM – that could meet this need.

IRH developed SDM based on data from a WHO study that contained detailed information about more than 7,000 menstrual cycles (Arevalo, 2000). SDM is appropriate for the vast majority of women who have most menstrual cycles between 26 and 32 days long (approximately 80% of cycles are within this range) (Arevalo, 2000). It identifies cycle days 8-19 as potentially fertile, based on the effective life of the gametes and the timing of ovulation. Most women who use SDM use CycleBeads®, a color-coded string of beads that helps them track their cycle lengths and identify the days they should avoid unprotected intercourse if they do not want to become pregnant.

[2] One source of international data is Demographic Health Surveys in various countries. Country-specific data can be accessed at http://measuredhs.com/.

The efficacy of SDM (failure rate of 5 with correct use, 12 with typical use) was established through field trials (Arevalo, 2002) in Bolivia, Peru and the Philippines. Some 500 women who received SDM services from trained providers in public and private sector clinics participated in the study. They were interviewed monthly for up to 13 cycles to assess use of and satisfaction with the method and determine pregnancy status.

The efficacy study, along with subsequent studies conducted by IRH and others in the U.S. and 14 developing countries, suggested that offering SDM benefits both clients and programs. It has the potential to increase FAM use and bring new users to FP (the majority of women who choose SDM have not previously used FP or have stopped using another method because they were dissatisfied with it [Gribble, 2008; Lundgren, 2007; Gribble, 2003]); and it addresses the FP needs of women who prefer non-hormonal, non-invasive methods.

SDM is feasible for programs to include in their range of services, as providers can acquire competency in SDM counseling with approximately two hours of training (Jennings, 2006), and clients can learn to use it correctly in a single session of 10-15 minutes (Gribble, 2008). Low-cost job aids, which have been tested in the U.S. and other countries, help providers maintain quality services; and client materials, appropriate for different cultures and literacy levels, support correct use of the method (Jennings, 2006; Lundgren, 2005). CycleBeads have proven invaluable in provider training, client counseling, and method use (Arevalo, 2002; Gribble, 2004; IRH, 2008). Findings from an OPA-funded study conducted by IRH to integrate SDM into FP services in a community health center in California have suggested that including SDM in programs may help increase the ability of providers to address couple issues with their clients (Lundgren, 2007).

III. Conceptual Framework

Introducing a new FP method into programs has great potential for expanding FP use; but in practice, the benefits have not always materialized as new methods have been added to public-sector programs (Simmons, 1997). The availability of a new option alone will not expand use or broaden choice unless the existing constraints faced by programs in delivering adequate services are addressed.

Therefore, this project used the **Strategic Approach to FP Method Introduction**, first articulated by the World Health Organization (WHO) in 1994 (Spicehandler and Simmons), as the strategy for integrating SDM into programs. The Strategic Approach provides a

systematic framework for introducing SDM and integrating it into services to maximize the benefit of the integration of a new method.

This framework stipulates that the decision to offer a new FP method should be based on needs perceived by stakeholders (including providers and clients) for such a method. The strategy for providing the method, including who offers it, counseling protocols, how it is described to clients, how information about it is shared with potential users, and how it is supported by the service delivery system, should be developed through a **participatory, transparent process** that focuses on client needs and quality services (as defined by Bruce, 1990). The participatory process includes institutional and community ownership, as well as transparency in decision-making.

Accordingly, the **WHO Strategic Approach** defines a three-phased research framework for introducing a new FP method: Phase 1: needs assessment; Phase 2; method integration and evaluation; and Phase 3: use of research results for policy and planning. Therefore, the Strategic Approach was used both to guide the research and to develop an intervention that has the potential for success.

In addition to the phase-wise approach to method integration, the Strategic Approach identifies three elements that influence the successful integration and use of a method as part of a systems approach (Figure 1): the potential **User** of the method; the **Technology** of the method itself; and the program context, or **Service**, in which the method is offered.

The **User** has FP needs and preferences as well as opinions and knowledge (correct or not) of particular methods. She may or may not have an accurate understanding of her fertility (fertility awareness) and her menstrual cycle. Clearly, these will affect her interest in FAM. Her menstrual cycle length will affect her ability to use SDM. A user also has a relationship with her partner that may influence her ability to use the method correctly – to avoid unprotected intercourse on her fertile days.

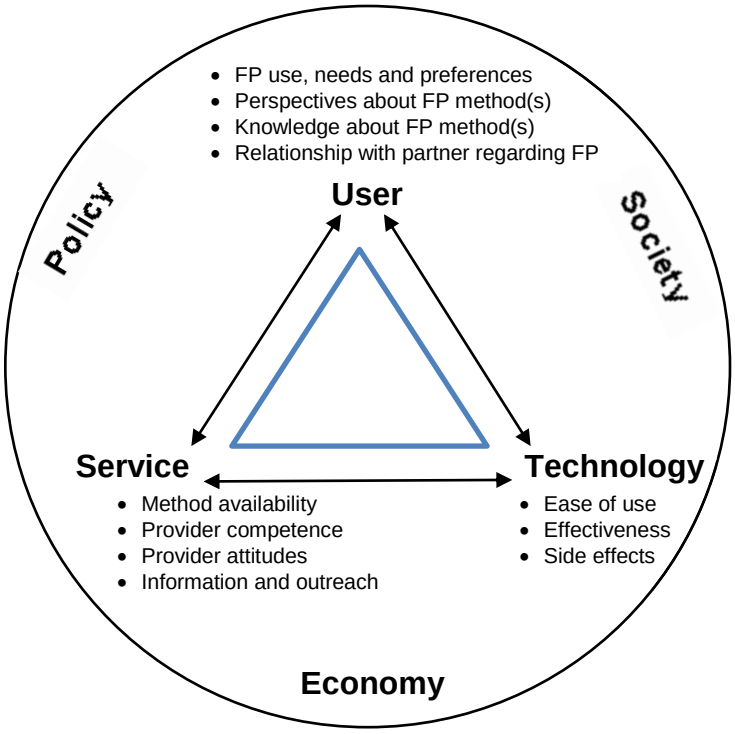
The **Technology** of the method, e.g., its ease of use, effectiveness, side effects, etc., influences the willingness and ability of providers to offer it and of clients to use it. As a FAM, SDM has no side effects. In fact, this is the primary reason women choose it (Gribble, 2008). It is effective, well within the range of a number of other user-directed methods (Hatcher, 2007).

SDM was designed to address concerns of providers and potential users about ease of use. It is critical that these technological attributes are communicated to providers, clients and other stakeholders. However, it also should be acknowledged that there are more effective methods and that avoiding unprotected intercourse for 12 days each cycle, as is required

for correct use, is not acceptable to every potential user. Therefore, self-assessment or screening by a provider is important.

The **Service** itself, that is, the way in which the method is offered, affects whether clients are aware of the method, understand its attributes, and learn how to use it correctly. The method has to actually be offered in the service site – information about it needs to be available in the waiting room, educators need to give clients information about it, community outreach activities need to include it, and providers need to mention it (in an accurate, unbiased manner) among all methods available. Providers need to be competent to offer the method, which requires training and supportive supervision; and they need to have an unbiased attitude about the method to ensure that they give the client balanced information.

Figure 1: Strategic Approach to FP Method Introduction



The Strategic Approach also considers three categories of environmental factors that may affect the decision to introduce a new FP method as well as the ultimate success of the method in attracting users: Policy, Society, and Economy. These three factors are beyond our control and thus were not studied directly. However, we attempted to observe and document how they influenced the availability and use of FAM in general and SDM in particular in the study context.

For example, with regard to **Policy**, the fact that Title X legislation requires that recipients of its funds provide a wide range of methods, including FAM, could positively influence the availability of SDM in Title X-funded services. However, for programs to fully integrate the method, it is important that they see the potential for FAM in general, and SDM in particular, to meet client needs, and that they consider it feasible to offer in the context of routine services. **Society** (which, in this case, includes key stakeholders whose opinions can affect the way FAM is perceived, how information is communicated, and how it is "positioned" as a FP choice) also can influence positively or negatively the availability and use of FAM. With regard to **Economy,** the fact that Title X

funds can be used to reimburse for FAM counseling, that training and counseling are relatively brief (no longer than that required for any other method, particularly as there is no need for re-supply visits), and that the cost of CycleBeads and other materials to support counseling and use of the method are low, all suggest that economic factors are favorable for successful SDM introduction.

IV. Study Design

The focus of the research was to evaluate the integration of SDM into existing services in Title X clinics and examine SDM uptake, provider and client perceptions regarding SDM, and satisfaction of SDM users with their method in this context. The project partners, study questions, and research methods are described below.

A. Research Partners

Led by Georgetown University's Institute for Reproductive Health, this study was implemented in conjunction with Cardea Services (formerly the Center for Health Training) of Oakland, CA, and JSI Research and Training Institute of Boston, MA. Cardea and JSI are the Title X Regional Training Centers for Region I and Region IX, respectively.

Cardea assisted three service delivery agencies – the Southwest Community Health Center[3] (SCHC) in Santa Rosa, California; Planned Parenthood Mar Monte's (PPMM) Modesto Health Center[4] in Modesto, California; and Marin Community Clinics[5] in Novato and San Rafael, California – to integrate SDM into their services (Figure 2). JSI worked with Health Quarters,[6] a non-profit provider of reproductive health care in Northeastern

[3] **Southwest Community Health Center** was, at the time of this research, a non-profit, federally qualified health center providing comprehensive health care to uninsured and underinsured people in the greater Santa Rosa area regardless of their ability to pay.

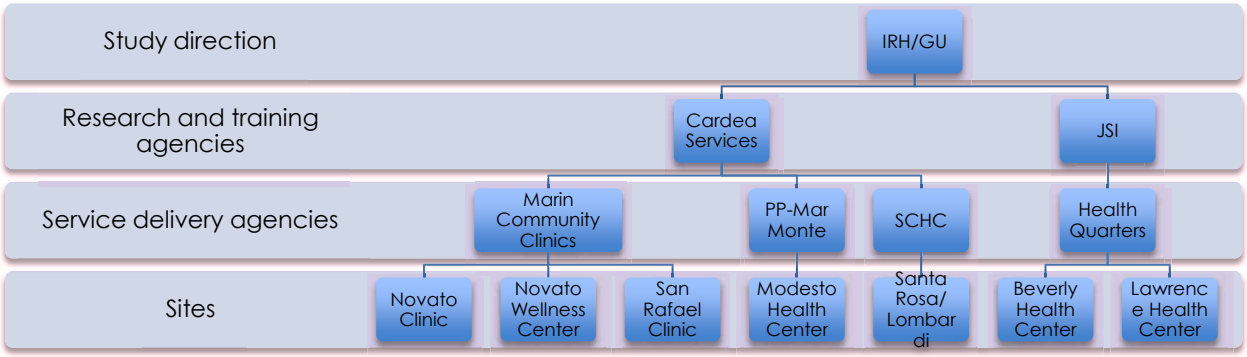
[4] **PPMM** clinics provide confidential reproductive health services including family planning, emergency contraception, testing and treatment of sexually transmitted infections, HIV testing and counseling, pregnancy tests, gynecological exams, and cancer screening.

[5] **Marin Community Clinics** is an independent non-profit organization and a federally qualified health center that provides quality primary care to uninsured residents living in the urban areas of Marin County, located north of San Francisco.

[6] **Health Quarters** is an independent, non-profit provider of confidential reproductive health care, prevention, and education services for low-income women, men, and teens in Northeastern Massachusetts. It offers medical and prevention services including gynecological and testicular exams, family planning and emergency contraception, cervical and breast cancer screening, sexually transmitted disease testing and treatment, and HIV and pregnancy testing and counseling.

Massachusetts, to integrate SDM into two clinics in its network. In addition to overseeing the training activities with the agencies, Cardea and JSI carried out the majority of the data collection under the direction of IRH.

Figure 2: Study organizational chart



Initially, the SCHC and PPMM were the only two California-based agencies that were part of the study. However, it became clear one year after the beginning of the study that SCHC would not be able to complete all that was required of them as an implementing agency in the study. For this reason, they left the study, and Cardea Services identified Marin Community Clinics (MCC) as an alternative partner. Therefore, with SCHC, we have collected needs assessment data and some SDM client interviews, but no other evaluation data. We started an accelerated needs assessment phase with Marin Community Clinics in January of 2010. It should be noted that MCC's Novato Wellness Center is a satellite family planning and teen clinic from the main Novato clinic; the two sites share staff. SDM was integrated into the services at both clinics, although most of the evaluation activities in Novato took place at the Novato Wellness Center.

B. Research Questions

The primary hypothesis for the study was that **the number of FAM users in participating clinics would increase as a result of SDM integration into clinic services**.

We used service statistics to determine the number of FAM users, and other methodologies, including simulated clients and interviews with providers and FAM users, to examine the factors influencing successful integration of SDM and method use. Because the study aimed to evaluate the effect of offering SDM on clients and on SDM use, we also examined the following study questions:

- Does including SDM among FP options increase the number of clients who choose FAM and/or the percent of FAM method users among the programs' clientele?
- Do clients who choose SDM continue to use it? Why, or why not?
- Do clients who discontinue SDM use another FP method? Which method do they choose (e.g., another FAM, oral contraceptives, condoms, etc.)?
- Is client satisfaction similar for users of SDM and other methods?
- How does use of SDM influence couples' relationships?

As described in Section III, the Strategic Approach to FP integration includes a needs assessment phase, which allowed us to consider additional questions of interest, including:

- How is information about FAM disseminated in outreach, education and counseling? Does that change when SDM is included via the Strategic Approach?
- How do FP providers and clients perceive FAM? How does that change when SDM is included in the program through the Strategic Approach?
- What are individual and institutional barriers to offering FAM? How can these barriers be overcome by including SDM through the Strategic Approach?

Further, because the effect on clients of offering SDM is closely linked with providers' attitudes toward FAM in general and SDM in particular, as well as with provider competence to offer the method, the study also addressed the following questions regarding the effect on providers of including SDM in the services they offer:

- Does training providers in SDM result in their achieving and retaining a sufficient level of competence to offer SDM services?
- Does engaging providers as active participants in the Strategic Approach improve provider attitudes toward FAM and SDM?

C. Methods

Figure 3 summarizes the data collection elements of the study, as they relate to program activities in the three phases articulated by the Strategic Approach. The data elements are described in detail below.

Figure 3: Data collection and program activities

	Phase 1 Needs assessment		Phase 2 SDM integration and evaluation				Phase 3
Data elements	Pre SDM integration			Process evaluation		Outcome evaluation	Post integration
Site assessment	√	Tailor SDM integration activities based on needs assessment results	Fully integrate SDM into existing services in participating clinics		Modify integration activities based on results of fidelity research		Use of research results for policy and planning
Provider & staff interviews	√					√	
Client focus groups	√						
Simulated clients				√			
Waiting room questionnaire	√						
Client follow up						√	
Service statistics	→	→	→	→	→	→	

PHASE 1: Needs Assessment

Research regarding the needs of clients, providers, and programs, as well as the current status of FAM services, perceptions, and use, is an integral part of the Strategic Approach to method integration. Therefore, prior to SDM integration, we assessed potential clients' knowledge, needs, and desire for FAM; provider knowledge, skills, attitudes and practices regarding FAM; service delivery systems and outreach activities in the selected clinics to determine how FAM is integrated into the services they offer; individual and institutional barriers that may hinder SDM uptake and use; and opportunities and challenges to adding SDM to the method mix. Results of the needs assessment were used to tailor the implementation plan to the specific context so as to maximize the impact of SDM integration activities. Results also served as baseline data, to better evaluate the impact of SDM integration.

The needs assessment consisted of the examination of service statistics from the previous year, a site assessment, provider interviews, focus groups with potential clients, and waiting room questionnaires.

Service statistics for the year prior to the start of study activities were analyzed to determine the extent of FAM use in participating clinics (% of new FP clients who chose FAM).

Site assessment: Study staff from Cardea, JSI, and IRH conducted a rapid assessment of participating clinics to determine current FAM-related activities, including available materials, clinic protocols, client intake and triage systems, and information, education, and

communication (IEC) strategies currently in use for other methods. Structured interviews with clinic managers shed more light on these and on other characteristics of service provision in the clinic.

Provider interviews: Brief semi-structured interviews were conducted with staff from the participating clinics (including clinicians, counselors, administrators, front desk personnel, and outreach staff) to assess FAM knowledge and attitudes and to explore interest in incorporating SDM into their programs. Potential barriers to SDM introduction such as provider preference for provider-dependent methods and distrust of FAM, as well as service delivery-related issues including perception of the amount of time and effort needed to provide FAM, were explored. Possible outreach approaches and materials were also discussed.

Community-based focus groups with potential clients: Outreach staff from participating service delivery organizations identified potential FP clients to be included in focus groups. Participants included women of reproductive age who were married or in union. We tried to achieve a balance between women currently using a FP method and those who were not. Focus group discussions explored FAM needs, perceptions, acceptability, and barriers to use, as well as socio-cultural factors that influenced family planning and FAM perceptions and use. Focus group guides were adapted to the current context from those used by IRH in related studies. Sessions were conducted by a moderator, and an observer took notes.

Waiting room questionnaires: We conducted a self-administered survey of clients in clinic waiting rooms to collect baseline information that could later be compared to information provided by SDM clients. All clients who chose to complete the form over a two-month period were to be included, to reach approximately 100 clients from each clinic. To maximize participation, the questionnaires were handed out to clients by front desk staff, who then collected the completed forms. The questionnaire included questions about fertility awareness, FP method use, method satisfaction, and basic socio-demographic information.

Results from the needs assessment were shared and discussed among all study partners and utilized to tailor SDM integration into services.

PHASE II: SDM Integration and Evaluation

Once SDM was integrated into clinic services, the fidelity of integration activities was tested to ensure that activities were correctly implemented and to gather information for the

clinics to improve their services. Evaluation activities were then conducted to test the study hypothesis and answer the research questions listed above.

a. Fidelity of SDM Integration

Major obstacles to successfully integrating a new FP method are the willingness and ability of providers to offer the method, and retention of competence in method counseling over time. To test these, we used simulated clients to gauge provider compliance and competence in SDM counseling at least three months after providers were trained in offering SDM. Using this methodology, trained simulated clients approach service providers seeking FP services. In most cases, the provider will believe that he/she is providing services to a real client. Immediately after the visit, the simulated client completes a checklist that measures provider behavior and attitudes, and describes the amount of information exchanged during the session. This information was then used to strengthen provider knowledge and/or compliance in the weak areas.

Before the simulated client visits, all providers in the participating clinics were informed about the simulated client visits and signed an informed consent form. The form provided information about the study and explained that they may be visited by a simulated client in the next few months.

We developed three profiles, all for women who desired a FAM: 1) a woman who was an appropriate candidate for SDM, 2) someone who would have difficulty using FAM correctly due to a violent/controlling partner, and 3) a woman whose menstrual cycles were out of the appropriate range for SDM use. Each of the participating clinics would be visited once for each profile, for a total of three visits per clinic. As the study progressed, we developed a fourth profile of a woman who was unsure of her cycle length, because providers identified this as an issue during the needs assessment phase.

b. Outcome evaluation

Data collection strategies for the outcome evaluation included service statistics, follow up interviews with SDM clients, and post-integration interviews with clinic staff.

Service statistics: Our primary hypothesis stated that as a result of SDM integration, the number of FAM users in participating clinics would increase. We analyzed service statistics routinely collected by Title X grantees to measure the number of individuals who chose to use FAM before and after SDM integration.

Client follow up: Clients who chose SDM were invited to participate in the study by clinic staff immediately after receiving SDM counseling, and were provided an IRB-approved study invitation form. For SDM clients who agreed to participate, we followed them for up to one year of method use, interviewing them at admission, then three, six, and 12 months after admission. Interviews included questions on continued use of the method, satisfaction with it, changes in the couple relationship, correct use and problems using the method. These would allow us to identify predictors of successful use of the method among Title X clinic clients.

Clients could choose SDM without participating in the study. The services clients received at the clinics were not influenced by their participation (or refusal to participate) in the study.

Our goal was to recruit at least 200 SDM users to the study over a 10-month period. We knew this would be a challenge because SDM was a new method that clients weren't aware of and because clinic staff had competing priorities beyond recruiting clients in to the study. As described later in this report, we did not reach this goal. In spite of the smaller sample size, the client interviews provided insight into SDM use patterns and satisfaction. To minimize loss to follow up, we provided a small incentive (in most locations, a gift card to a local store) to participants for each interview completed. Interviews were conducted by trained Cardea and JSI staff. Forms were sent to IRH for data entry and analysis.

Staff interviews: About a year after staff training, JSI and Cardea conducted a second round of provider and staff interviews, similar to those conducted during the needs assessment phase. These allowed us to compare changes in attitudes following SDM integration and provided additional information used to develop recommendations for future FAM integration. Table 1 summarizes the main variables and data sources.

Table 1: Variables and data sources

VARIABLE	DATA SOURCE
Number of clients choosing to use SDM	Service statistics
Percent of SDM users among program clientele	Service statistics
Continued use of SDM	Client follow-up interview
Client's satisfaction with SDM	Client follow-up interviews
Client's satisfaction with other FP methods	Waiting room questionnaire
Changes in quality of couples' relationship	Client follow-up interview
Provider perceptions regarding SDM	Provider interviews
Barriers to offering FAM	Provider interviews
Provider ability to offer the method correctly	Simulated clients
Providers actually offering the method	Simulated client

V. Needs Assessment Findings

The needs assessment phase took place in 2009 at Health Quarters, SCHC, and PPMM-Marmonte's Modesto Health Center. It took place in 2010 at Marin Community Clinics. Findings from the needs assessment components are described below.

A. Service statistics

Service statistics for the year prior to the start of study activities were reviewed to determine the extent of FAM use in participating clinics. Of the 13,923 female family planning clients served by the study clinics[7] from January to December, 2008, only two FAM users were reported. These users were categorized generally as "FAM" users on their Family Planning Annual Report for Title X; the specific method each client used was not indicated.

These data indicate that the number of FAM users from each of the participating clinics was negligible prior to SDM integration. This is likely because no fertility awareness-based method was institutionalized or systematically offered at these clinics at that time. However, since some providers reported teaching about FAM and/or distributing CycleBeads during staff interviews, FAM use is likely underreported. Nevertheless, there was the potential to see a significant increase in the number of FAM users once SDM was introduced.

B. Site assessment

A rapid assessment of each clinic was conducted through interviews with clinic managers to assess the feasibility of SDM integration and determine current FAM-related activities.

Study staff discussed a range of issues with the managers including client intake and triage systems, protocols for follow-up visits for new FP users, billing systems, and information, education, and communication (IEC) strategies currently in place for other methods. They also discussed the role of each type of staff in SDM integration, how SDM would fit into family planning counseling, what forms would be used or created to document and/or

[7] Clinics included in this statistic were Health Quarters Lawrence and Beverly sites, Planned Parenthood Mar Monte Modesto Health Center, and Southwest Community Health Center. Marin Clinics (the Novato and San Rafael sites combined) had 2514 unduplicated female users in 2009 (the year before they joined the study) but did not track FAM users separately as they did not join the Title X program until late 2009.

consent SDM users, type and duration of SDM training, how SDM may be incorporated into educational materials and outreach activities, paying for SDM clients, CycleBeads storage, and how clinic relationships with external organizations could help or hinder the integration process.

A structured site assessment guide (Appendix A) was adapted from IRH's work overseas. A breakdown of findings from the site assessment by clinic are presented in Appendix B. Overall observations include:

- *Population served*: Mostly low-income, culturally-diverse, Spanish-speaking. **Exception**: Health Quarters-Beverly, which serves a mostly Caucasian population with a large number of college students.
- *Services*:
    - Most of the clinics are reproductive-health focused. **Exception**: Marin Community Clinics offers primary care. However, its satellite site, the Novato Wellness Center, is reproductive health-focused.
    - The client first sees a medical assistant for initial family planning counseling before seeing a clinician.
    - FAM is not formally offered; patients who request a natural method are referred to the clinician, who may discuss BBT, Billings, or Calendar methods with the client.
    - Appointments are scheduled every 15-20 minutes, with flexibility.
- *Fees*: For clients paying out-of-pocket, a sliding fee scale is available. For California clinics, most clients are covered by Medical and Family PACT reimbursement programs. For Massachusetts clinics, most clients are covered by the state, Title X, or private insurance.
- *Community outreach*: Outreach budgets are typically small. Community outreach efforts are centered around exhibiting at local health fairs and doing community talks.

Overall, the site assessments suggested that there would be no major problems to integrate SDM into service delivery systems in any of the clinics, as the flow for an SDM client would be similar to that of any other family planning client, with the bulk of the counseling being done by a medical assistant, health educator or counselor, followed by an exam if requested by the patient and any additional counseling done by the clinician.

Financing was not an issue at this time because clinics could be reimbursed for counseling time for SDM and because CycleBeads were donated by IRH. However, CycleBeads procurement was identified as an obstacle to future integration and scale up because CycleBeads are not covered by insurance plans.

Many counselors and clinicians utilized multi-method counseling aids (such as handouts or posters) to guide them in their counseling. While these came from outside the organization and could not be altered, SDM-specific educational materials and posters could be provided to all of the participating clinics to serve as supplemental counseling aids.

Together, study staff and the clinic managers identified the steps that would be required to incorporate SDM into clinic systems, including how to document and bill for FAM users and CycleBeads storage, and made took the steps appropriate for each agency. Clinic staff provided input into the development and adaptation of informational materials to be used in the clinics, including job aids, client brochures, and posters.

C. Staff interviews

A total of 37 health center staff involved in providing family planning services to clients were interviewed from the study clinics prior to SDM integration (Table 2). This group included 14 clinicians, four nurses, 17 counselors and health educators (including medical assistants), and two administrative staff. Interviews were conducted by Cardea, JSI, and IRH staff using an interview guide (Appendix C), and most questions were open-ended.

These interviews revealed that FAM availability at the clinics was limited. At most of the clinics, the non-clinical staff (medical assistants, counselors, and health educators) lacked information about FAM and therefore were not able to offer it. If a client requested a natural method, the counselor would refer the client to the clinician.

Table 2: Number of pre-integration staff interviews conducted at each site, by role

	CLINICIANS	NURSES	COUNSELORS/ HEALTH ED.	ADMINISTRATIVE STAFF	TOTAL
Health Quarters – Beverly	1	-	2	-	3
Health Quarters – Lawrence	1	1	4	-	6
Southwest Community Health Center	3	-	4	-	7
Planned Parenthood Mar Monte – Modesto	3	2	3	-	8
Marin Community Clinic – Novato Clinic and Wellness Center	2	-	1	2	5
Marin Community Clinic – San Rafael	4	1	3	-	8
Total	**14**	**4**	**17**	**2**	**37**

Most of the clinicians indicated they had experience offering FAM or NFP but did not offer it on a regular basis. As one clinician said, “This is not part of my counseling routine, but if

someone wanted it, I'd go over it." Some clinicians had their own way of teaching how to use NFP and gave calendars to patients to track their menstrual cycle. Others offered FAM such as Basal Body Temperature and the Billings Method to interested clients. A few had undergone training on SDM and had given out CycleBeads.

Factors that could influence SDM integration

In general, staff at all of the clinics were in favor of offering a FAM – and in particular, SDM – in order to meet the needs of their clients seeking such a method. "The more options available to our clients, the better," was a sentiment echoed by staff at all of the sites. Nearly all providers said they would be comfortable offering SDM and having their clients use it, although some added a caveat, such as, "as long as the client is comfortable with the risks involved and has all the information necessary," and, "as long as the patient is responsible."

QUOTES FROM CLINIC STAFF:

"We have patients who do believe in birth control but don't like the hormones."

"CycleBeads are definitely a step up from using nothing."

"The more options available to our clients, the better."

"Those who have a sense of their own empowerment would readily accept it."

However, some of the clinicians were skeptical about the effectiveness of FAM. One said that she would offer FAM only to someone who couldn't use hormones or was seeking pregnancy. Another stated that FAM was "better than not using anything." Some of the staff had concerns about their clients' interest in and ability to use SDM. They thought that lower effectiveness rates for FAM compared with hormonal methods might discourage potential users, and that clients' general lack of fertility awareness might result in a lack of confidence in the method.

The main facilitating and constraining factors for SDM integration mentioned by staff are summarized in Table 3.

Table 3: Factors cited by providers that could affect SDM availability and uptake

FACILITATING FACTORS	POTENTIAL CONSTRAINING FACTORS
• Interest in offering FAM to expand options • Enhanced ability to meet needs of clients seeking a natural or non-hormonal method • Characteristics of method - easy to use, cost effective, and promotes body awareness	• Uncertainty about patient demand • Cultural and partner issues; "machismo;" inability of some clients to negotiate sex and/or condoms • Lack of fertility awareness among clients • Clients might forget to move the ring on CycleBeads every day • Lack of confidence in the method among staff and/or clients

In particular, the PPMM-Modesto site serves a large Hispanic and Catholic population among whom staff felt the method would be well accepted. Modesto staff also mentioned that the method might appeal to migrant workers because the method requires no follow-up or resupply. At the Lawrence site, providers suggested that members of the first generation Latino immigrant community might be particularly interested in the method. Outreach staff at the Lawrence site said they had already been talking about the method in community talks and found that it has sparked interest, saying "people are always very eager to hear about it when I bring it up."

D. Community-based focus groups

Outreach staff from participating service delivery organizations identified potential FP clients – in this case, women who were either not using a family planning method or who were less than satisfied with their current method – to participate in community focus groups. Participants were recruited through flyers posted in the clinic and at public locations such as grocery stores; online via Facebook and Craig's List; and word of mouth. Participants included women of reproductive age who were married or in union. Some participants were currently using a FP method, and some were not.

Seven focus group discussions were conducted, with a total of 64 participants ranging in age from 18 to 45 (Table 4). Study staff were unsuccessful in their attempts to recruit participants for focus groups in Novato, CA, due to lack of community response to postings. There was no Spanish focus group conducted in Beverly, MA because the clinic serves a primarily English-speaking population.

Table 4: Number of participants in each focus group

	SANTA ROSA, CA (SCHC)	MODESTO, CA	LAWRENCE, MA	BEVERLY, MA	SAN RAFAEL, CA
English FGD	3	3	7	6	9
Spanish FGD	11	11	5	-	9
Total	**14**	**14**	**12**	**6**	**18**

Focus group discussions explored FAM needs, perceptions, acceptability, and barriers to use, as well as socio-cultural factors that influence family planning and FAM perceptions and use. Sessions were recorded. A moderator from Cardea Services or JSI conducted the sessions using a focus group discussion guide designed for this study (Appendix D), and another Cardea or JSI staff member took notes.

Knowledge about fertility

Focus group participants were asked when a woman could get pregnant. Although many participants believed that a woman is fertile during certain times of the month, most participants lacked correct knowledge about when a woman is fertile. Some participants said a woman could get pregnant when a she is ovulating and/or around the middle of her cycle. However, many participants did not know when a woman is fertile. Responses to the question of when a woman can get pregnant included:

- Every day but her period
- Before you get your period
- After you get your period
- Fourteen days before your period
- A few days after you get your period
- Most days except for one or two days

It was clear from the discussions that there was a general lack of fertility awareness knowledge.

Family planning practices

Participants were asked about family planning practices among the women they know. Participants indicated that commonly used methods included the pill, patch, shot, ring, IUD, and condoms. Traditional non-hormonal methods were also mentioned, including withdrawal, "counting days," and drinking diluted camphor.

Participants explained that there were many women who wished to avoid pregnancy but did not use a family planning method. Reasons for not using a method included the following:

- Fear or dislike of side effects like weight gain, mood swings, nausea, and irregular bleeding
- Lack of knowledge about available methods
- Lack of time or motivation to either go to the clinic or use a method
- Religious beliefs
- Lack of confidence in birth control due to past method failures
- Partner issues including reluctance to use condoms and disagreement over whether to prevent pregnancy
- A belief that they would not get pregnant *("They think…it won't happen to them."*)

Participants also listed problems that women they know have experienced with methods that made it difficult for them to use their method correctly and/or to continue method use.

These included forgetting to take the pill, experiencing the ring move around during intercourse, and feeling that condom use was inconvenient and reduced spontaneity.

> "Me personally, I never have the time to go to the doctor to get birth control and I didn't have any health insurance for a period of time."
>
> "I've tried a couple of different birth controls and I haven't liked a lot of them. I have bad reactions."
>
> "For some women, methods do not work, so they don't want to use anything."

Participants felt that there was a need for additional birth control options. They were asked what the characteristics of an ideal method would be. Responses included:

- No side effects
- More natural
- Non hormonal
- High effectiveness
- Not invasive
- Does not involve daily use
- Involves men
- Long duration

> "Oh yes, we need something new. At least, I am tired of the pill."
>
> "I don't like the idea of something in me all the time and that I can't take out."

Opinions about SDM and CycleBeads

Participants were given an introduction to SDM and CycleBeads and asked for their opinion of the method. The general response was positive. Some participants said they would choose the method because it does not have hormones. They thought the method would be good for learning about one's cycle and involving men. Some women, however, said they would be hesitant about using the method because they wanted greater protection from pregnancy. There was also a concern that many women may wish to use the method but have menstrual cycles that don't fall within the range specified for SDM use, and that some women might be forgetful and/or might not use the method correctly.

A summary of participant's responses regarding why women would or would not use the method is provided in Table 5.

Table 5: Suggested reasons for use or non-use of SDM according to focus group participants

WHY WOMEN WOULD USE IT	WHY WOMEN WOULD NOT USE IT
• No side effects • Natural • Nothing to put in your body • Easy to use • Simple • Involves men • Economical • Reusable and long-lasting • Good for understanding one's cycle • Good for women who were not too worried about pregnancy	• Prefer a more effective method or lack confidence in method • Out-of-range cycles • Lack of understanding of the menstrual cycle • Dislike of condoms (during the fertile days) • Difficulty remembering to move the ring • Teenagers would not use it because (perception that) they are not as responsible • No protection from sexually transmitted infections • Not trendy right now

When asked what men would think about this method, some participants said they thought men would like it because it did not require additional action on their part (e.g., using a condom, taking something, paying for something). Some thought that men would like it because they would only have to use condoms or withdrawal during the 12-day fertile window. Participants said they thought that having a visual tool like CycleBeads would spark communication about sex and fertility within the couple and would help the man to learn about and understand the method.

However, participants thought that some men might not like it because they would want greater protection against pregnancy. Participants said that it was important to educate men on the method, that both the woman and her partner should agree to use the method, and that there should be trust and open communication within the couple in order to successfully use the method.

Comments from focus group participants about SDM/CycleBeads and…

Fertility awareness:

"I always wanted to do the calendar thing, but I never knew how to do it."

"It's a great educational tool if anything. I never knew, none of us knew, the exact dates [when a woman can get pregnant]."

Using a "natural" method:

"I think the biggest thing is no side effects."

"I think it's a good thing not to have additional chemicals added to your body."

"My sister might like it – she's a vegetarian and rides her bike."

"It's great that you don't have to keep buying a method, only if you want to use condoms for those 12 days. It's also good that you are not creating garbage."

"I like that it is less wasteful and cheaper in the long run."

Ease of use:

"Compared to other methods, the amount of responsibility required to remember it is so low, which is awesome. This would totally work for me."

"It's natural, easy, simple. I can ask my partner, 'Honey move the little thing for me.'" [Referring to the black ring]

Potential problems:

"Well, there will be some [people] that would need convincing, but if you explain to them how it works, like how you are teaching us, I think they will use it too."

"I think I would worry about having unprotected sex at any point – it is nerve wracking to me."

"My cycle is irregular, so this method wouldn't work for me."

"Many men won't use condoms, so there would be risks on those white bead days."

"I do like it, but I'd rather it be an app on my phone; I'm really into electronic gadgets."

[Note: Since this interview, the iCycleBeads smartphone app has become available.]

E. Waiting room questionnaires

A self-administered survey of clients in clinic waiting rooms was conducted to collect baseline information that could later be compared to information provided by SDM clients. While the waiting room questionnaire was technically part of the impact evaluation (Phase 2), it was done during the needs assessment period before the start of the integration of SDM into clinic services.

To maximize participation, the questionnaires were handed out and collected from clients by front desk staff. The questionnaire (Appendix E) included a fertility awareness question to gauge what clients knew about when during her cycle a woman could become pregnant. Clients were then asked if they were currently using a FP method and whether they were satisfied with their chosen method. Basic socio-demographic information was also collected. A total of 594 questionnaires were completed (Table 6).

Table 6: Number of questionnaires completed, by clinic

CLINIC	# OF QUESTIONNAIRES COMPLETED
Health Quarters - Beverly	115
Health Quarters - Lawrence	105
Marin Community Clinics-Novato Wellness Center	100
Planned Parenthood MM-Modesto	99
South West Community Health Center	175
Total	**594**

The majority of respondents (55.1%) were between the ages of 20 and 30 years old, while 19.7% were under 20, and 25.2% were 31 and above. Some 49.5% of respondents had graduated high school; an additional 31.4% had completed college. Approximately 46% spoke English as their primary language at home; 30.5% were Spanish speakers and another 22% spoke both English and Spanish at home.

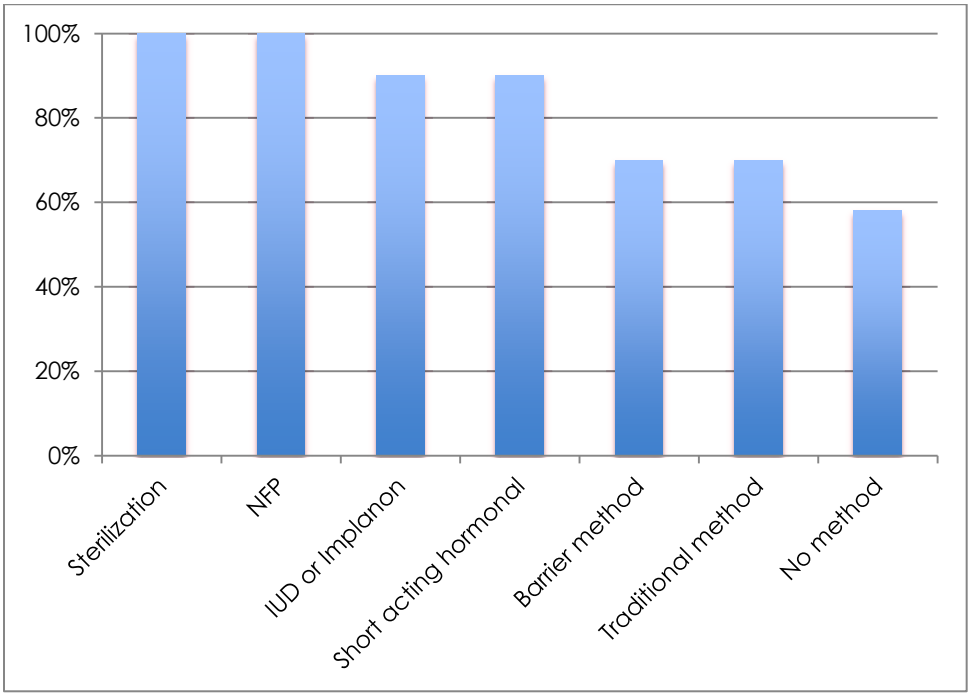
The majority of respondents had children – specifically, 21.5% had one child, 26.2% had two or three children, and 5.7% had four or more children. The rest (46.5%) had no children. The majority (56.5%) expressed a desire to have (more) children in the future. Respondents used a variety of family planning methods, as indicated in Table 7.

Table 7: Methods used by respondents to waiting room questionnaire

METHOD	NUMBER	PERCENTAGE
Short acting hormonal (pill, patch, ring, shot)	219	39.2
Nothing	144	25.8
Barrier	78	14.0
IUD or Implanon	75	13.4
Sterilization	22	3.9
Traditional (withdrawal or rhythm)	16	2.9
NFP	4	0.7
Total	**558**	**100%**

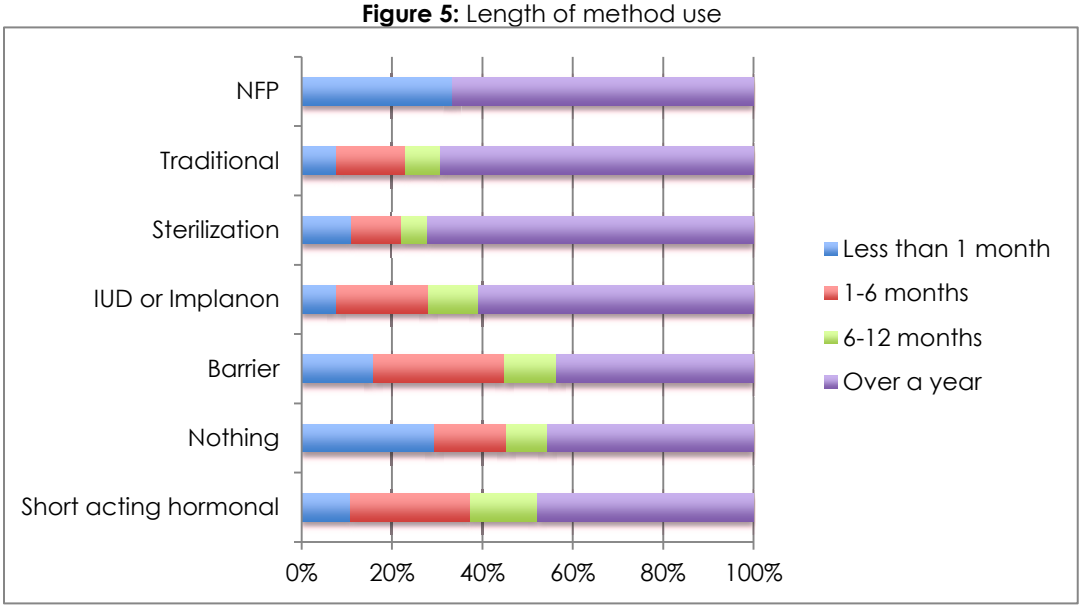
When asked how satisfied they were with their current method, 84.9% of respondents claimed to be satisfied or very satisfied. Only 371 respondents answered this question, with over 220 respondents leaving this question blank. As shown in Figure 4, the highest reported levels of satisfaction were with sterilization and NFP (100%) and with IUD, Implanon, or short acting hormonal method (approximately 90.5%).

Figure 4: Percent of respondents satisfied with current method



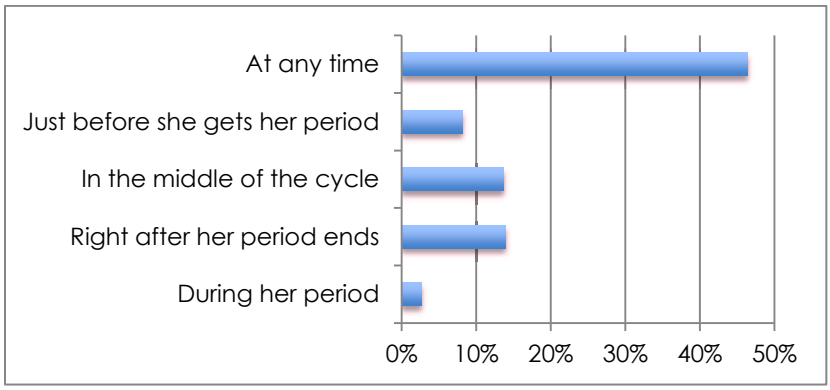
Approximately half of respondents (50.7%) indicated that they have been using their method for over a year (n=406). Figure 5 shows the breakdown by method category.

Figure 5: Length of method use



The questionnaire included a question to gauge fertility awareness. This question was, "In your opinion, when can a woman get pregnant if she is not using any birth control?" Respondents were allowed to check more than one answer. Only 11.6% of respondents gave the correct answer ("in the middle of the cycle," without checking off any other answers), whereas the largest number of respondents (46.4%) indicated that a woman could get pregnant at any time. All responses are shown in Figure 6.

Figure 6: Responses to "When can a woman get pregnant if she is not using any birth control?"



F. Implications of needs assessment

The results of the needs assessment activities suggested that SDM integration would be feasible at all clinics and accepted by providers and clients. The focus group discussions showed that there was a demand for a new method – particularly, for a method with no

hormones or side effects and one that involved men – among communities served by the clinics. SDM would not meet the needs of all women – for example, those who desired a highly effective (99%+) method, whose partners were not amenable to using such a method, or who would forget to move the ring every day. Nevertheless, these results confirmed that SDM integration would be appropriate and would meet the needs of some women seeking a non-hormonal method.

Within the clinics, the relatively low satisfaction levels among barrier and traditional method users as well as non-users, as indicated by the waiting room questionnaire, suggest that there are clients who may be better served by an additional non-hormonal method option.

The mixed responses to the fertility awareness questions by focus group participants and respondents to the waiting room questionnaires suggested a need for education on fertility awareness, for which CycleBeads would be a useful tool. However, lack of understanding of fertility could cause some potential clients to doubt CycleBeads' effectiveness.

Providers at the participating clinics were in favor of expanding options for their clients and open to learning about and offering SDM. While there was some skepticism about the effectiveness of FAM, there was also considerable enthusiasm among providers about the ability to better meet the needs of those clients seeking a non-hormonal or natural method.

From a systems perspective, there appeared to be no barriers to method integration that could not be resolved with minimal effort for the purposes of the study. However, CycleBeads procurement likely would be a challenge in the future as the method was not on insurance formularies or included in government-sponsored family planning reimbursement programs.

VI. SDM Integration

Utilizing the results of the needs assessment, Cardea, JSI, and IRH worked with the service delivery agencies to integrate SDM into family planning services. Following method integration, simulated clients were sent to each clinic to ensure the fidelity of the intervention and provide constructive feedback to the clinics.

A. Integration process

The SDM integration process included three main components: (1) integration into clinic systems and establishment of method-related protocols; (2) staff training and support; and (3) awareness-raising and outreach activities.

(1) Systems integration

To ensure that adequate systems were in place within the service delivery agencies to facilitate the integration of SDM, billing procedures, reporting forms, and clinic protocols for medical services were modified as needed using information from the site assessment. Procedures and/or forms were put in place as needed to document SDM users. IRH sent CycleBeads to each organization, which incorporated them into their supplies and logistics systems. Health Quarters developed a counseling protocol for SDM and included it in their systems. No major changes were required in supervision systems or clinic flow.

A job aid for SDM counseling was adapted from job aids used by other IRH projects with significant input from the clinics to ensure that they were relevant and useful to their clinic's practice. These aids were given to clinic staff and placed in each counseling room (Appendix F). SDM fact sheets were developed for California and Massachusetts to be given to those users who choose SDM as their method or simply want more detailed information on it. Cardea developed the fact sheet used in California in the style of their other fact sheets and was available in English and Spanish (Appendix G). The sheet used in Massachusetts was developed by IRH and Health Quarters, with input from JSI, in the format of all of Health Quarters' method specific brochures, available in English and Spanish.

(2) Staff training and support

Cardea, JSI, and IRH conducted trainings for providers and counselors at each site (Table 8). Where possible, whole-site training was utilized in order to create a supportive environment for offering SDM and to prepare all levels of staff to fulfill their respective roles regarding SDM integration. Although SDM training is typically two hours, these training sessions lasted up to four hours in order to allow time to review the educational materials designed for use by the clinics (job aids and client materials) as well as study objectives and procedures (i.e., how to invite SDM clients to participate in the study). In general, clinic staff preferred shorter trainings. For smaller groups (3-4 people), trainings were tailored to their specific needs and were under 2 hours.

Table 8: SDM Trainings Held at Study Sites

CLINIC/SITE	TYPE OF TRAINING	DATE	NUMBER OF PEOPLE TRAINED	TRAINERS
Health Quarters – Beverly, MA	SDM counseling & study procedures	August 12, 2009	8 (3 clinic staff and 5 administrative staff)	Katherine Cain, IRH Myriam Hernandez-Jennings, JSI
Health Quarters – Lawrence, MA	SDM counseling & study procedures	August 13, 2009	7 (5 clinic staff and 2 outreach staff)	Katherine Cain, IRH Myriam Hernandez-Jennings, JSI
Southwest Community Health Center – Santa Rosa, CA	SDM counseling & study procedures	September 11, 2009	7	Kimberly Aumack-Yee, Consultant Renee Marshall, Cardea
Planned Parenthood Mar Monte – Modesto, CA	SDM counseling & study procedures	September 3, 2009	23	Kimberly Aumack-Yee, Consultant Beatriz Reyes, Cardea
Planned Parenthood Mar Monte – Modesto, CA	SDM counseling & study procedures (for those who missed initial training)	November 13, 2009	4	Beatriz Reyes, Cardea
Marin Community Clinic – Novato, CA (Included staff from Novato's main PHC clinic and Novato Wellness Center, a family planning and teen clinic)	SDM counseling & study procedures	February 25, 2010	10	Renee Marshall, Cardea
Health Quarters – staff from both Beverly and Lawrence sites	Refresher training on SDM counseling & study procedures for all staff including 2 new staff	February 25, 2010	11	Katherine Cain, IRH Myriam Hernandez-Jennings, JSI
Planned Parenthood Mar Monte – Modesto, CA	SDM counseling & study procedures (for new staff who missed prior trainings)	August 6, 2010	3	Beatriz Reyes, Cardea
Marin Community Clinic – San Rafael, CA	SDM counseling & study procedures	September 10, 2010	8	Renee Marshall and Johanna Rosenthal, Cardea

The information gleaned from the providers and counselors during the needs assessment enabled study staff to tailor the trainings to their needs. For example, the trainings emphasized certain items that came up in the needs assessment including SDM effectiveness, how to ensure proper screening of clients, and how to encourage and support correct use and male involvement. The trainings also addressed couple dynamics, taking into account the contextual issues that may inhibit correct use. Since FAM was not part of the counseling routine for many staff, it was stressed that SDM should be incorporated into counseling when all methods are reviewed.

Study staff conducted follow-up visits to sites throughout the year, including attending staff meetings to check in with staff and ensure any questions they had regarding offering SDM were addressed. IRH and JSI conducted a refresher training for Health Quarters after six months because they had some new staff.

(3) Awareness-raising and community outreach

To inform potential clients of the availability of a new method – namely, SDM – at the clinics, it was important to conduct awareness-raising activities both within the clinic and out in the community.

SDM was integrated into IEC materials and outreach activities at clinic sites. The CycleBeads poster (Appendix H) developed by Cycle Technologies (the manufacturer of CycleBeads) was provided to all study clinics for posting within the clinic and around the community.

In addition to the posters, outreach cards were developed for use by the California clinics and Health Quarters (Appendix I). These cards were made available within the clinic and were handed out in the community during home visits, community talks, and health fairs.

Study staff worked with the service delivery agencies' outreach staff to integrate SDM into ongoing outreach efforts targeted to both women and men and to refine outreach strategies to reach communities identified in the needs assessment as those with a high potential demand for the method. Outreach activities included displays about SDM in health fairs and community events, placing information about SDM in public service announcements in community newspapers and social media websites, and engaging the involvement and support of community leaders and other community-based organizations.

Examples of PPMM-Modesto's outreach activities included talks at seven community locations to 269 contacts in January, 2010, and an educational visit to additional location with 50 contacts the following month. A press release in English and Spanish was sent to at least 12 community centers and two local newspapers, including one Spanish language paper.

Health Quarters also engaged in outreach efforts. A sample of their outreach activities is as follows:

- Promoting CycleBeads in Lawrence at community talks, presentations around town, home visits, health fairs (Lawrence Community Works Expo, New England Community College, Catholic Charities) and also at *bodegas* (grocery stores) and beauty salons.
- Sent posters and brochures with cover letter to 33 churches in Lawrence and 26 churches in Beverly.
- Sent posters and brochures with cover letter to holistic health providers and yoga studios in the Lawrence, Salem and Beverly areas.
- Posted fliers in natural food stores, yoga studios, beauty salons, coffee shops, and other women-centric establishments.
- Promoted at six Condom Week tables at local colleges.
- Wrote an article that appeared in the North Shore Community College newspaper and the Salem State Health e-newsletter.
- Sent article in Spanish about SDM integration to two Spanish language papers in Lawrence (*Rumbo News* and *Siglo 21).*
- Included an article about CycleBeads in Health Quarters' email newsletter – sent to 2,000 contacts.
- Mentioned CycleBeads during a radio interview at a Spanish language station (1490).
- Posted link to www.cyclebeads.com from HQ website home page and also linked on Birth Control page.
- Posted message on Health Quarters' Facebook page with link to CycleBeads' Facebook page.

Due to budget restrictions, it was not possible to conduct large scale or mass media communications efforts such as television or radio advertisements.

Promotoras in Lawrence, MA

As the study progressed, in spite of all the efforts by Health Quarters to raise awareness of SDM in the community, SDM user numbers remained low, while Health Quarters' capability to do community outreach decreased due to staff transitions. Therefore, JSI engaged *promotoras* (female health promoters) from another JSI project to conduct outreach and education among Latino residents of Lawrence, Massachusetts.

Three *promotoras* attended a training program conducted by Flor Maldonados of Health Quarters and Myriam Jennings of JSI. They received training on the various methods of birth control and how each method worked, including SDM.

All three *promotoras* lived in Lawrence, were familiar with the city, and in previous projects had conducted educational programs in the city. They hung posters and spoke individually with people in locations where Latino residents gathered. The locations included *bodegas* (neighborhood grocery stores), laundromats, Latino churches, at community events and in public housing.

A second group of five women from several Latino churches who had previously been involved in a JSI environmental health project also were engaged to participate in the project. The women were hired by the *Centro de Apoyo Familiar* – Center for Assistance to Families, a Lawrence based non-profit with office in one of the churches. The training was conducted by Myriam Jennings of JSI. It included the same elements as the training received by the *promotoras*.

These women conducted community outreach and education in several of the Latino churches. One of the women conducted a workshop in her church with 25 women present. The other women reached approximately 40 women by passing out educational cards and speaking with individual women.

The hiring of the *promotoras* appeared to be effective, as Health Quarters noticed an increase in the number of SDM inquiries and clients following the *promotoras'* community outreach efforts.

B. Process evaluation - Simulated Client Visits

We used simulated clients to gauge provider compliance and competence approximately three months after initial training in SDM counseling.[8] Simulated client visits were conducted at Southwest Community Health Center and Planned Parenthood Mar Monte-Modesto in November and December 2009. At MCC-Novato Wellness Center, they were conducted in the summer of 2010; at MCC-San Rafael, they were conducted in the fall of 2010.

[8] The exception to this was at Health Quarters, where clinic staff were at first reluctant to participate in simulated client visits. Once they signed off on the visits, JSI staff had difficulty recruiting women to play the role of simulated clients and then to get trained simulated clients to follow through on their visits. Late in the project – in mid 2012 - two simulated clients were identified and trained, and they each visited the Lawrence clinic. One of them also visited the Beverly clinic but could not be seen due to an administrative issue.

The simulated clients were trained by Cardea, JSI, and IRH staff to play the role of a client who would choose a fertility awareness-based method if given the option, with a pre-determined profile about life circumstances and reproductive health history. Immediately after each visit, the simulated clients completed a checklist to indicate the amount of information exchanged during the session (Appendix J). In all, 18 simulated client visits were conducted (Table 9).

Table 9: Summary of simulated client visits

PROFILE	PROFILE DESCRIPTION	NUMBER OF SIMULATED CLIENT VISITS					
		PPMM-Modesto	**SCHC**	**MCC-Novato**	**MCC-San Rafael**	**HQ-Lawrence**	**Total**
A	Meets cycle length criteria AND she and her partner can avoid unprotected intercourse on fertile days	2	1	1	1	2	**7**
B	Meets cycle length criteria BUT **partner may not want to use condoms or avoid intercourse on fertile days**	1	1	2	1	0	**5**
C	**Out-of-range cycles**; she and her partner can avoid unprotected intercourse on fertile days	1	0	1	1	0	**3**
D	**Unsure about cycle length**; she and her partner can avoid unprotected intercourse on fertile days	1	0	1	1	0	**3**
	TOTAL No. of Visits	**5**	**2**	**5**	**4**	**2**	**18**

A summary of the results from the visits is as follows:

Profile A: Simulated clients for this profile represented ideal candidates for SDM, with cycles the right length to use the method and the willingness and ability to avoid unprotected intercourse. Out of the seven simulated clients who fit this profile, six left their appointments with CycleBeads in hand; the other one was informed about the mucous method and advised to "Google" CycleBeads. Of the six who got CycleBeads, there was a noticeable lack of questions about the woman's partner; one of them was not screened completely; and incomplete method information was given to one of them. For the most part, however, the clients who left with the method received good counseling and instruction on how to use CycleBeads.

Profile B: Simulated clients for this profile represented women whose menstrual cycles were the right length to use SDM but whose partners were unwilling to use condoms or avoid intercourse during the fertile days. Although all five simulated clients were screened (including being asked if they and their partners would be able to avoid unprotected intercourse on the fertile days), all of them walked out of the clinic with CycleBeads. Although it was possible that some of the clients did not emphasize enough their partners'

unwillingness to use condoms or avoid intercourse during their presentation at the clinics, it is also possible that the providers did not take seriously enough their comments about their partners. At least a few of these simulated clients should have not been offered SDM and instead should have been counseled on other methods.

Profile C: These simulated clients played the role of a woman who could (along with her partner) avoid unprotected intercourse on the fertile days, but who had menstrual cycles that were not regularly in the 26-32 day range required to use SDM. One of them was not screened properly, received CycleBeads, and was told she could start using them right away. The other two were given CycleBeads but told to wait and track their menstrual cycle before relying on them as a birth control method.

Profile D: These clients would have no problem avoiding unprotected intercourse during the fertile days, but were unsure about their cycle length. One of them left the clinic with no method; another was given pills to try (the provider thought pills would be good for her because she was African American); and the other received CycleBeads but received poor counseling on their use and was referred to the CycleBeads website.

Overall, the simulated client visits revealed strengths and weaknesses pertaining to SDM counseling. A main strength was that the vast majority of simulated clients received good information on how to use CycleBeads. The main weakness was that some providers did not adequately screen the client, or did not respond appropriately upon hearing the client's response to screening questions.[9]

The results of the simulated client visits specific to each clinic were shared with each agency in an effort to improve services. Study staff reinforced the key screening and counseling messages and reviewed how to handle various client scenarios with staff during staff meetings at the respective clinic sites.

It should be noted that the initial two simulated client visits to SCHC revealed problems at the site, including poor service on both the administration/front-desk end as well as during counseling. Management was informed of these difficulties, although they contributed to the need for study staff to identify an alternate agency to participate in the study.

[9] For women with irregular cycles, the appropriate response would have been to help them find another method. For women who were unsure about their cycle length, this would have meant advising them to track their cycles for a couple months – and teaching them how to do so – before starting CycleBeads. For women whose partners were unwilling to use condoms or avoid intercourse during the fertile days, the appropriate response would have been to help the women choose another method that will work for her until a time comes when her partner is willing to participate in CycleBeads use.

VII. Evaluation Findings

This study used several methods to evaluate the effect of SDM integration. Service statistics were collected each month to evaluate whether SDM integration resulted in an increase in the number of FAM users at each clinic. Post-integration staff interviews were conducted to evaluate provider perspectives following SDM integration and identify barriers to offering FAM. Finally, interviews with SDM clients were conducted to understand SDM use patterns, continuation, and satisfaction.

A. Service statistics

Table 10 presents the number of new SDM users reported at each clinic for the duration of the study, according to service statistics.

Table 10: Number of nonduplicated SDM users from service statistics

CLINIC NAME/LOCATION	# OF USERS	REPORTING PERIOD	AVG # OF FEMALE FP VISITS/YEAR
Health Quarters – Beverly, MA	9	Sept '09-June '11 (22 months)	900
Health Quarters – Lawrence, MA	32	Sept '09-June '11 (22 months)	1,200
PPMM-Modesto, CA	27	Sept '09-July '11 (23 months)	12,000
MCC – San Rafael, CA	41	Aug '10-June '11 (11 months)	10,800
MCC – Novato, CA (main clinic)	28	May '10-June '11 (14 months)	6,000
MCC – Novato Wellness Center (family planning clinic)	61	Mar '10-June '11 (18 months)	1,200
TOTAL	**198**		

The 198 SDM users generated over the course of the study is obviously far greater than the two FAM users that were reported in 2008, prior to SDM integration. It is interesting to note the lack of correlation between clinic size and number of FAM users, as some of the clinics that had smaller numbers of family planning visits per year produced a greater number of SDM users (proportionate to clinic size) than some higher-volume clinics.

While it was not the focus of this study, some participating clinics occasionally gave CycleBeads to women who wanted to achieve pregnancy to help them identify their fertile days. These women are not included in the above numbers and were not invited to be interviewed as part of the study.

B. Staff interviews

A total of 25 clinicians, nurses, medical assistants, and counselors from participating clinics were interviewed after having offered SDM for at least nine months to determine how their perspectives on SDM may have changed after having offered the method and to learn how they incorporated the method into their counseling routine. (See Appendix K for the interview guide.) All participants were female. Table 11 lists the number of participants from each clinic, by profession.

Table 11: Staff interviews conducted during evaluation phase

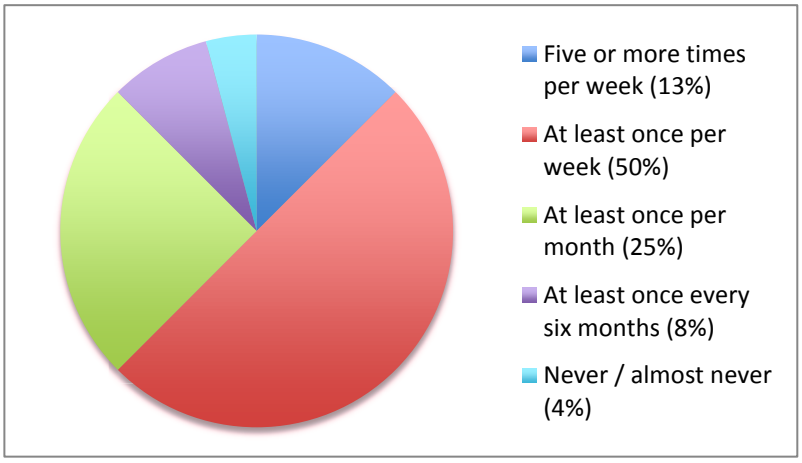
SITE	CLINICIANS	MANAGERS*	NURSES	MA/COUNSELORS	FRONT DESK	OUTREACH	TOTAL
PPMM-Modesto	2	1	1	3	-	2	9
MCC-Novato	1	-	-	1	1	-	3
MCC-San Rafael	1	1	1	2	-	-	5
HQ-Beverly	1	1	-	1	-	-	3
HQ-Lawrence	1	1	-	2	-	1	5
Total	6	4	2	9	1	3	**25**

*In most cases, the managers also saw patients, either clinically or for counseling.

Approximately 95% of respondents indicated that they had discussed SDM with clients since having been trained, and 80% said at least one of their patients chose SDM. When asked how frequently they discussed SDM with patients, 62.5% said they discussed SDM at least once per week (Figure 7).

All of the staff members interviewed (100%) stated that they found it easy (either very easy or somewhat easy) to teach women how to use SDM. About 91% said it was either very easy or somewhat easy to add SDM to their counseling routine. All (100%) said it was either very easy or somewhat easy to process the paperwork for a SDM client.

Figure 7: How frequently staff discussed SDM with clients



Perceptions of SDM and FAM

Staff members generally had a positive attitude regarding SDM and FAM in general. All of them believed SDM was effective enough to offer as a birth control method in their clinic, and all felt that their agency should continue to offer the method after the study was over.

When asked to rate on a scale of one to five how important it was to include a FAM among the method options available at the clinic (one being not at all important, five being very important), the average ranking was 4.58. One third of staff members interviewed believed that patient satisfaction with services increased as a result of SDM integration. (The rest noticed no change or said they did not know.) Approximately 87% of respondents felt that CycleBeads were either somewhat or very useful for involving men in family planning.

The most common reasons staff members gave as to why it was important to offer a FAM such as SDM included the need to offer a wide range of options; the need to provide non-hormonal options for women who desired them; and the need to have a method for women whose religious beliefs left them with few options.

A couple staff members were not as enthusiastic about offering SDM. One nurse practitioner said, "For women in general, it's important to offer [a FAM such as SDM], but for our clientele, it's not the best option." A health educator said of SDM, "It's something new and another option, it's fabulous to have it, but at the same time, STDs, responsibilities, having to remember [to move the black ring on CycleBeads everyday], and what if the partner says 'yes' [to using SDM to prevent pregnancy] but then really wants to get her pregnant. I work a lot in the Hispanic community and they often want to get their wives pregnant."

When asked what type of woman SDM would work best for, one medical assistant said, "Every woman was really different. I didn't notice a particular type of person who chose this method." Other staff listed a variety of characteristics, including the following:

- Committed, monogamous relationship
- Cycles the appropriate length
- "Older women" – mid-20's to mid-40's
- Women who don't do well on hormones
- Women who are motivated, responsible, and mature
- Can communicate with their partner / partner agrees to use the method
- Stable home life
- Familiar with their cycle and/or wants to know about their body
- Already use a calendar-based method
- Have a high-enough education level to comprehend how the method work

Staff members explained why it was important to offer a FAM such as SDM

More choices for clients:

"I need to be able to offer every method possible." – Nurse practitioner

"The more options that someone has, the better. Sometimes we think a particular method should work for everyone, but they should be able to use the method that works best for them." – Manager

"Because we want to offer different options for patients to choose from that will help them not get pregnant and this is an easy and effective method to offer." – Medical assistant

"Patients have mentioned that they appreciate them offering a new method." – Manager

Meeting women's needs:

"There are women out there that cannot take hormones, and there are also women who have religious beliefs that limit the type of BCM they can use." – Health educator

"Many women don't want to use any method and want to be more natural in avoiding pregnancy. There aren't that many, but the ones that are interested are really interested." – Medical assistant

"It opens the doors for people with certain religious backgrounds who don't want to use birth control. Partners are more involved. It gives women a tool to help them say no. A lot of Hispanic men don't like to wear condoms and women don't know how to say no to men. This helps them." – Health educator

"For the few women who got the method they were surprised and satisfied with the CycleBeads." – Registered nurse

Fertility awareness/body knowledge:

"There's such a knowledge deficit about our bodies, and this is such a great way to get people in tune with their bodies. If you don't understand your body, you don't understand how hormonal contraception works. If you understand your fertility, the methods make more sense and it's not such a mystery. There's so much paranoia without much knowledge." – Nurse practitioner

Clinic flow and counseling time

Staff members generally said that SDM integration had no effect on clinic flow. As one medical assistant said, "It [SDM counseling] went with the flow. I would introduce it during intake so the provider didn't have to repeat it."

A minority of staff felt that counseling time was an issue with SDM. One medical assistant said, "It just took a lot more time to talk about it. You explain it because they ask, but they're not always interested. It can be difficult to explain to certain populations – those less educated or who don't read or write." A nurse said, "It takes more time to explain it compared to other methods." However, the majority of respondents did not feel that SDM counseling took more time. As one nurse stated, "It doesn't take any longer to teach someone to use CycleBeads than to use the ring or patch. The teaching/counseling portion doesn't take long."

Barriers to staff being able to offer SDM/CycleBeads

There were four main barriers cited by staff members regarding offering SDM.

1) **Staff forgetting to offer it**. As one manager said in reference to SDM, "Staff forget that we have it." One nurse practitioner said, "We forget [to mention it] because it's not ingrained." Similarly, a registered nurse said, "My biggest challenge has been remembering to offer it."

> "I don't know if you can get funding from Family PACT [CA's family planning program]. Then it would be on more people's radar."
> – Registered nurse
>
> "I think the clinicians need to be more aware of it and to remember to offer it as a method." – Nurse practitioner

   Making SDM counseling aids available to staff did not always help them remember to offer the method, as some staff did not know where to find the counseling aids. One medical assistant said, "I don't know where the job aid is. I don't recall seeing it or the fact sheet in the rooms." A few respondents suggested that it would help them if the method was included on existing method lists and multi-method counseling aids used by the clinic.

2) **Client preference for other methods**. Many clients indicated a preference for another method before receiving information about SDM. As one medical assistant said, "Usually they know what they want when they come in." Also, patients looking for the most effective method available weren't interested in SDM.

3) **Clients not meeting the eligibility criteria**. Staff indicated that many of their clients either were unfamiliar with their menstrual cycles or reported irregular menstrual cycles, often as a result of having polycystic ovarian syndrome (PCOS). Some staff reported a lack of partner willingness to cooperate in method use or an inability for the woman to negotiate sex or condom use. One medical assistant said, "My patients have not been good candidates for the method, so I have not offered it."

4) **Inability to dispense the method during community talks**. Outreach workers from Modesto described encountering many women during their outreach work who were interested in the method – mostly Catholic Hispanic women they met at migrant camps and community centers – but who could not travel to the clinic because they did not have access to transportation or child care. Outreach workers could not give these women CycleBeads because organizational protocol prohibited health educators from distributing any family planning method, including condoms. The manager of this site indicated that they were trying to find a solution to this problem, such as a mobile clinic. However, budget constraints have been an issue.

Barriers for clients to be able to choose SDM

Clients face barriers that make it difficult for them to choose SDM as their family planning method. The four main barriers cited by staff members are as follows:

1) **Do not meet eligibility criteria**. This includes not having cycles within the appropriate range for SDM use; having a partner who is unwilling to avoid unprotected intercourse during the fertile days; and STI risk.

2) **Lack of transportation to the clinic**. As one health educator said, "There are stay at home moms who don't drive – they have to wait for their partners to get home from work to take them [to the clinic]." A manager also said, "A lot of women who live in the rural areas can't get here."

3) **Lack of confidence in the method**. As one medical assistant said about SDM, "[Some] people don't feel it's as safe [as some other methods]."

4) **Lack of community awareness.** Again and again, respondents cited a lack of community awareness on CycleBeads as a barrier for clients to use the method. As stated by a nurse practitioner, "I don't think there's a lot of advertising in the community. I haven't seen it in magazines. We introduce [SDM], but patients don't ask for it because they don't know it exists." As one medical assistant said, "There needs to be more promotion on the method to get the word out."

"They might be interested, but their periods aren't regular." – Medical assistant

"[There is a] lack of partner cooperation, lack of willingness to use condoms, hesitancy to introduce the idea by the female. Women don't feel empowered to say no." – Manager

"If a client says that their partner is not willing to use condoms or abstain from sex then I will offer to have the partner come in and go over the CycleBeads process and how they work with me." – Manager

"Patients should know that CycleBeads are available at the clinic before they even come in for their appointment."
– Nurse practitioner from Mass.

"You really need to get it on the internet or TV, especially for those who don't have access to other forms of birth control or for those who don't have insurance or [who have] no steady access to a provider. It's something you don't have to refill or maintain. [CycleBeads is] long term no-brainer birth control."
- Nurse practitioner from CA

Ideas for overcoming barriers

To raise awareness of the method, staff members suggested mass media communications such as television as well as enhanced community outreach efforts. For raising awareness within the clinic, many staff members indicated that displaying CycleBeads posters where clients could see them was an effective strategy.

> "We have the poster hanging in our waiting room and bathroom, and the clients will reference them when meeting with me." – Manager
>
> "The best way [to raise awareness in the clinic] was having the posters because the patients would ask us about it. If they seemed interested, I would explain [CycleBeads]." – Medical assistant
>
> "Make sure you have plenty of posters everywhere in multiple languages, that materials are available in all exam rooms, and that support staff totally understand the method." – Nurse practitioner

To ensure that staff would not forget to mention the method to clients, one manager gave the following advice to other managers who wish to integrate the method: "Talk about [SDM] every month at every staff meeting. It falls out of people's minds. People were losing job aids. Continually bring it up and talk about it. It's not the most important method, but it's the newest one."

Challenges for clients to use SDM successfully

Many staff members said that they didn't know how SDM users fared with the method because they didn't see them again. Of those who had heard from SDM clients, the most common reported challenges to using SDM successfully or continuing with the method were that the client discovered that her cycles were not in the 26-32-day range, and trouble remembering to move the black ring on CycleBeads.

> "I've had a few patients come back and say their periods weren't as regular as they thought. Usually longer. Most say they're happy with [CycleBeads], though I haven't seen everyone back again." – Nurse practitioner, California
>
> "One [client reported that her] partner said that the last [white bead] day wouldn't be a problem [to have unprotected intercourse]." – Manager
>
> "I personally have not had clients come back that have been using CycleBeads. I know that two women got pregnant while using the method, but they did not come back to talk about what went wrong." – Nurse practitioner, Massachusetts

C. SDM client interviews

Clinic staff invited clients who received SDM to participate in the study and collected their contact information. Study staff from Cardea and JSI called these clients to interview them within two weeks after their clinic visit (admission to the study).[10] Clients were then followed up three, six, and twelve months following their admission interview. (See Appendices L and M for the admission and follow-up interview guides.)

Table 12 lists the number of interviews conducted by site for each time period. Many clients could not be reached for follow-up interviews in spite of multiple attempts to contact them. While Health Quarters' Beverly site participated in the study, none of the clients they recruited could be reached for an interview. Also, the Southwest Community Health Center only recruited clients for a short period of time before the center stopped participating in the study. However, study staff continued to follow up those clients. Clients from Novato came primarily from the Novato Wellness Center.

Table 12: Number of SDM client interviews conducted

CLINIC	ADMISSION	3-MONTH	6-MONTH	12-MONTH
PPMM-Modesto	12	7[11]	6	3
Southwest Community Health Center	4	4	3	1
Marin Community Clinics – Novato	17	7	1[12]	2
Marin Community Clinics – San Rafael	3	0[13]	2	2
Health Quarters – Lawrence	5	3	0	0
Total	**41**	**21**	**12**	**8**

Due to the relatively small number of clients interviewed, the results presented here are not generalizable.

Admission interview

The admission interviews, conducted within one month after a client received the method, provided information on the characteristics of participating SDM users (Table 13), why they chose SDM, and how they heard about the method. Study staff interviewed 41 clients by phone. Over 20 more women who received SDM agreed to participate in the study but could not be reached for an interview.

[10] In some cases, it took up to a month for study staff to reach the clients by phone.
[11] An additional client was not interviewed at 3 months due to a gap in the study's IRB approval that overlapped with the time her interview was due. However, she was interviewed at 6 months and found to be continuing with the method.
[12] For the same reason, a participant could not be called at the time of her 6-month interview but was reached at 12 months and found to be continuing with the method.
[13] For the same reason, two participants from the San Rafael site could not be called at the time they were due for a 3-month interview but were reached at 6 months and found to be continuing with the method.

Of the 41 clients reached upon admission, 36 were using SDM to prevent pregnancy and met the eligibility criteria for method use. Of the other five clients reached, two desired to become pregnant within the next six months, one had become pregnant (unspecified whether intended or not), one decided not use the method because she couldn't remember to move the ring, and the other decided not to use the method because she found it inconvenient to have to avoid intercourse or use a condom during the white bead days.

Table 13: SDM user characteristics (n=36)

AGE RANGE	18-45 (MEAN=27; MEDIAN=26)
Language spoken at home	56.1% English, 24.4% Spanish
Education level	41.1% Completed at least 1 year of university 26.5% Graduated high school 11.8% Graduated vocational/technical school
Religion	8% Christian; the rest reported "none" or did not answer the question
Parity	54.5% no children 18.2% had 1 child 12.1% had 2 children 6.1% had 3 children 9.1% had 4 children
Married	35.3%

Of the 36 respondents using SDM to prevent pregnancy, approximately 20% reported never having used a family planning method in the past. Of those who had ever used a method in the past, the majority reported having used the pill and/or male condom. A minority reported having used injections, NuvaRing, withdrawal, the IUD, the patch, foam/jelly, some form of NFP, and/or the rhythm method. Of the methods used in the two months before starting SDM, the most common methods cited were condoms (16 users), withdrawal (5 users), and some form of natural family planning/FAM or the rhythm method (5 users).

Table 14 lists the most common reasons women chose SDM. Respondents were permitted to select more than one response.

Table 14: Top reasons for choosing SDM (n=36)

No hormones and no side effects	75%
It's "natural"	33%
Easy to use / convenient	28%
Complements or replaces a FAM client was already using	11%

Less common reasons for choosing SDM cited by clients included cost-effectiveness; curiosity to try something new; religious/moral reasons; effectiveness; enjoy learning about one's menstrual cycle; did not want an IUD or Implanon; environmentally friendly; and fits with existing condom use.

When asked how they planned to handle the fertile days (respondents could choose more than one option), 72% said they planned to use condoms, and 33% said they planned to abstain from sexual intercourse. A few respondents indicated they would use withdrawal, spermicidal foam, or "other forms of sexual contact."

Approximately 93% of respondents said they heard about CycleBeads from the health center, whether through contact with a staff member or seeing a brochure or poster at the center. Other sources of information about CycleBeads included the internet, word of mouth, and nursing school.

Follow-up interviews

Follow-up interviews with clients at three and six months after admission provided insight into continuation, satisfaction, correct use, and how method use affected their relationship. Follow-up interviews at 12 months asked about continuation as well as more detailed questions on partner communication regarding sex and pregnancy prevention.

Continuation: Of the 21 clients reached after three months, 15 were still using SDM to prevent pregnancy. Of the six who were not, two had experienced at least one out-of-range cycle and were using CycleBeads to track their cycle while using condoms and/or withdrawal as their primary method, hoping to transition to SDM once they were certain that their cycles were the appropriate length. Four had discontinued using SDM due to the following reasons:

- End of relationship
- Trying to achieve pregnancy
- Unintended pregnancy resulting in miscarriage – had been correctly using the method
- Unintended pregnancy – had unprotected intercourse on white bead day and later used emergency contraception

Three additional clients continued to use SDM at three months but were not called for an interview due to a lag in continuing approval by the IRB. These clients were later interviewed at six months and found to be continuing with the method.

At six months, 12 clients were reached for interviews, and 10 were still using SDM to prevent pregnancy. Of the two who discontinued, one had gotten pregnant (unspecified

whether intended or not) and one discontinued due to out-of range cycles, switching to condoms.

At twelve months, eight clients were reached for interviews, and six were still using SDM to prevent pregnancy. Of the two who discontinued, one had gotten pregnant (unintended) and one desired a more effective method and switched to the IUD.

Use: At three months, all 15 SDM users interviewed reported using the method correctly in the following ways:

- Moving the black band to the red bead the day their period starts
- Marking the first day of their period on the calendar
- Moving the black band one bead each day
- Avoiding unprotected intercourse on white bead days

However, seven respondents reported being confused about how to use CycleBeads to track their cycle length each month to ensure that their cycles were not too short or too long to use the method.

Thirteen respondents reported having *avoided* unprotected intercourse on the white bead days during their most recent cycle. Of the two respondents who reported *having* unprotected intercourse on these days, one said it was because she forgot she was on a white bead day and later used emergency contraception. The other said that she considered the first three white bead days as "free" days when she was unlikely to get pregnant.

At six months, responses were similar to those at three months, although two users reported that while they still used SDM (i.e., avoiding unprotected intercourse on days 8-19 of their cycle), they used a calendar rather than CycleBeads to track their cycles.

Satisfaction: At three months, all of the 15 continuing SDM users reported being either satisfied or very satisfied with SDM, and 14 said SDM was easy to use. When asked what they liked most about SDM, by far the most common answer cited by 12 respondents was ease of use. Other characteristics cited by respondents as to why they liked SDM included effectiveness (3 users), the fact that it is "natural" (3), low cost (3), enjoyed tracking the cycle (3), and religious reasons (1). When asked what they liked least about CycleBeads, the majority of respondents said "nothing," but three of them cited difficulty remembering to move the black ring on CycleBeads; two cited concerns about effectiveness; one cited difficulty in moving the black band; and one of them cited difficulty in remembering to mark the calendar on the first day of their period.

At six months, responses were similar as at three months, with 100% of continuing users reporting being either satisfied or very satisfied with SDM.

Comments from respondents on what they liked about SDM, from follow-up interviews at 3 and 6 months:

"I've used the calendar method before and find that this method is much easier because of how CycleBeads are set up. It's easier to see when you're fertile."

"I can visually see my cycle laid out for me."

"[I like that] I don't have to take a pill or injection."

"[With CycleBeads] you can be responsible without side effects. It's not stressful."

"[I like] having more control about when to have sex or not."

"It helps me keep track of my cycle and know where I am."

A user from California shared the following with study staff during her 12-month interview:

"I have been doing acupuncture with Chinese herbs. I never had regular cycles until now, and I never had a way of checking my cycle before. It's amazing, I can't believe how wonderful they [CycleBeads] are. I carry it with me, in my purse, sometimes around my neck. The only thing I would want to change is to make is smaller. Nice and convenient. I take them with me when I travel. I can't believe that something so small can make a difference in your life. I bring them to doctor's appointments and we discuss things going on with my body while referring to the beads. Thank you for changing my life! It's been wonderful."

Effect on relationship: At three months, six of the 15 continuing users interviewed stated that their relationship with their partner had changed for the better since they began using SDM; the rest reported no change. All respondents indicated that SDM was acceptable to men. Respondents said that men participated in SDM use by using a condom or abstaining on the fertile day, but also by reminding the woman to move the black ring on CycleBeads; helping to move the black ring; buying condoms; or simply by being responsible and supportive in general.

Some of the people whose relationship changed for the better said (combination of quotes from interviews at 3 and 6 months):

"It's easier to talk about fertility, and now we share responsibility for sex."

"When it's not a white bead day when there is a need to use condoms, it feels more intimate."

"There is less stress in the relationship because my partner and I know when we can have unprotected sex and when I can get pregnant."

"We can talk about birth control more easily and have better communication now."

"It's easier because I was getting burned from spermicides and had to hear complaints [from my partner] about condoms."

Partner communication: Clients who had been using SDM for 12 months were asked a series of questions regarding communication with their partner. Seven respondents answered these questions. All of them reported that they felt comfortable talking with their partner about preventing a pregnancy. Six of the women stated that the decision to avoid a pregnancy was made jointly by her and her partner; one woman said she made the decision herself. Responses to questions about decision-making around sex are provided in Table 15.

Table 15: Responses by SDM users to questions about sexual decision-making

	ALWAYS	SOMETIMES	NEVER
The woman feels she can let her partner know when she wants to have sex	6	1	0
The woman feels she can let her partner know when she doesn't want to have sex	6	1	0
The partner takes into account how the woman feels when he wants to have sex	7	0	0
Partner becomes angry if woman does not want to have sex on days when she can get pregnant	0	1	6
Partner becomes angry if woman does not want to have sex on days when she is not concerned about getting pregnant	0	2	5

These results indicate that SDM users interviewed after one year of use felt empowered to communicate with their partner about sex.

VIII. Discussion

In this section, we will review some of the limitations and challenges faced over the course of this study; consider answers to the study questions and their implications; and discuss the value of utilizing the strategic approach as a framework for contraceptive introduction.

A. Limitations

The main limitation of this study is the small sample size of SDM users. Clinic staff had difficulty recruiting SDM clients into the study and reported that many of their clients declined to participate because they were concerned about confidentiality and did not want to share their contact information.

To compound that, study staff encountered difficulty in reaching SDM clients by phone after they were recruited into the study. The manager of at least one of the clinics warned

study staff that their client population tended to be transient, changing phone numbers and addresses frequently, and that clinic staff often had difficulty reaching their clients by phone with test results. To reach users, study staff employed different strategies including calling the client at different times of day and contacting the participants via text message and/or email to arrange the phone interview. In cases where the participant listed an alternate contact person, study staff attempted to reach the participants through their alternate contact. Sometimes these efforts were successful, and sometimes they were not. Consequently, many clients who were recruited could not be interviewed, and nearly half of the participants were lost-to-follow up between their admission and their 3-month interview.

Additionally, administrative issues caused a delay in the processing of this study's continuing IRB application by Georgetown University, causing client recruitment and interviews to be put on hold between November 2010 and February 2011.

Because of the small sample size, the information we learned about women who received SDM from Title X clinics is not generalizable. Also, we were unable to conduct some of the analyses we had planned, including comparing the satisfaction of SDM users to that of the users of other methods, and identifying predictors of successful method use.

B. Hypothesis and study questions

1) Effect of SDM integration on number of FAM users

The primary hypothesis for the study was that the number of FAM users in participating clinics would increase as a result of SDM integration into clinic services. This hypothesis was shown to be true. For example, Health Quarters had reported zero FAM users from January through December, 2008, the year prior to the study. However, during the study period of 23 months starting in September of 2009, Health Quarters reported a total of 41 users from these two clinics combined. Similarly, whereas PPMM-Modesto Health Center had reported only one FAM user in 2008, it reported 27 SDM users during a 23-month period after SDM was integrated.

While it was possible that FAM use was underreported prior to the study, this clearly shows that SDM integration increased the number of FAM users in the participating clinics that had FAM user data before and after SDM integration.

At the same time, the overall number of FAM users remained low with respect to the total number of female family planning clients – less than 1%. This largely has to do with

method demand – namely, that clients didn't know the method was available, and therefore did not ask for it – and the fact that there were missed opportunities at the clinic to inform clients about the method.

Method demand

Because SDM was a new method, there was a lack of awareness among the populations served by the study sites about what CycleBeads were and their availability at the clinics. Women tend to learn about birth control methods from word of mouth and television advertisements and in many cases already know what method they want when they arrive at the clinic for their appointment. However, nearly all (93%) of SDM users in this study first heard about the method during their visit to the health center.

Unlike many other family planning methods, SDM is a low-cost method with no backing from pharmaceutical companies with large marketing budgets. Communications and outreach staff from the service delivery agencies were able to leverage their existing resources to integrate SDM into their outreach efforts. However, budget constraints (both the study budget and the outreach budgets of the service delivery agencies) precluded the implementation of mass media campaigns to spread the word about the availability of a new method and limited the size and reach of local efforts.

The fact that SDM is a relatively new method with few users (and therefore little to no word-of-mouth "buzz"), along with the fact that there were no mass media communications, resulted in fewer users than otherwise might have been expected.

Even some opportunities to raise awareness of the method within the clinic were missed. For example, many staff indicated that posters in exam rooms and waiting rooms were an efficacious way of informing their clients about the method. However, we found that not all clinics were able to keep CycleBeads posters up for the duration of the study for a variety of reasons including policy restrictions and the priority placed on other types of posters such as STI awareness.

Clinic systems and institutionalization

As part of the strategic approach to method integration, study partners incorporated SDM into client education and counseling. Many staff relied on multi-method posters or brochures as counseling aids, such as those provided by affiliate- or national-level Planned Parenthoods or pharmaceutical companies. Our study was unable to modify these and therefore provided SDM-specific educational materials including counseling guides, brochures, and posters to the clinics. CycleBeads were added to kits located in the

counseling rooms that contained samples of all methods and used by staff as counseling aids. Having CycleBeads and educational materials on hand in the counseling rooms was useful for informing clients about the method.

Some clinicians, medical assistants, and health educators particularly appreciated having a FAM to offer their clients and made SDM part of their regular counseling routine. However, we found that some clinic staff still forgot to offer the method and, for example, did not know where to find the counseling guides that were on file in the exam rooms. Some staff also told us that, since it was a new method, it was not yet on their "radar screens." Additionally, some clinic managers found that if they did not repeatedly remind their staff of this new method, some would forget to offer it. This resulted in missed opportunities to educate clients about SDM.

On a more macro level, some of the study organizations found themselves dealing with organization-wide issues that affected their ability to focus their attention on ensuring that their staff regularly informed clients about SDM, including funding cuts, staff absences and turnover. Also, this study took place during a time when state and national-level family planning authorities were promoting long-acting reversible contraceptives (IUD and implants). All of these issues affected the degree to which clients could access SDM/CycleBeads.

During the needs assessment phase, there did not appear to be serious obstacles to method integration. It was only as the study progressed that these systems-related issues became apparent. Of course, some of these issues could not have been avoided – namely, organizational issues (such as staff absences and turnover) that do not have to do with which methods are offered. But it is clear that if SDM/CycleBeads were integrated at higher levels, including organization-wide (which could have meant method integration into multi-method counseling guides) and state-wide (which could have impacted the priority given to the method, particularly by managers and clinicians) – the integration process likely would have had greater impact, and SDM would have been an option for more clients.

2) SDM use, continuation, and satisfaction

While the results of SDM user interviews are not generalizable due to the small sample size, it is worth noting that satisfaction among SDM clients who participated in this study was very high. The majority of SDM clients interviewed in this study continued to use it. Those who discontinued did so largely because they realized that their menstrual cycles were not the appropriate length for SDM use. Others discontinued due to concerns about efficacy, change in relationship status, or pregnancy (intended or unintended).

The women in this study who discontinued SDM for reasons other than pregnancy tended to switch to another method. We did not interview enough of these women to identify patterns of switching, but the users we interviewed switched to a variety of methods including condoms, pills, patch, and IUD.

Follow up interviews with SDM clients indicated that a number of them noticed an improvement in their relationship, as CycleBeads use facilitated their communication about pregnancy prevention and the timing of intercourse. It also enabled condom users to identify a time of the month when condoms and/or spermicides were not needed and therefore enhanced the sense of intimacy in the relationship.

3) Staff perspectives and ability to offer FAM

Staff perceptions of FAM seemed to improve as a result of their experience offering SDM/CycleBeads. Both before and after training, staff were supportive of integrating SDM in order to expand options for their clients. Whereas many providers expressed skepticism about the method's effectiveness prior to training, post-integration interviews indicated that all of them felt that the method was effective enough to be offered at their site and that their site should continue to offer SDM after the study was completed.

Staff competence in offering the method was generally good. Simulated client visits revealed areas for improvement in counseling: specifically, screening. Also, the confusion on the part of some SDM users regarding how to use CycleBeads to monitor their cycle length (i.e., how to tell if their cycle was too short or too long for SDM use) suggests that this aspect of CycleBeads use should be emphasized more during counseling. This is a similar finding to other service delivery areas around the world.

4) Barriers to offering FAM

This process of integrating SDM into clinic services enabled clinics to overcome a major barrier to offering FAM. Prior to SDM integration, only clinicians were trained to discuss FAM with clients. However, the integration process (specifically, SDM training) enabled non-clinical staff – i.e., medical assistants, counselors, and health educators – to counsel clients on FAM, specifically SDM. For clients interested in a FAM, this reduced the counseling burden on clinicians. It also enabled more clients to learn about SDM, as in most cases it is the non-clinical staff who provide an overview of the method options and assist the client in choosing a method before she sees the clinician.

However, integration of SDM into clinic service delivery did not address a major barrier for FAM availability, and that is that many people who needed the method were not reached. For example, in California, outreach workers met many Hispanic women in rural areas who

were interested in the method but did not have transportation to the clinic. Promotora visits in the Lawrence, Massachusetts, community also revealed unmet demand for such a method and interest in SDM. It was apparent that many women and couples who would have been interested in the method could not obtain it because they either didn't know about it or could not access services.

C. Utility of the Strategic Approach to contraceptive introduction

As discussed in Section III, the WHO's Strategic Approach to FP method introduction provided the conceptual framework for this intervention. This approach called for a phase-wise, participatory approach to method integration, and previous sections of this report described in detail how the first two phases – namely, the needs assessment phase and the integration/evaluation phase – were carried out.

1) Advantages and limitations of the Strategic Approach

There were many advantages to utilizing the Strategic Approach to method introduction. During the needs assessment phase, interviews with clinic staff provided information that was used to tailor the integration process (particularly the training and the design of the educational materials). Allowing staff the opportunity to voice their opinions and contribute to the process had value because it enabled the integration process to be more of a collective decision, rather than a decision imposed from outside interests. Taking the time to conduct a needs assessment gave the staff some time to get used to the idea of integrating a new FAM prior to integration activities proceeding at full-steam ahead.

The site assessment process (interviews with managers to understand which aspects of organizational systems would be affected by integration of a new method) was useful for planning for the necessary adjustments to clinic systems, materials, and forms. Regarding the community focus groups, the interest from focus group participants in a new method such as SDM served as a confirmation to agency leadership that moving forward with SDM integration would be worthwhile.

The evaluation phase was important to ascertain if the integration process resulted in an overall improvement to services and should be continued and/or recommended to other organizations. Both the process evaluation and outcome evaluation yielded valuable information that was utilized by the participating clinics. Providers found the SDM client interview results particularly insightful since providers usually do not see SDM clients for follow-up visits.

However, the strategic approach as it was carried out in this project also had limitations. For example, when SDM services are expanded to more clinics, engaging in a series of focus groups, provider interviews, and site assessments in every community in which SDM services could be integrated would be resource intensive and likely not feasible. In addition, while the information collected by the needs assessment provided valuable and useful information, it was limited in its ability to identify all the potential barriers that would affect the success of the integration process, and it did not necessarily illuminate solutions to the barriers that were identified. A primary example of one of these barriers was the fact that SDM was not included in (and could not be integrated into) the multi-method counseling guides used at some of the participating clinics.

In another example, focus groups in Modesto indicated that there was a large population of Hispanic women in the area who would likely be interested in such a method. In fact, health educators confirmed this interest during their community visits. However, our interpretation of the needs assessment data did not take into account that most of these women lacked transportation to the health center where they could obtain the method, nor did it enable us to identify a way overcome this barrier to access.

2) Elements that affected the success of the integration process

As described in Section III, the Strategic Approach identifies elements that influence the successful integration and use of a method: namely, the potential **User** of the method; the **Technology** of the method itself; and the program context, or **Service**, in which the method is offered. It also considers three categories of environmental factors that may affect the decision to introduce a new FP method as well as the ultimate success of the method in attracting users: **Policy**, **Society**, and **Economy**. Table 16 provides examples of how these factors influenced the availability and use of SDM in the study context.

Table 16: Selected factors that influenced method availability and use according to factors specified by the Strategic Approach to Contraceptive Introduction

KEY ELEMENTS OF INTEGRATION	USER	TECHNOLOGY	SERVICE
	• There was a high level of satisfaction by continuing SDM users. • Not all interested clients were eligible to use SDM; screening is required. • Lack of awareness of SDM meant clients were unlikely to ask for the method unless they learned of it at the clinic.	• Ease of use was a major benefit cited by users. • Ease of teaching was cited by staff. • Method effectiveness was satisfactory to users and staff. • Use requires cycle length to be within a specified range and partner compliance.	• The quality of SDM counseling was generally good, but the evaluation pointed to areas for improvement such as screening. • SDM counseling fits within normal clinic flow. • Lack of institutionalization of the method within the larger organization (e.g., lack of inclusion in multi-method materials and organizational policies) hindered client education. • Providers sometimes forgot to mention the method during counseling, reflecting the need for managers to remind staff about this new method until it becomes part of their regular counseling routine.
ENVIRONMENTAL FACTORS	POLICY	SOCIETY	ECONOMY
	• A policy prohibiting health educators from distributing the method during community outreach was a barrier to access. • Lack of emphasis by state and national-level family planning policymakers negatively affected availability.	• Clients and community members were interested to learn about SDM. • Some clinics served a client population in which many women were limited in their ability to negotiate sex. • Many women who desire the method the most cannot access services; special efforts are required to reach them.	• SDM is low-cost and does not require resupply. • Counseling time can be reimbursed. • CycleBeads are not on insurance formularies or part of state FP programs such as FPact in CA, so procurement might be an issue going forward. • Lack of marketing dollars for CycleBeads compared with other methods limited awareness-raising opportunities.

IX. Use of Research for Policy and Planning

The third phase of the Strategic Approach to FP introduction involves disseminating study results and planning for the utilization of findings. The purpose of this phase is to share lessons learned with service delivery organizations and networks across the country that may want to incorporate FAM into their services so that they may better meet the needs of

their clients and ultimately reduce unintended pregnancies. Study staff have engaged (and continue to engage) in efforts to disseminate and utilize study findings and have developed informational products based on project experience that can assist programs who wish to introduce SDM into their family planning services.

Dissemination of study results

The results of the evaluation were shared with and discussed among all study partners, including the staff of the service delivery agencies that were involved in the research. IRH/GU has been informed that the leadership of these agencies has started considering and/or planning for expanded availability of SDM to other sites. Study partners shared their experiences and research results within their regions through workshops given at regional Title X conferences (Region IX) and through regional Title X meetings and listserves (Region I). IRH/GU shared the evaluation results at a presentation at the Title X National Family Planning Conference in August of 2011 and other conferences including the annual meeting of the American Public Health Association (APHA). Several more presentations are anticipated for 2012. A full list of presentations by IRH/GU is included as Appendix N.

Additional means of disseminating and planning for utilization of project results are being pursued, including email newsletters and social media dissemination, production and dissemination of a brief fact sheet, academic journal articles, and in-person meetings with key national and regional family planning decision-makers.

Capacity building based on programmatic experience

Based on the experiences of this project and research results, IRH/GU, Cardea Services, and JSI developed a *CycleBeads® Integration Guide* that is available online at http://www.CycleBeadsToolkit.com. Developed with input from all study partners and a small group of family planning professionals from across the country, this user-friendly document provides guidance and tools (including checklists, sample job aids, client materials, reference materials, and training resources) for program directors and managers who wish to integrate SDM into their family planning services.

The *CycleBeads® Integration Guide* has been disseminated to IRH/GU's email list through an "e-blast" (email newsletter) and to the email lists of study partners. Hard copies were available at the Title X National Family Planning Conference in August of 2011 and at the annual meeting of the American Public Health Association in November of 2011. A postcard containing the toolkit's web address and key topics covered is also being disseminated at

various health-related conferences. These products will be available at the Title X Reproductive Health Clinical Conference in August of 2012, in addition to other venues. Another product developed by this project based on the perceived needs and experiences of clinic staff who participated in this study is a counseling video that can be used for provider training. Cardea Services produced this video, which demonstrates effective screening and counseling on SDM. The video contains scenes with three different clients and features expert commentary on each scene. This video will be available in mid-2012 on DVD and instant streaming via YouTube and the websites of IRH and Cardea.

In addition to these informational products, live and online training opportunities are being pursued. IRH/GU will present a skills session on SDM at the Title X Clinical Conference in August of 2012. A webinar on SDM, to be advertised nationally, is also being planned for 2012. Cardea and JSI now have in-house capacity to train on SDM, and because they are regional training centers, they can respond to requests for in-person training from agencies in their respective regions.

X. Conclusions and Recommendations for Scale-Up

This study demonstrated that SDM and CycleBeads can be successfully introduced into family planning service delivery at Title X clinics, from reproductive-health-focused organizations such as Planned Parenthood and Health Quarters to facilities providing the full range of primary care services such as Marin Community Clinics. Managers perceived that integrating the method into existing clinic-based systems was relatively simple and straightforward; providers found that counseling on the method fit within the clinic flow.

Most clients chose the method because it was natural with no side effects and were able to use it successfully and satisfactorily. Staff of service delivery agencies perceived that offering SDM added value to their services because it enabled them to provide more options for their clients and to better meet the needs of clients seeking a non-hormonal method. Health center staff found SDM easy to teach. Clients found the method easy to use.

While these are valuable lessons that can inform future integration efforts, the impact of SDM integration in this study was constrained by the fact that it only took place at the clinic-level. Larger-scale integration – for example, at the organizational, state, and/or national level – will be required to meet client demand for a method such as this and to reach more women with information and services. Future, larger-scale integration efforts should take the following into consideration:

Utilize mass media campaigns to raise awareness of the method. Raising awareness of the method through media such as newspapers, magazines, radio, television, or the

internet, in a context of informed choice, would increase client knowledge of the method so that clients do not need to rely on the health center as their only source of information. This should be complemented by educational efforts within the clinic, such as display of posters and other informational materials.

Integrate SDM into multi-method counseling materials. Future integration projects should undertake an effort to revise multi-method materials in order to ensure that staff who rely on these materials do not neglect to mention SDM to clients who may be interested. At the same time, managers should remind staff to make the method a regular part of their counseling routines.

Include CycleBeads in reimbursement programs. Although CycleBeads are significantly cheaper than many other family planning methods and do not require resupply, the fact that they are not part of most public sector reimbursement programs or private insurance formularies poses a barrier to procurement. To ensure that agencies can access the method and that method cost does not make it prohibitive for low-income clients, CycleBeads must be included in reimbursement programs such as California's Family PACT.

Find ways to reach rural areas with services so that lack of transportation to the clinic is not a barrier to access. This is likely an issue for all methods, not only SDM. However, unlike many clinical methods, SDM is an education-based method that can easily be offered by non-clinical staff using a simple visual tool (CycleBeads). Therefore, it is well-suited for distribution by outreach workers and *promotoras*.

The lessons learned from this experience were utilized in the development of products that can be used by organizations that integrate SDM into their services; namely, the *CycleBeads® Integration Guide* (available at www.CycleBeadsToolkit.com) and counseling videos. In addition to the study results, these products can inspire and inform future integration efforts.

In summary, this experience suggests that it is feasible and beneficial to offer SDM in Title X clinics. Like all methods, SDM is not appropriate for all clients, but was chosen by many who sought a non-hormonal method. Integration of this method enables clinics to easily offer a fertility awareness-based method and therefore to better achieve their mission of offering a wide range of options to meet their patients' needs. However, sustainable, widespread integration of SDM in the United States likely will not occur until SDM is included into state and national family planning norms and until the broader family planning community takes action to ensure that this method option is accessible to all.

References

Arévalo M. 1997. "Expanding the availability and improving delivery of natural family planning services and fertility awareness education: providers' perspectives." *Advances in Contraception* 13: 275-81.

Arévalo M, Sinai I, and V Jennings. 2000. "A Fixed Formula to Define the Fertile Window of the Menstrual Cycle as the Basis of a Simple Method of Natural Family Planning." *Contraception* 60(6): 357-360.

Arévalo M, Jennings V, and I Sinai. 2002. "Efficacy of a new method of family planning: the Standard Days Method." *Contraception* 65: 333-338.

Bruce J. 1990. "Fundamental Elements of Quality of Care." *Studies in Family Planning* 21 (2): 61-91.

Díaz M. 1997. "Gender, sexuality and communication issues that constitute barriers to the use of natural family planning and other fertility awareness-based methods. *Advances in Contraception* 13: 303-309.

Fehring RJ, Hanson L, and JB Stanford. 2001. "Nurse-midwives' knowledge and promotion of lactational amenorrhea and other natural family-planning methods for child spacing." *Journal of Midwifery and Women's Health* 46: 68-73.

Fowler, CI, Lloyd, SW, Gable, J, Wang, J, and Krieger, K. 2011. *Family Planning Annual Report: 2010 National Summary*. Research Triangle Park, NC: RTI International. Accessed 1/10/12 from http://www.hhs.gov/opa/pdfs/fpar-2010-national-summary.pdf.

Gribble JN. 2003. "The Standard Days Method of Family Planning: A Response to Cairo." *International Family Planning Perspectives* 29(4): 188-191.

Gribble J, Jennings V, and M Nikula. 2004. "Mind the gap: responding to the global funding crisis in family planning." *The Journal of Family Planning and Reproductive Health Care*; 30(3): 155-157.

Gribble J, Lundgren R, Velasquez C, and E Anastasi. 2008. "Being strategic about contraceptive introduction: the experience of the Standard Days Method." *Contraception*; 77(3): 147-154.

Hatcher R, Trussell J, Nelson A, Cates W, Stewart F, and D Kowal. 2007. Contraceptive Technology 19th Revised Ed. New York: Ardent Media, Inc.

Institute for Reproductive Health. 2008. "Comparison of Standard Days Method® User Tools." Washington, D.C.: Georgetown University for the U.S. Agency for International Development (USAID).

Jennings V and H Landy. 2006. “Explaining ovulation awareness-based family planning methods.” *Contemporary OB/GYN* 48-54.

Lundgren R, Gribble J, Greene M, Emrick G and M Monroy. 2005. “Cultivating Men's Interest in Family Planning in Rural El Salvador.” *Studies in Family Planning* 36 (3), 173–188.

Lundgren R, Lavoie K, Aumack Yee K, and S Schweikert. November 2007. “Responding to the Unique Needs of Women: How relevant are partners in family planning counseling?” Presentation at American Public Health Association Annual Meeting.

Pulerwitz J, Gortmaker S, and J DeJong. 2000. “Measuring Sexual Relationship Power in HIV/STD Research.” *Sex Roles* 42(7/8); Psychology Module: 637-643.

Mikolajczyk RT, Stanford JB, and M Rauchfuss. 2003. “Factors influencing the choice to use modern natural family planning.” *Contraception* 67: 253-8.

Silvonek AL. May 2004. “The Standard Days Method: Nurse-midwife and nurse practitioner perceptions of a new method of family planning.” Presented at the 49th Annual Meeting of the American College of Nurse-Midwives, New Orleans, LA.

Simmons R, Hall P, Diaz J, Diaz M, Fajans P, and J Satia. 1997. “The strategic approach to contraceptive introduction.” *Studies in Family Planning* 28(2):79-94.

Simmons R, Fajans P, and R Ghiron. 2007. Scaling up health service delivery from pilot innovations to policies and programmes. World Health Organization, ExpandNet: Switzerland.

Snowden R, Kennedy K, Leon F, Orense V, Perera H, Phillips R, Askew I, Flynn A and L Severy. 1988. “Physicians’ Views of Periodic Abstinence Methods: A Study in Four Countries.” *Studies in Family Planning* 19(4), 215-226.

Spicehandler J and R Simmons. 1994. Contraceptive Introduction Reconsidered: A Review and Conceptual Framework. WHO/HRP/ITT/94.1. Geneva: World Health Organization.

Stanford JB, Thurman PB, and JC Lemaire. 1999. Physicians’ knowledge and practices regarding natural family planning. *Obstetrics and Gynecology* 94(5 Pt 1): 672-8.

Vernon R, Rocuts K, and J Medina. 1987. “The Provision of Natural Family Planning Services At Public Health Centers in Colombia.” *International Family Planning Perspectives* 13(4): 121-127.

Appendices

A. Site Assessment Guide

Standard Days Method Introduction in Title X Clinics – V. 12.09.08

Organizational Mission and Leadership	Comments
1) How does the organization's mission statement and goals support the provision of natural methods within a range of family planning methods? Describe the organization's leadership structure.	
2) How supportive is senior level management staff of the decision to incorporate the SDM? Describe the interest/motivation of senior staff for introducing the SDM.	
3) Does the organization currently provide natural methods/FAM? If so, which methods? Do they refer clients for NFP/FAM? Request a copy of any NFP/FAM materials they have/use.	
4) What linkages or ties to other public and private organizations does the organization have that might influence (positively or negatively) the organization's ability to provide the SDM? E.g., community organizations, religious organizations, etc.	
5) How will the decision to incorporate the SDM be communicated throughout the organization?	
6) Who will be responsible for management oversight of the SDM integration at the site?	
7) Are any steps required at the organizational and management level to support the introduction of the SDM? Describe.	

Service delivery structure	Comments
1) Describe the current range of family planning services available.	
2) In what way will introduction of the SDM benefit the existing clientele of the organization? Describe the socio-economic and demographic profile of existing clients. Request service statistics with a breakdown of ethnicity, language, method choice etc. and attach.	
3) Do you think that introduction of the SDM allow the organization to reach new clients? Describe the profile of potential new clients.	
4) Describe the normal staffing structure of the service delivery centers and role/duties of all levels of staff as they to FP services. What role might the different staff roles play with regards to the SDM?	
5) Does the organization have existing norms and service delivery protocols for the provision of family planning services? Describe these norms/protocols. Is NFP/FAM in the medical services protocol?	
6) Describe the counseling process. How much time is allotted for counseling? How are barrier methods offered? How is informed choice facilitated? Are all methods described/ presented? How?	
7) How will service delivery staff be informed of their role in integrating the SDM? Who will be responsible for introduction of the SDM at the service delivery level?	
8) What additional steps are required to ensure quality provision of the SDM within the existing services? Describe the necessary steps.	
Client Flow Process	**Comments**
1) Describe the client flow within the facility for family planning services. (making a map	

may be useful). List the # of exam rooms, counseling rooms, etc.	
2) Will client-flow patterns be adapted to address the particular needs of SDM clients? How? What will be the client-flow pattern for a first-time user interested in information on the SDM? Describe. Initial visit vs continuing client?	
3) Will male partners be able to or encouraged to participate in a SDM visit? How do you envision this happening?	
Counseling	**Comments**
1) How much time is allotted for counseling? How flexible is this? Can the organization be reimbursed for extended counseling time on a RH/FP topic? Are staff concerned about time constraints? Describe the organization's existing counseling protocol for RH/FP.	
2) Is there any area pertaining to counseling in which the staff might benefit from more training in order to offer the SDM?	
3) What type of job aids/support materials do counselors use for FP? Describe how the SDM could be integrated into these existing materials. *Show TCHC job aid and SDM checklist – ask if they would be appropriate or useful. Request suggestions for the best tools for them.	
4) Review (and obtain samples of) client materials for other methods. What type of materials (and how many different types of materials) would be needed for an SDM client? Show IRH's existing client materials (CB insert, double folded brochure, "All about CB" fact sheet) and ask about appropriateness for the clinic (including client literacy level, language, and cultural considerations). Should any of these be adapted/ modified? If so, how?	
5) Obtain samples of consents used for other methods. What type of consent form would be required for SDM? (e.g., general FAM consent or SDM-specific?)	

6) Chart review: how are charts used to document counseling, follow-up, etc? Request copy of the blank form.	
7) Will any additional steps be required to incorporate quality counseling for new and follow-up SDM users? Describe.	
Information, Education, & Communication	**Comments**
1) Describe the printed IEC materials (brochures, posters, etc) available. Are materials easily accessible to clients should they want to take them home? How are they displayed? Posters on the walls? What kind?	
2) Show CT/TCHC IEC materials (2-sided card, CT poster) and ask about appropriateness for the clinic (including client literacy level, language, and cultural considerations), how they could be adapted/ modified.	
4) Does the organization have educational activities within the clinic? If so, how may SDM be incorporated?	
5) Does the facility take advantage of the client's waiting period to provide additional information and education opportunities? Describe what materials/mechanisms are available, e.g. TV, VHS, displays, wall hangings, printed materials.	
6) Does the organization have on going community outreach and education activities? Describe these activities and how the SDM can be incorporated into them. (e.g. male involvement, teen program, other?)	
7) Who is responsible for IEC and community outreach at the facility level? What is the approval process/who needs to approve materials?	
8) What additional steps are needed to change or improve IEC and community outreach in support of quality SDM services? Does the	

organization have the capacity or experience communicating through radio, newspaper, etc? Are IEC materials given to community members through outreach? Request a copy.	
Training	**Comments**
1) Does the organization have institutionalized training for service providers and other professional staff? Describe the types of training.	
2) Does the organization offer both in-house and external training programs? Describe the types of training offered.	
3) Does the organization have in-house trainers? Describe the profiles of the trainers.	
4) What type of training will be most appropriate for the introduction of the SDM? (e.g. 2-hour training, full-day, etc.)	
5) Can the SDM be easily incorporated into existing training materials? Describe what type of adaptations will be necessary. Describe.	
6) What providers will receive training on the SDM? Describe the training needs by provider profile, e.g. counselors, nurses, physicians, support staff, community promoters.	
7) What type of follow-on training evaluation activities will be necessary to ensure that providers have the appropriate skills on-the job? Are staff at the site supportive of follow-up training activities like shadowing? Other approaches?	
8) Who will be responsible for overseeing the adaptations and implementation of the training for the SDM? Does someone at the site need to approve training plans?	
9) What additional steps will be required to change or improve training in support of quality SDM services?	

Service Fees	**Comments**
1) Does the organization currently charge a fee for family planning services? Describe the fee structure.	
2) Does the organization currently charge for counseling services? Describe the organization's policy. Will SDM counseling be covered under the organizational fee structure? If so, how?	
3) Will clients be charged for receiving the SDM? If so, how will fees be determined?	
4) How does the organization financially support those who are at or below the poverty level/unable to pay for services? Request copy of the eligibility screen form (for those in government funded programs).	
5) What additional considerations will need to be taken into account to ensure that CycleBeads are affordable and accessible to interested users?	
Procurement, Logistics and MIS ***Note: for study purposes IRH will provide CycleBeads free of charge to participating clinics. Nevertheless, some procurement questions remain to assist with potential post-study SDM integration into systems.**	**Comments**
1) Does the organization have an existing procurement system in place for the purchasing of family planning commodities and supplies? Describe the current procedures.	
2) Does the organization currently have a centrally managed logistics and distribution system for distributing medical supplies and information materials to its service sites? Describe.	
3) Will the organization be able to efficiently and effectively distribute SDM materials to its service sites? Where will CycleBeads materials be stored at service sites?	

4) Who will be responsible for logistics of CycleBeads and SDM support materials?	
5) What type of system is in place to collect information on service statistics? Collect existing forms and reports that are available. Describe what types of service delivery statistics are collected (e.g. new vs. continuing users). Request copy of latest print out of this data (if not already provided).	
6) How will information on the SDM be incorporated into the MIS of the organization, so that SDM users may be tracked? Request form.	
7) How will SDM counseling be accounted for on billing/reimbursement forms? Request form.	
Management & Supervision	**Comments**
1) How is provision of family planning services managed and supervised? What is the supervisory framework (i.e. who reports to whom)? Describe existing systems and how SDM services might be supervised and supported.	
2) Does the organization have any special mechanisms in place to evaluate patient and/or employee satisfaction?	
3) Does the organization have existing monitoring systems in place to monitor staff performance?	
4) Is there a mechanism in place to provide client feedback to providers and other staff?	

B. Overview of Site Assessment Findings by Clinic

	PPMM-Modesto	Health Quarters-Lawrence	Health Quarters-Beverly	MCC-Novato & Novato Wellness Center	MCC-San Rafael
Clientele	40-50% clients are Latino; most are 18-24 yrs of age	Mostly Latino, low-income	Mostly Caucasian, non-Latino, college students age 20-29	Low-income, uninsured, diverse.	Over 90% of clients are 200% or below poverty level. More than 60% of clients are mono-lingual Spanish-speaking.
Services	Reproductive health services. FAM not formally offered - requests for FAM referred to RN or NP who can discuss fertility awareness	Reproductive health services. FAM not formally offered – clinician can discuss tracking cycle on calendar upon request	Reproductive health services. FAM not formally offered – clinician can discuss fertility awareness with interested clients	Primary care, including FP services, at main clinic; FP and teen services at Wellness Center. Clinicians offer FAM – BBT, calendar and Billings.	Clinicians can offer FAM including secretion-based methods, BBT and calendar.
Counseling	Health service specialist (HSS) has 15 minutes for counseling – RN also counsels – prior to exam	Appointments every 20 minutes with flexibility. Counselor does preliminary counseling followed by NP for additional teaching	Appointments every 20 minutes with flexibility. Counselor does preliminary counseling; NP can answer additional questions	Appointments every 15 minutes with flexibility. MAs do counseling before patient sees clinician. No exam needed at initial visit.	Appointments every 15 minutes with flexibility. MAs take vitals, determine whether a pregnancy test is needed, provide method counseling prior to the clinician visit.
Outreach	Outreach activities include male involvement and classroom based teen programs; health fairs; community discussions	Clinic has an additional site in town – "Heritage site" – where two outreach staff are based. Follow promotora model to reach out to Latino community.	Outreach conducted by Director of Community Education – mostly classroom talks, attendance at local fairs and community meetings, etc.	Presence at an annual health fair. New mom support group and breast health promotoras. A press release can be sent to Marin paper and Latin radio stations.	Can incorporate fertility awareness information with general SRH and teen SRH education. Health fairs as well as general FP outreach through Family PACT. Press releases.
Fees	Mostly covered by MediCal and Family PACT; sliding scale for those who are not eligible. Clinic can be reimbursed for counseling visit.	$25 copay; rest covered by state, Title X, or private insurance. Sliding scale for those who are not eligible or have no insurance. Clinic can be reimbursed for counseling.	$25 copay; rest covered by state, Title X, or private insurance. Sliding scale for those who are not eligible or have no insurance. Clinic can be reimbursed for counseling.	Most are Family PACT or MediCal eligible. Sliding scale also available. As appropriate, will bill for "counseling only" visits.	(Same as Novato)

C. Interview Guide for Clinic Staff, Needs Assessment

Interview guide for Family Planning Providers

STANDARD DAYS METHOD INTRODUCTION IN TITLE X CLINICS

Objectives of the semi-structured provider interviews

A portion of clinic staff involved in provision of family planning services will be interviewed to assess:

1. FAM knowledge and attitudes
2. Interest in incorporating the SDM into their programs
3. Potential barriers to SDM introduction
4. Service delivery-related issues
5. Possible outreach approaches

Results of the interviews will help guide the development and implementation of SDM introduction into the service of participating clinics, identify possible barriers, explore strategies to overcome these barriers, and identify feasible outreach strategies. Interviews will be recorded to facilitate note-taking. Consent shall be obtained from the interviewee before proceeding.

Clinic: _____	**Provider Code: _____**
Introduction	
What is your role in the clinic? • How long have you worked here? • What is your profession/training? (doctor, nurse, student, administrator, etc.) • Do you have direct interaction with patients/conduct counseling? • Do you provide family planning counseling? • How (else) do you interact with patients?	
What kinds of birth control methods do your patients generally prefer? • Why do you think that is the case? • Do you have any sense of how satisfied they are with the methods they choose? • How often do patients switch to different methods? What are typical reasons for switching?	

• Do most patients already have a method in mind when they come to the clinic? How did they learn about that method? • Do you ever see men for birth control counseling?	
How do you help patients determine which birth control method is best for them? • Do issues ever surface which you find difficult to address? For example? • Are there issues you consider when counseling patients of different cultural backgrounds? What about recent immigrants?	
Do you use any tools or educational materials when counseling patients? (pamphlets, fact sheets, posters, anatomical models, etc.) • Describe what you use. • How do you use them?	
Fertility Awareness-Based methods (FAM)	
5. What comes to mind when you hear the phrase natural family planning? What about fertility awareness-based (FAM) methods?	
6. Are you familiar with any FAM (i.e. "natural") methods of family planning? What are some that come to mind?	
7. Do you have experience offering FAM (natural) methods? • Which ones? • Are these offered currently in the clinic? • Who provides them / counsels on them? • Have you received any NFP/FAM training? Explain. • If not, would you like to be trained in FAM? Why/why not?	
8. In general, how do you feel about offering FAM (natural) methods? • Do you ever see patients that request a FAM/natural method or that you think would be interested in one?	

• Do patients ever ask you for a non-hormonal, non-device method? If so, how do you respond? • How comfortable would you be with your patients using a FAM/natural method, if that was their preference? Why? Probe: For providers who currently offer a FAM/natural method: • Are they accepted by patients? • How easy is it to teach your patients to use them? • How easy is it for your patients to use them? • How effective are they? • Do patients that choose them continue to use them?	
9. What barriers exist for patients to use FAM (natural) methods?	
10. What barriers exist for you to offer FAM (natural) methods?	
11. Have you heard of the Standard Days Method (CycleBeads)? • If so, what have you heard about it? • How did you first hear about it? • Have you, or others at your clinic, offered the Standard Days Method/CycleBeads to patients? • If so, describe your experience.	
12. *For providers who have heard of CycleBeads:* How would you feel about offering the Standard Days Method/CycleBeads (as an option, along with all the other methods available), to the patients at your clinic? • Do you think it would be accepted? • How easy is it/do you think it would be to teach your patients to use them? • How easy do you think it would be for your patients to use them? • Do you think they are sufficiently effective to offer to your patients? • How comfortable would you be with your patients using CycleBeads, if that was their	

preference? Why?	
13. What does your clinic do to let people know about your services? • How do you inform potential patients about the family planning methods you offer?	
14. What do you think would be some effective strategies to let people know about the Standard Days Method/ CycleBeads?	

Thank you for your time!

D. Focus Group Discussion Guide

FOCUS GROUP DISCUSSION GUIDE

STANDARD DAYS METHOD INTRODUCTION IN TITLE X CLINICS

Location and date:_____

Number of Participants: _____

Moderator: _____

Observer/notetaker: _____

A. INTRODUCTION

(Moderator: please read the sentences in quotations exactly as they are written.)

- Presentation of moderator and observer
- Welcome and thank participants
- Objective of the meeting: *"We are interested in learning about your opinions on birth control. This is a very important topic because our organization wishes to offer a new natural birth control method, with no side effects. Before doing this, we would like to learn more about birth control practices in your community, as well as what you think about this new method. There are no right or wrong answers – we are looking for your thoughts and opinions."*
- Confidentiality: *"Everything we talk about today is confidential and will not be discussed outside of this meeting. No one's name will appear in the reports we will prepare. We will be talking for approximately an hour and a half. If there is any part of the discussion you do not wish to participate in, you don't have to."*
- Tape recorder: *"The opinion of each one of you is very important to us. We will be taking notes; however, it will not be possible to take notes of everything that is said. Therefore, we have brought a tape recorder so that we won't miss any part of the conversation. Is it alright with you if we use the tape recorder?"*
- Consent form*: "Finally, we would like to have your consent to participate in this discussion group, to indicate that you are participating voluntarily and that you understand your rights. Please read the consent form if you wish to participate."*

- Payment*: "You will receive a $20 gift card as a thank you for your participation. In order to receive the card you must participate in the entire discussion."*

Moderator: For those who agree to participate, please have each participant fill out an anonymous card with the following demographic information:

  - Their age
  - Highest year of education completed
  - Marital status
  - Whether or not they are currently using a birth control method
  - What birth control method are they using (if any)
  - Number of children (if any)
  - Race/Ethnicity
  - Language(s) spoken at home

B. ICE BREAKER

In this exercise, we would like to get to know each other a little bit.

*(The Moderator shall select **one** of the following questions to pose to the group.)*

- What is something you have done for fun lately?
- Name something you're looking forward to.
- What are you most proud of in your life so far?
- Can you share a decision you have made that was difficult for you, but you are proud you made it?

C. BIRTH CONTROL

Let's begin our discussion by talking about birth control use among the people that you know.

1. To start, if a woman is not using any form of birth control, can she get pregnant anytime she has sex [vaginal intercourse], or only on certain days? Explain.
   - Which days can a woman become pregnant if she has sex?
   - Is there any way to know which days she can become pregnant? How?

2. For women that wish to avoid pregnancy, where do they get information about birth control methods?

3. What kinds of birth control methods do women commonly use?

   - Where do they get their methods?
   - Are men involved in making choices about birth control?

4. Are there some women who wish to avoid pregnancy, but don't use a birth control method? If so, why?

5. What problems do you think women, or couples, have with birth control methods?
6. Do you think there is a need for new birth control methods? Why? If so, what would be an ideal family planning method?

D. UNDERSTANDING OF THE STANDARD DAYS METHOD / CYCLEBEADS

I am going to explain a new method of birth control to you, and then I would like to ask your opinion about it. This method is called the Standard Days Method, and it is used with a visual tool called CycleBeads. It is a natural birth control method, with no side effects. It is based on the fact that there are certain days between one period and the next when a woman can get pregnant.

The Moderator shall explain how to use CycleBeads and give a demonstration using cyclebeads. Key talking points follow:

- CycleBeads represent a woman's menstrual cycle. Each bead represents one day.
- On the first day of a woman's period, she moves the black band to the red bead and marks her calendar.
- Each day, she moves the back band to the next bead, in the direction of the arrow.
- When she is on a brown bead, she is not likely to get pregnant.
- When she is on a white bead, she can get pregnant. To avoid pregnancy, she and her partner should avoid sex or use a barrier method such as condoms on those days.
- When she gets her period again, she skips any remaining beads and puts the black band on the red bead again.
- This method works best for women whose periods come about once a month.
- If a woman gets her period before she reaches the dark brown bead, or if her period does not come by the day after the last bead, she should not use this method.

CycleBeads were developed by the Institute for Reproductive Health at Georgetown University. This method was tested in an international study that showed it is more than 95% effective when used correctly. This means if a 100 women use it correctly for one year, about 5 will get pregnant.

Now that we have explained CycleBeads to you, we would like your opinions on this new method.

7. Do you have any questions about this method?
   - Can anyone tell me the key points about how to use this method?

     (MODERATOR: Correct any misunderstandings and/or answer any questions participants have about the method.)

E. ACCEPTABILITY AND USE OF CYCLEBEADS

8. Now that you know about this method, what do you think about it?

- Why do you say that?

9. Of all the available methods, do you think some women and couples would choose this method? Why?

- If this was available, would any of you be interested to try it? What makes you say that?
- Would there be some people who would not want to use this method? Why?

10. Do you think that this method will be easy or difficult to use?

- Why might some people find it easy to use?
- Why might some find it difficult to use?

11. What would men think about this method of birth control?

12. We mentioned earlier that when using CycleBeads, couples do not have sex or they use a barrier method such as condoms on the days when the woman is on the white beads. How might a woman feel about not having sex, or using condoms or another barrier method during these days?

    - How might a man feel?
- Could there be potential disagreements or problems with managing these 12 days?
- How might these be resolved?

13. Do you think most couples who use this product, would always:

    1. Avoid sex during the 12 days when the ring is on any white bead
    2. Use a condom during these 12 days
    3. Do something else

(explore these issues in more depth)

14. What would a couple do if they have sex without a condom during a day when the woman can get pregnant (when the ring is on any white bead)?

F. RAISING AWARENESS

Now that we have talked about what type of interest there might be for CycleBeads, let's talk about how to let people know about it.

15. What would be the best way to reach couples who might be interested in this method to tell them about it and where it is available? *(Moderator: Probe for low-cost ways.)*

- What is the best way to reach women?
- What is the best way to reach men?
- Where should this method be available?
- Should men and women be taught about the method together?

16. We have developed some pamphlets about CycleBeads. One is a 2-sided card that informs people about the method. The other is a folded brochure for people who have selected CycleBeads and explains the method in more detail, such as how to use it. (*Moderator: Hand out samples of these pamphlets and give the participants a few minutes to look at them. Then, ask questions the following questions about the two-sided card. Next, ask the same questions about the folded brochure.)*

- Would you be likely to pick up either of these materials if you saw them displayed in a clinic? Why or why not?
- What do you like about this material?
- Is there anything that bothers you?
- Is anything confusing?
- What do you think about the pictures?
- What should be changed about this material?

17. Is there anything else you would like to share about your feelings about this method?
- How do you feel about CycleBeads being available near here soon?

Moderator: Thank participants, invite participants for refreshments, and distribute thank-you gifts.

E. Waiting room questionnaire

health quarters

Please tell us about yourself

Our clinic would like to serve you better. By answering these questions, you will help us learn how to improve the services we offer to you. There are no right or wrong answers to these questions.

This questionnaire is a part of a study being conducted by Georgetown University, JSI Research and Training Institute, and Health Quarters. You don't have to fill it out if you don't want to, and it will not affect the health care you receive. Your responses will not be shared with your health care provider or anyone else at the clinic. More information about the study and your rights is on the reverse side.

Thank you for your help!

Are you using a birth control method now? If so, which method(s) are you using? ***Check all that apply.***

- ☐ Not using a method now
- ☐ Tubal ligation (female sterilization)
- ☐ Vasectomy (male sterilization)
- ☐ Pill
- ☐ Patch
- ☐ NuvaRing
- ☐ IUD (Mirena or Paraguard)
- ☐ Depo/Injection
- ☐ Implanon
- ☐ Condom
- ☐ Female condom
- ☐ Diaphragm
- ☐ Foam/Jelly
- ☐ Withdrawal (pulling out)
- ☐ Natural family planning
- ☐ Rhythm Method)
- ☐ Standard Days Method (CycleBeads)
- ☐ Other (which?) _____

How long have you been using this method(s)?

- ☐ Less than 1 month
- ☐ 1-6 months
- ☐ 7-12 months
- ☐ More than a year

How satisfied are you with your method(s)?

- ☐ Not using a birth control method now
- ☐ Very satisfied
- ☐ Satisfied
- ☐ Not satisfied

Did your partner help you decide to use the method(s)?

- ☐ Yes
- ☐ No

How old are you?

- ☐ Younger than 20 years old
- ☐ 20 – 25 years old
- ☐ 26 – 30 years old
- ☐ 31 – 35 years old
- ☐ 36 – 40 years old
- ☐ 41 – 45 years old
- ☐ Older than 45 years old

What is the highest level of school that you completed?

- ☐ Elementary school
- ☐ Middle or Junior High school
- ☐ High school
- ☐ College (2-year or 4-year degree)

What language do you usually speak at home?

- ☐ English
- ☐ Spanish
- ☐ Both English and Spanish
- ☐ Other (which?) _____

In which country were you born?

- ☐ United States
- ☐ Another country (which?) _____

How many living children do you have?

- ☐ Don't have any children
- ☐ 1
- ☐ 2 – 3
- ☐ 4 or more children

Do you want to have any or more children in the future?

- ☐ Yes
- ☐ No
- ☐ Don't know / not sure

In your opinion, when can a woman get pregnant if she is not using any birth control?

- ☐ During her period
- ☐ Right after her period ends
- ☐ In the middle of her menstrual cycle
- ☐ Right before she gets her next period
- ☐ At any time (all of the above)

Thank you for your responses!

F. Provider Job Aid

Provider Job Aid

A Strategic Approach to Offering CycleBeads

For Clients Interested in CycleBeads

1. **Ask:**
   - Do your periods usually come about a month apart?
   - Do your periods come when you expect them?
   - Can you and your partner use a condom or another barrier method, or abstain from sexual intercourse for 12 days in row?

   If she answers YES to all the above questions, she can use CycleBeads.
   - If the woman knows the first day of her last period she can start CycleBeads today.
   - If the woman has recently had a baby, is breastfeeding, using a hormonal method, or had a miscarriage or abortion, refer to **When To Start CycleBeads** chart for specific instructions.
   - If the woman has had unprotected intercourse since her last period, offer pregnancy/STI testing and EC, if applicable.

2. **Give CycleBeads to the client and show her how she will use them. Discuss the calendar and CycleBeads brochure.**

3. **Talk about how the couple will prevent pregnancy during the days when the ring is on a white bead.**
   - Discuss potential use of barrier methods and abstinence.
   - Discuss other forms of sexual activity that have no pregnancy risk (i.e. oral sex, mutual masturbation, etc.).

4. **Assess risk of STI/HIV and what protection client and partner(s) are using.**

5. **Remind her to check that her period comes between the dark brown bead and the last brown bead.**

When to Start CycleBeads

Circumstances	When to Start
Knows the first day of her last period and has regular, monthly cycles	Start CycleBeads **today.** Move the ring to the correct bead.
Does not know the first day of her last period and has regular, monthly cycles	Start CycleBeads on the first day of her **next period.**
Postpartum or breastfeeding	Wait until after 4 periods. Start after her **last two periods have been about a month apart**.
3-month shot user	Wait until shot's 90-day protection ends, and **last three periods have been about a month apart**.
Hormonal method user (the pill, patch, ring, implant, or hormonal IUS)	Start CycleBeads when her **last three periods* have been about a month apart**. * After discontinuing hormonal method
Had a miscarriage or abortion in the past month OR Used EC	Start CycleBeads on the first day of her **next period** (if her periods were about a month apart before she got pregnant or used EC)

Invite Clients into CycleBeads Study!*

Describe the CycleBeads research project and ask if the client would like to participate. If yes, obtain a signed research consent form and tell the client:

- Purpose of the study is to see how family planning clients use the method.
- Someone from JSI will call them soon to follow up.
- Three more calls will happen at 3, 6 and 12 months after this clinic visit.
- Benefit is individual attention and $10.00 per call.

** A client can choose CycleBeads without being in the study.*

health quarters

Where can you get CycleBeads®?

Call your local public health or family planning clinic for information. It is recommended that anyone interested in this method be taught by a trained family planning provider. You can also purchase CycleBeads at http://cyclebeads.com.

Center for Health Training
614 Grand Avenue, Suite 400
Oakland, CA 94610-3523

510.835.3700 - p
510.625.9307 - f

oakland@jba-cht.com
www.centerforhealthtraining.org

Revised 2009

Standard Days Method® using CycleBeads®

How CycleBeads work:

CycleBeads® are a string of 32 color-coded beads that represent the days of the menstrual cycle. They help the woman keep track of her cycle days, identify whether or not she is fertile on that day, and monitor her cycle length. The brown beads represent the days that you are very unlikely to get pregnant. In order to use CycleBeads, your periods must come about a month apart (26-32 days).

How to use CycleBeads:

Each bead represents a day of the menstrual cycle. The cycle BEGINS on the first day of your period. The cycle ENDS the day before your next period starts. Your period is when you have menstrual bleeding. Your cycle includes all days from the start of one period to the day before your next period. Each time you get your period, a new cycle begins.

(continued)

The day you get your period, move the ring to the RED bead, and you can also mark that day on a calendar. Move the ring one bead each day, even on the days when you have your period. When the ring is on a WHITE bead, you are more likely to get pregnant. During these days you should abstain from sexual intercourse, use a condom or another barrier method, or engage in sexual activity where there is no risk for pregnancy.

On the days where the ring is on a BROWN bead, you are very unlikely to get pregnant. You can have unprotected sexual intercourse. When you start your next period, move the ring to the RED bead again. Skip over any beads that are left.

It is important that you remember to move the ring every day. If you forget to move the ring, check on your calendar for the date you got your last period. Starting with that day, count the number of days that have passed, including today. Then starting with the red bead, count the same number of beads and place the ring on the bead for today.

Effectiveness:

About 5 in 100 women will get pregnant in one year (95% effectiveness) if they use CycleBeads correctly and consistently every time (perfect use). If you do not use CycleBeads correctly and consistently every time, e.g. if you have unprotected sex on a white bead day (typical use), your chance of pregnancy goes up.

Benefits:

It is a natural alternative for women who don't want to use hormones. CycleBeads are reusable, inexpensive and environmentally-friendly. This method helps to better understand the menstrual cycle. It may also promote communication between partners.

GENERAL REFERENCE: Contraceptive Technology (CT): 19th Rev. Ed., 2007 and CT Update (monthly newsletter).

CycleBeads are an acceptable method for people with religious concerns about other birth control methods.

Potential side effects and disadvantages:

There are no side effects with this method.Women with cycles shorter than 26 days, or longer than 32 days, cannot use this method. Users must be able to abstain from sex, use a condom or other barrier method, or engage in other types of sexual activity on the white bead days. You must keep track of your cycle and move the ring each day. If you recently had a baby, are breastfeeding, or you recently used another birth control method, talk to your healthcare provider before using CycleBeads.

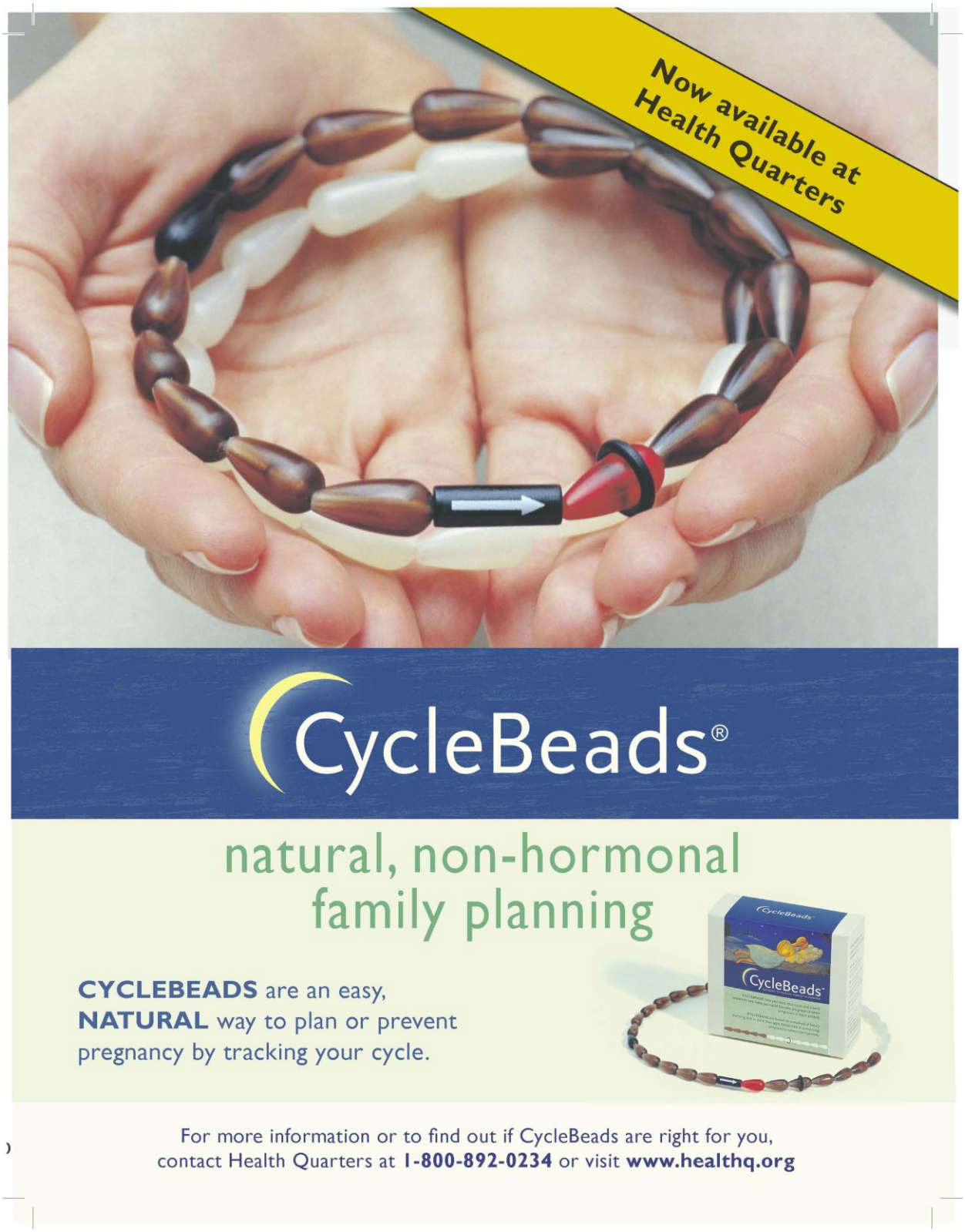
Potential risks:

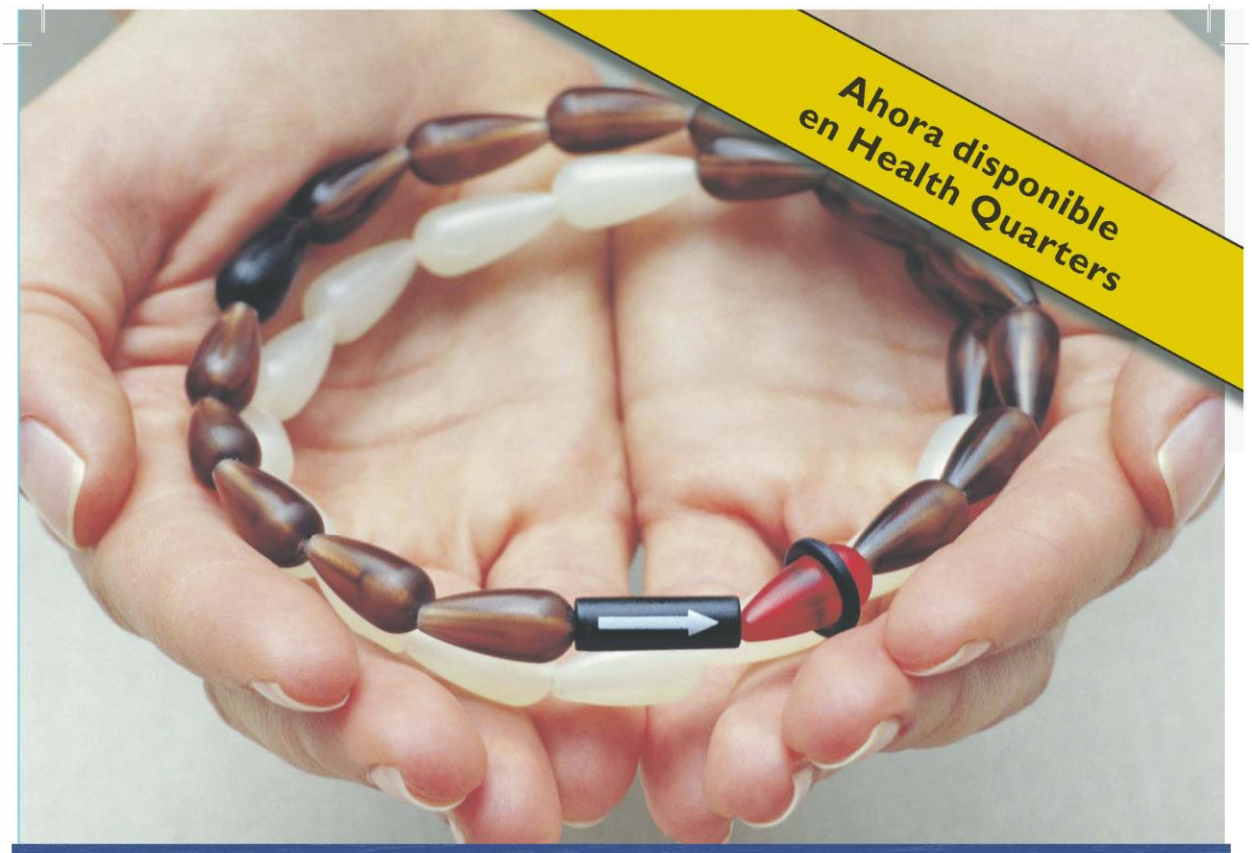
CycleBeads offer no protection against HIV/AIDS or sexually transmitted diseases (STDs).

Call your provider if:

- You get your period before you reach the dark brown bead; this means your cycle is shorter than 26 days.
- Your period does not start by the day after you reach the last brown bead; this means your cycle is longer than 32 days.
- You think you might be pregnant because you have not gotten your period.
- You had unprotected sex on a WHITE bead day. You should go immediately to your nearest provider or pharmacy to get emergency contraception (EC). A prescription is not required for EC if you are 17 or older. For a local EC provider, call the emergency contraception national toll-free hotline (1-888-NOT-2-LATE) or visit the website www.not-2-late.com.

H. CycleBeads Poster





Collar del Ciclo®

planificación familiar natural sin hormonas

El Collar del Ciclo es una forma fácil y natural para planear o prevenir el embarazo seguiendo su ciclo mestrual.

Para obtener más información o para averiguar si el Collar del Ciclo es apropiado para usted, contacte a Health Quarters al **1-800-892-0234** o visite **www.healthq.org.**

I. CycleBeads Outreach Cards

Collar del Ciclo®

Una nueva opción en métodos anticonceptivos

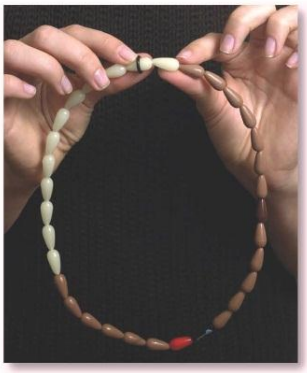
- Es una opción **natural** que **no tiene efectos secundarios.**
- Es **fácil de usar** y es **eficaz** para evitar un embarazo.
- Funciona dándole seguimiento al ciclo menstrual de la mujer.
- **El Collar del Ciclo®** es una forma sencilla para que las **parejas compartan la responsabilidad** de planear la familia y usar un método anticonceptivo.

El Collar del Ciclo no protege contra el VIH/SIDA u otras infecciones de transmisión sexual.

Planificación Familiar Natural

health quarters
www.healthq.org

¿Qué es el Collar del Ciclo?



- El Collar del Ciclo® es un collar de perlas de colores que se usa para llevar la cuenta de los días del ciclo menstrual de la mujer.
- Llevando la cuenta de los días con el Collar, la mujer sabe en qué días puede quedar embarazada. En esos días la pareja puede usar un condón, otro método de barrera, o evitar las relaciones sexuales para prevenir un embarazo.
- El Collar del Ciclo se basa en un método natural de planificación familiar con eficacia del 88-95% cuando se utiliza correctamente.
- Health Quarters puede ayudarle a determinar si el Collar del Ciclo es adecuado para usted.

Este método no protege contra el VIH/SIDA u otras infecciones de transmisión sexual.

health quarters
www.healthq.org

Para más información llamar a:

Beverly:
19 Broadway
978-922-4490

Lawrence:
101 Amesbury Street, Suite 202
978-681-5258

439 South Union St., Suite 203
978-208-4760

CycleBeads®

A New Birth Control Option

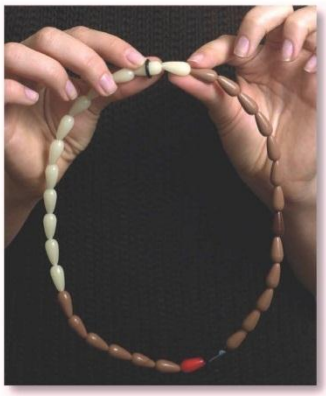
- It is a **natural, non-hormonal method** with **no side effects**.
- It is **easy to use** and **effective** in preventing pregnancy.
- It works by **tracking** a woman's menstrual **cycle**.
- **CycleBeads®** are a simple way for **couples** to **share the responsibility** of birth control and family planning.

CycleBeads do not protect you from HIV/AIDS or other diseases people can get from having sex.

Prevent Pregnancy Naturally

health quarters
www.healthq.org

What Are CycleBeads?



- CycleBeads® are a string of color-coded beads used to track each day of a woman's menstrual cycle.
- By following the beads, a woman knows the days when she can get pregnant. On these days a couple can use a condom, another barrier method, or abstain from sexual intercourse.
- CycleBeads are based on a birth control method that is 88-95% effective when used correctly.
- Health Quarters can help you determine if CycleBeads are right for you.

health quarters
www.healthq.org

For more information call

Beverly:
19 Broadway
978-922-4490

Lawrence:
101 Amesbury Street, Suite 202
978-681-5258

439 South Union St., Suite 203
978-208-4760

J. Simulated Client Checklist

Mystery Client Observation Checklist

Check one: **Profile A ☐ Profile B ☐ Profile C ☐ Profile D ☐**

This checklist is to be completed by mystery clients immediately upon exiting the clinic and out of sight of clinic staff. It should then be submitted to the study coordinator.

Write down the required information below.

1	Name of Facility:
2	Date: Year: Month: Day: Time in: Time out: Total time:
3	My name:

Instructions for Subsequent Items

For each item, answer the question, Was it present in the counseling session? Check one of the boxes to the right signifying, Yes, No, or Do not remember (DNR). Please write any important comments in the margin or at the end of the checklist.

A	Interpersonal relations during counseling	Yes	No	DNR
1	The counseling session was interrupted			
2	The provider appeared rushed			
3	Other people in the clinic could hear what I said			
4	The provider was friendly to me			
5	The provider treated me respectfully			
6	I felt he/she cared for my health			
7	The provider asked me if I had any questions			
8	The provider responded to my question(s)			

B	**Need Diagnosis** ***The provider asked me:***	**Yes**	**No**	**DNR**
1	Confirmed that I wasn't using any method (or was using condoms)			
2	Why I stopped using the pill (or shot)			
3	If I plan to have more children in the future			
4	Date of my last menstrual period			
5	If I had discussed birth control with my husband/partner			
6	If I have a specific method in mind			
C	**Method options**	**Yes**	**No**	**DNR**
	Mark yes for each of the type of birth control method that the provider mentioned:			
1	Hormonal methods (e.g., pill, patch and shot)			
2	IUD			
3	Barrier methods (e.g., condom, sponge, diaphragm)			
4	Natural methods (e.g., SDM/CycleBeads)			
5	**Condoms** are the only birth control method that also protects against sexually transmitted infections.			
6	Asked me to choose a method			
7	I felt free to choose the method I preferred			
8	Showed me pictures or samples of birth control methods			
D	**Contraindications** ***The provider asked:***	**Yes**	**No**	**DNR**
1	Whether my periods come about a month apart (or verified that my cycle length is between 26-32 days)			
2	If I would be willing to avoid unprotected sex on my fertile days			

3	Whether my husband/partner would be able abstain or use a condom on my fertile days			
4	Whether I can communicate with my husband/partner about sex			
5	Whether my husband/partner or I are at risk for STIs			
6	Provider told me I need to wait a while before starting this method.			
7	Provider told me that this method would not work for me.			
8	Since SDM would not work for me, other methods were offered			
E	**Method Characteristics** ***The provider explained to me:***	**Yes**	**No**	**DNR**
1	That CycleBeads have no side effects or health risks			
2	That the pregnancy is likely if you have unprotected sex on a fertile (white bead) day			
3	That the dark brown bead is used to track cycle length			
4	That CycleBeads do not protect against STIs			
F	**Use Instructions for CycleBeads** ***The provider told me:***	**Yes**	**No**	**DNR**
1	To move the black band/ring to the red bead the day my period starts			
2	To mark the first day of my period on the calendar			
3	That I must move the black band/ring every day			
4	To always move the black band/ring in the direction of the arrow			
5	To check the calendar if I forget to move the black band/ring			
6	That the brown beads represent days in which I can have sex			
7	Told me to avoid unprotected sex on the white bead days			
8	Told me to discuss with my husband how we will handle the fertile (white-bead) days			

9	Told me that if my period comes before the brown bead, that is a short cycle			
10	Told me that if my period does not come by the day after the last brown bead, that is a long cycle			
G	**Follow up** ***The provider:***	**Yes**	**No**	**DNR**
1	Gave me a package of CycleBeads			
2	Told me when I could start using CycleBeads			
3	Helped me put the ring on the appropriate bead			
4	Offered to talk with my husband/partner			
5	Advised me what to do if my cycle was too short or too long			
5	Told me to return to the clinic if my cycle was too short or too long more than once			
6	Verified that I understood what he/she had explained to me			
7	Showed me the instructional insert			
8	Told me to contact the clinic if I had any questions or concerns			
9	Told me to return if I would like to switch methods			
10	Offered me condoms			
11	Told me about Emergency Contraception			
12	Offered me Emergency Contraception			
H	**Clinic Environment** ***During my visit, I observed:***	**Yes**	**No**	**DNR**
1	CycleBeads samples (including during counseling)			
2	CycleBeads flyers or pamphlets on display			
3	CycleBeads poster on wall			
4	Written information about other birth control methods (information sheets, booklets, posters)			

5	Birth control information for men			
I	**Summary/outcome of visit**	**Yes**	**No**	
1	I went home with CycleBeads			
2	I was told to wait before using CycleBeads			
3	I received counseling or referral for another FAM/NFP: Describe:_____			
4	I received a different method Which method:_____			
5	Received counseling or referral for partner/violence issues: Describe:_____			

Comments:

K. Interview Guide for Clinic Staff, Evaluation Phase

Version 27May2010

SDM/CycleBeads Introduction Study
Provider Survey #2

The purpose of this survey is to assess provider perceptions regarding the SDM/CycleBeads and learn about their experiences offering it. Every effort will be made to ensure the information provided is kept confidential to the extent possible, meaning that any results reported or published will not be linked with the interviewee's name.

Instructions to interviewer: All clinic staff who provide family planning counseling services should be interviewed individually and in private. Prior to the interview, the interviewee should have read, signed, and received a copy of the informed consent form, if they did not already sign one for their interview last year. The interviewer should retain a copy of the informed consent form. It should be made clear that you are seeking their assistance in learning about their experience in order to find ways of improving the quality of services offered by facilities in general, and are not evaluating the performance of the facility or of them individually. For each item, please circle or describe the response as appropriate.

#	Questions	Coding categories and responses	Skips
101	Clinic	Health Quarters – Beverly..... 1 Health Quarters – Lawrence ..... 2 PP Mar Monte..... 3 MCC-Novato..... 4 MCC-San Rafael..... 5 Other: (specify)_____..... 6	
102	Provider Identification Code (obtained from provider code list)	_____	
103	Sex of staff member	Female..... 1 Male 2	
104	Interviewer's name	_____	
105	Date of interview	_____	
Part 1: General information			
To begin, I'd like to ask you a few basic questions about yourself.			
106	What is your role in the clinic**? *(circle all that apply)***	Manager/Assistant Manager ..... 1 Counselor (non-clinical) ..... 2 Clinician..... 3	

#	Questions	Coding categories and responses	Skips
107	***Clinicians only***: What is your license?	Nurse (RN)..... 1 Nurse practitioner..... 2 Nurse midwife..... 3 Physician assistant (PA)..... 4 Other_____	
108	How long have you worked at this health center?	# of years: _____ If less than 1 year, # of months:_____	
	Part 2: SDM/CycleBeads integration efforts		
	Now I'd like to ask you about your participation in the CycleBeads integration efforts.		
201	Did you participate in a study-related training on CycleBeads?	Yes..... 1 No..... 2	→ 205
202	If not, why not?		
203	Do you know how to counsel clients on CycleBeads?	Yes..... 1 No..... 2	
204	How did you learn about Cycle Beads?	Colleague told her about CycleBeads ..... 1 Took online SDM/CycleBeads course..... 2 Participated in a different training (SPECIFY WHERE)_____..... 3 Read materials 4	
205	How would you rate your knowledge of CycleBeads on a scale from 1 to 5, with 1 being low and 5 being high?	Low High 1.....2.....3.....4.....5	
206	Since the study began, have you discussed CycleBeads with any family planning patients?	Yes..... 1 No..... 2	
207	How frequently do you find that you discuss CycleBeads with patients? (***Read options and select one***)	Five or more times per week ..... 1 At least once per week..... 2 At least once per month ..... 3 At least once every 6 months ..... 4 Never/almost never 5	→ 209
208	Why is that?		

#	Questions	Coding categories and responses	Skips
209	Have any of your patients started using CycleBeads?	Yes ..... 1 No 2	
210	How easy or difficult was it for you to add CycleBeads to your counseling routine? (***Read options and select one***)	Very easy ..... 1 Somewhat easy ..... 2 Somewhat difficult ..... 3 Very difficult 4	→ 211
210a	Why do you say that?		
211	How easy or difficult was it to complete the paperwork required to process or document a CycleBeads user according to your clinic's protocols? (***Read options and select one***)	Very easy ..... 1 Somewhat easy ..... 2 Somewhat difficult ..... 3 Very difficult 4	→ 301
211a	Why do you say that?		
	Part 3: Offering SDM/CycleBeads		
Next I'd like to ask you a couple of questions about offering the Standard Days Method with CycleBeads.			
301	How easy or difficult do you find it to teach women how to use CycleBeads? (***Read options and select one***)	Very easy ..... 1 Somewhat easy ..... 2 Somewhat difficult ..... 3 Very difficult ..... 4 Don't know 9	→ 302
301a	Why do you say that?		
302	When you counsel on CycleBeads, do you talk about partner communication with regard to method use?	Yes ..... 1 No ..... 2 N/A 3	
303	How useful do you think CycleBeads are for involving men in family planning?	Very useful ..... 1 Somewhat useful ..... 2 Not useful ..... 3 Don't know 9	→ 304

#	Questions	Coding categories and responses	Skips
303a	Why do you say that?		
304	Do you believe that CycleBeads are effective enough to offer as a birth control method at your site?	Yes.....1 No.....2 Don't know.....3	→ 305
304a	Why do you say that?		
305	What type of women do you think CycleBeads work best for? ***PROBE***: Please explain.		
306	What barriers exist for clients to be able to choose CycleBeads as their method?		
307	Do you know of any challenges your clients have encountered that have made it difficult for them to use CycleBeads successfully?		
308	What, if any, barriers exist for you to be able to offer CycleBeads?		
309	On a scale of 1 to 5, how important do you think it is to include a fertility awareness-based method such as SDM/CycleBeads among the methods options offered at your clinic? (1 = not at all important, 5 = extremely important)	1.....2.....3.....4.....5	
309a	Why do you say that?		
310	This clinic will be involved in recruiting CycleBeads clients for the study for approximately one more year. Do you think that the clinic should still offer CycleBeads after the study is completed next year?	Yes.....1 No.....2 Don't know.....3	→ 401

#	Questions	Coding categories and responses	Skips
311	Why not?		
	Part 4: SDM/CycleBeads-related materials		
	Now I'd like to ask you about CycleBeads communication materials.[NOTE TO INTERVIEWER: You should have these materials on hand to show the interviewee if possible.]		
401	In conjunction with the training, you received a job-aid with key counseling points about CycleBeads screening and use. How useful was this job-aid? (***Read options and select one***)	Very useful ..... 1 Somewhat useful ..... 2 Not useful..... 3 Don't know..... 9	402
401a	Why do you say that?		
402	Do you have any suggestions for improving this job aid? (Please indicate.)		
403	How useful is the CycleBeads package insert for helping women learn how to use CycleBeads? (***Read options and select one***)	Very useful ..... 1 Somewhat useful ..... 2 Not useful..... 3 Don't know..... 9	
404	How useful was the CycleBeads fact/sheet (CHT fact sheet in CA) or brochure (HQ CycleBeads Brochure used in MA) for helping women understand how to use CycleBeads? (***Read options and select one***)	Very useful ..... 1 Somewhat useful ..... 2 Not useful..... 3 Don't know..... 9	
404a	Do you have any suggestions for improving the insert or fact sheet/brochure?		
405	How useful was the CycleBeads poster in raising awareness about CycleBeads within the clinic?	Very useful ..... 1 Somewhat useful ..... 2 Not useful..... 3 Don't know..... 9	
405a	How do you know this?		

#	Questions	Coding categories and responses	Skips
406	How useful was the outreach card in raising awareness about CycleBeads?	Very useful ..... 1 Somewhat useful ..... 2 Not useful..... 3 Don't know..... 9	
406a	How do you know this?		
407	Do you have any suggestions for improving these materials? (If so, please indicate.)		
408	Do you have any additional ideas about how to raise awareness about CycleBeads?		
Part 5: CycleBeads integration effect on services			
Now I would like to ask you about the effect of CycleBeads integration on clinic services.			
501	How do you think efforts to include CycleBeads in your services affected patient satisfaction with services? Do you think satisfaction increased, decreased, or remained the same?	Increase..... 1 Decrease ..... 2 Remain the same ..... 3 Don't know..... 9	
501a	Ho w do you know this?		
502	What other changes, positive or negative, did CycleBeads integration have on clinic flow or operational functioning?		
Part 6: Looking ahead			
Next year, which is the last year of the study, we would like to share our experiences with other organizations who would like to offer a fertility awareness-based method.			
601	If a director of an organization that provides family planning services said she was going to integrate CycleBeads into services and asked you for advice, what are one or two things you would tell her?		

#	Questions	Coding categories and responses	Skips
602	In collaboration with your organization, Georgetown University, JSI, and the Center for Health Training would like to put together a toolkit for other organizations who wish to integrate CycleBeads. In your opinion, what are the most important things that should be included in this toolkit?		
603	With regard to the training, what are your thoughts on how the training could be improved?		
604	We would also like to put together a video to share with other organizations who would like to learn how to include CycleBeads in their services. Do you have any thoughts on what would be helpful to share in a short video?		
605	Do you have any other thoughts/ ideas about what type of information could be shared with others with regard to integrating CycleBeads into their family planning choices available at their clinics?		
That's all the questions I have for you today. Thank you very much for your time. ***We ask you to keep inviting CycleBeads patients into the study for approximately one more year (until Spring 2011). Your director will advise you when you no longer need to do this. Do you have any questions about how to invite participants in the study, which form they need to fill out, or where to send the form?***			

L. Interview Guide for Clients, Admission

ADMISSION FORM

TO BE COMPLETED DURING THE FIRST OR SECOND WEEK AFTER THE USER HAS RECEIVED THE STANDARD DAYS METHOD/ CYCLEBEADS

ADMISSION FORM	
Write down the user's identification number. Also write down her information in the study registry.	_____- _____ Clinic Number
Date of the Interview: ____/_____/_____ Day Month Year	Date of Birth of the Participant: ____/_____/_____ Day Month Year
Interviewer name: _____	
Interview format: Phone ___ In person ___	
INTRODUCTION	
1 a. How did you hear about the Standard Days Method, or CycleBeads? **(Mark all that apply)** 1___Health service 2___Flyer or brochure 3___Poster 4___Internet 5___Radio Ad 6___Newspaper 7___Word of mouth 8___Other:_____	
1 b. Who told you about CycleBeads? **(Mark all that apply)** 1__Healthcare provider 2__Friend/neighbor 3__Family member 4__Health promoter 5__Husband/partner 6__Other _____	
2. Did your husband/partner receive instructions on how to use CycleBeads? 1___ Yes → From who? 1___ You 2___ Healthcare provider 3___ Other (Specify):_____ 2___ No	

3 a. Are you using CycleBeads (that is, the Standard Days Method) to prevent pregnancy?

1___ Yes (or planning to) ➔ **SKIP TO QUESTION 4**
2___ No

3 b. Why aren't you using CycleBeads?

1__Partner did not want to use it
2__I didn't like using it
3__I didn't understand how to use it
4__I'm using CycleBeads to get pregnant
5__ Other _____

➔ **END THE INTERVIEW AND WITHDRAW FROM STUDY**

INTERVIEWER: VERIFY IF THE SDM IS AN APPROPRIATE METHOD FOR THIS COUPLE

4. Does your period come about once a month?

Optional Probe:
Do your periods usually come about a month apart?

1___ Yes

2___ No ➔ **The method isn't appropriate for the couple. End interview and withdraw her from the study.**

3__Not sure ➔ **REMIND HER THAT SHE CAN USE CYCLEBEADS TO TRACK HER CYCLE LENGTH.**

5. Will you and your partner be able to avoid sex or use another method such as condoms on the days you can get pregnant?

1___ Yes

2___ No ➔ **The method isn't appropriate for the couple. End interview and withdraw her from the study.**

6. Are you currently taking birth control pills?

1___Yes ➔ **The Method is not appropriate for the user. End the interview and withdraw her from the study.**

2___ No

7. Have you received an injection for birth control in the past three months?

1___Yes ➔ **The Method is not appropriate for the user. End the interview and withdraw her from the study.**

2___ No

INTERVIEWER: VERIFY THAT THE USER CAN PARTICIPATE IN THE STUDY
8. Would you like to become pregnant during the next 6 months? 1___Yes ➔ **End the interview & withdraw her from study, but she can use the method.** 2___ No
GENERAL QUESTIONS
9. What was your age on your last birthday? _____
10. What was your partner's age on his last birthday? _____
11. What is your religion? 1____ Christian - Catholic 2____ Christian - Protestant 3____ Jewish 4____ Muslim 5____ Hindu 6____ Buddhist 7____ Agnostic/athiest 8____ Other (Specify:_____)

12a. What is the highest level of schooling you have finished? **Put an "X" for the educational level and circle the highest number of years completed**	12b. What is the highest level of schooling your partner has finished? **Put an "X" for the educational level and circle the highest number of years completed**
1___ I never went to school 2___ Primary 1 –2 –3 –4 –5 –6 3___ Basic (Middle) 7 - 8 -9 4___ High School 1 –2 –3 –4 5___ Technical/Vocational 1 –2 –3 6___ University 1 –2 –3 –4 –5 –6	1___ I never went to school 2___ Primary 1 –2 –3 –4 –5 –6 3___ Basic (Middle) 7 - 8 -9 4___ High School 1 –2 –3 –4 5___ Technical/Vocational 1 –2 –3 6___ University 1 –2 –3 –4 –5 –6

13. What language do you usually speak at home? 1____English 2____Spanish 3____Other (Specify: _____)

14. How many living children do you have?_____

(IF NONE, SKIP TO 16)

15. What is the age of your youngest child? # of years _____
If less than 1 year, # of months _____

16. Are you married? 1___ Yes

2___ No

17. Have you ever used a family planning method to prevent pregnancy?

1_____ No, I have never used any method to prevent pregnancy. ➔ **Skip to Question 20.**

2_____ Yes

18. What methods have you used?

(INTERVIEWER: Probe: "Anything else?")

- ☐ Pill
- ☐ Patch
- ☐ NuvaRing
- ☐ IUD (Mirena or Paraguard)
- ☐ Depo/Injection
- ☐ Implanon
- ☐ Condom
- ☐ Female condom
- ☐ Diaphragm
- ☐ Foam/Jelly
- ☐ Withdrawal (pulling out)
- ☐ Natural family planning
- ☐ Rhythm Method
- ☐ Other (which?) _____

19. In the past two months, which method of family planning were you using before you began using CycleBeads?

- ☐ Used no method in past two months

- ☐ Pill
- ☐ Patch
- ☐ NuvaRing
- ☐ IUD (Mirena or Paraguard)
- ☐ Depo/Injection
- ☐ Implanon
- ☐ Condom
- ☐ Female condom
- ☐ Diaphragm
- ☐ Foam/Jelly
- ☐ Withdrawal (pulling out)
- ☐ Natural family planning
- ☐ Rhythm Method
- ☐ Other (which?) _____

20. Why did you choose to use CycleBeads instead of using another family planning option? **MARK ALL OF THE RESPONSES MENTIONED**

1___ It is low-cost/cost-effective
2___ My husband opposes using another method
3___ It doesn't affect my health and doesn't have side effects/I don't have to take or use anything/It does not effect breastfeeding
4___ Religious/moral reasons
5___ It is easy to use
6___ It is effective
7___ It is natural
8___ It is environmentally friendly
9___ Other (Specify)

_____

21. What have you and your husband/partner decided to do during the fertile days? (Mark all that apply)

1___ Abstain from sex
2___ Use condoms
3___ Withdrawal
3___ Other: _____

PARTNER COMMUNICATION

I would now like to ask you some questions about your communication with your husband/partner.

22. Can you let your husband/partner know when you want to have sex? **(Interviewer: Read options)**

1____ Always
2____ Sometimes
3____ Never
4____ Don't know

23. Can you let your husband/partner know when you **don't** want to have sex? **(Interviewer: Read options)**

1____ Always
2____ Sometimes
3____ Never
4____ Don't know

24. Does your husband/partner take into account how you feel when he wants to have sex? **(Interviewer: Read options)**

1____ Always
2____ Sometimes
3____ Never
4____ Don't know

25. Who makes the decision to prevent a pregnancy?

1____ Husband/partner
2____ Myself
3____ Both
4____ Other

26. Do you feel comfortable talking with your husband/partner about prevening a pregnancy?

1____ Yes
2____ No
3____ Depends, explain _____

27. When you and your husband/partner are together, do you feel embarassed or talk very little about birth control?

1____ Yes
2____ No
3____ Depends, explain _____

28. On days when you are concerned about getting pregnant, does your husband/partner become angry if you don't want to have sex?

1____ Always
2____ Sometimes
3____ Never
4____ Don't know

29. What about on the days when you are not concerned about getting pregnant, does he get angry?

1____ Always
2____ Sometimes
3____ Never
4____ Don't know

NOW LET'S TALK ABOUT WHEN YOU THINK A WOMAN HAS THE RIGHT TO REFUSE SEX.

30. Couples do not always agree on everything. Please tell me if you think a woman is justified in refusing to have sex with her husband or partner when:

	YES	NO	DON'T KNOW
She knows he has an STI?	☐	☐	☐
She knows he has sex with other women?	☐	☐	☐
She has recently given birth?	☐	☐	☐
She is tired or not in the mood?	☐	☐	☐
She is on a fertile day? (white bead day)	☐	☐	☐

COMMENTS:

THANK HER FOR HER PARTICIPATION AND TELL HER YOU WILL CALL HER AGAIN IN A FEW MONTHS

OFFER TO SEND HER THE INCENTIVE AND VERIFY HER ADDRESS

M. Interview for Clients, Follow-Up

CLIENT# _____-_____

FOLLOW-UP QUESTIONNAIRE

Check the number corresponding to this follow-up interview

Follow-Up Month

_____3

_____6

_____12

TO BE FILLED OUT BY THE INTERVIEWER	
CLIENT'S IDENTIFICATION CODE	_____-_____ Clinic User
CLIENT'S BIRTH DATE	_____/_____/_____ Day / Month / Year
INTERVIEW DATE:	_____/_____/_____ Day / Month / Year
DATE OF LAST INTERVIEW:	_____/_____/_____ Day / Month / Year
MODE OF INTERVIEW:	____Phone _____In person

First Interview Attempt – Date: _____/_____/_____

Result
1_____ Available to be interviewed
2_____ No answer [Call back]
3_____ Inconvenient time [Call back:_____]
4_____ Moved away/invalid number

Second Interview Attempt – Date: _____/_____/_____

Result
1_____ Available to be interviewed
2_____ No answer [Call back]
3_____ Inconvenient time [Call back:_____]
4_____ Moved away/invalid number

Third Interview Attempt – Date: _____/_____/_____

Result
1_____ Available to be interviewed
2_____ No answer [LFU]
3_____ Inconvenient time [LFU]
4_____ Moved away/invalid number [LFU]

If you can't reach her after three calls, utilize the alternate contact information and/or contact persons to try to reach the participant. If you still cannot reach her, mark the box below.
☐ Client could not be found and is lost to follow-up.

Follow up module

1	Are you still using Standard Days Method/CycleBeads to prevent pregnancy? 1)_____ Yes 2)_____ No ➔ **Skip to #23**
2	Are you using the beads (CycleBeads) to keep track of your cycle? 1)_____ Yes ➔ **Skip to #4** 2)_____ No
3	How do you keep track of your cycle?? 1)_____ Mark a calendar 2)_____ Other:_____
4	INTERVIEWER: check cover page of form **If this is follow up 12 check here:** ☐ ➔ **SKIP TO # 22** **ALL OTHERS: CONTINUE**
5	INTERVIEWER: Note responses offered spontaneously on left side of box. For items not mentioned, ask about them and mark the prompted boxes Can you explain to me how you are using cyclebeads?

			Sponta-neous	Agreed when prompted	Disagreed when prompted	Not tracking cycle with CycleBeads
	A	Move black band to the red bead when period starts	1)____	2)____	3)____	4)____
	B	Mark first day of period on calendar	1)____	2)____	3)____	4)____
	C	Move black band one bead every day	1)____	2)____	3)____	4)____
	D	No unprotected sex on white bead days	1)____	2)____	3)____	4)____
	E	Unprotected sex allowed on dark bead days	1)____	2)____	3)____	4)____

6	How do you know if your cycle is too short to use CycleBeads? **(don't read the answer, mark all mentioned)** 1) _____ If my period comes before reaching the dark bead. 2) _____ If I reach the end of the necklace and my period has not returned. 3) _____ Count days on calendar 4) _____ Don't know 5) _____ Other:_____
7	How do you know if your cycle is too long to use CycleBeads? **(don't read the answer, mark all mentioned)** 1) _____ If I come to the end of the necklace and my period hasn't come 2) _____ Count days on calendar 3) _____ Don't know 4) _____ Other:_____
8	Do you move the ring everyday, including those days when you have your period? 1)_____ Yes 2)_____ No 3)_____ Not using CycleBeads to track cycle
9	If you don't wish to become pregnant, when should you avoid unprotected sex, according to CycleBeads? **(don't read the answer, mark all mentioned)** 1)_____during the white beads 2)_____during the brown beads 3)_____Between days 8-19 4)_____During your period 5)_____Right after your period ends 6)_____In the middle of the menstrual cycle 7)_____Right before your period starts 8)_____At any time 9)_____Other:_____

10	What do you and your husband/partner generally do to prevent pregnancy on your fertile days (white bead days)? 1)_____ Abstain from Sex 2)_____ Use condoms 3)_____ Withdrawal 4)_____ Other: _____
11	During your last cycle, did you have unprotected sex, that is, sex without a condom, withdrawal, or any other method, when the ring was on the white beads (days 8-19, for those who keep track on a calendar)? 1) _____ Yes 2) _____ No → **Skip to #13**
12	Did you use Emergency Contraception afterwards? 1) _____ Yes 2) _____ No
12a	What was the reason that you had relations during the fertile days without using a condom or another method? 1) _____ I forgot/was confused 2) _____ My husband/partner insisted 3) _____ No particular reason 4) _____ Desired or ambivalent about pregnancy 5) _____ OTHER:_____

13	How does your husband/partner participate in the use of CycleBeads? **(mark all that apply)** **PROBE: Anything else?** 1) _____ He moves the ring on CycleBeads 2) _____ He marks the calendar 3) _____ He reminds me to move the ring 4) _____ He asks me if we can have unprotected sex 5) _____ Not have sex on white bead/fertile days 6) _____ Use condom on white bead/fertile days 7) _____ Use withdrawal on white bead/fertile days 8) _____ Buy condoms 9) _____ Follow instructions on how to use method 10) _____ Other:_____ 11) _____ Don't know 12) _____ He does not participate
14	In your opinion, how easy is it to learn how to use CycleBeads? 1) _____ Easy 2) _____ Difficult 3) _____ Neither easy or difficult 4) _____ Don't know
15	In your opinion, how easy is it to use CycleBeads? 1) _____ Easy 2) _____ Difficult 3) _____ Neither easy or difficult 4) _____ Don't know
16	In general, would you say you are very satisfied, satisfied, or not satisfied with CycleBeads? 1) _____Very Satisfied 2) _____Satisfied 3) _____Not satisfied

17	Now I would like to ask you about your opinion about CycleBeads. Please tell me if you agree or disagree with the following statements, or if you don't know				
			YES	NO	DON'T KNOW
	A	CycleBeads is hard to understand			
	B	CycleBeads is hard for your husband/partner to understand			
	C	CycleBeads is easy to use			
	D	CycleBeads is an effective method in preventing pregnancy when used correctly			
	E	CycleBeads is affordable			
	F	CycleBeads is hard to obtain			
	G	Few women use CycleBeads in your community			
	H	Use of CycleBeads is against your religious beliefs			
			YES	NO	DON'T KNOW
	I	CycleBeads is acceptable to men			
	J	CycleBeads does not have side effects			
	K	CycleBeads does not cause health problems			
	L	CycleBeads interferes with sexual relationship			
18	What do you like most about CycleBeads? **(don't read the answer, mark all mentioned)** 1) _____ It is low-cost/cost-effective 2) _____ My husband/partner opposes using another method 3) _____ It doesn't affect my health and doesn't have side effects/I don't have to take or use anything/It does not effect breastfeeding 4) _____ Religious/moral reasons 5) _____ It is easy to use 6) _____ It is effective 7) _____ It is natural 8) _____ It is environmentally friendly 9) _____ Other: _____				

19	What do you like least about CycleBeads? **(don't read the answer, mark all mentioned)** 1) _____ Need to abstain during fertile days 2) _____ Lack of spontaneity 3) _____ Difficulty remembering to move the band 4) _____ Difficulty remembering to mark the calendar 5) _____ Concern about effectiveness 6) _____ Other (Specify) _____
20	Since you began using CycleBeads, has your relationship with your partner changed for the better, changed for the worse, or not changed? 1) _____ Better 2) _____ Worse 3) _____ No change
21	Why do you say that?

Exit module

22	Do you plan to continue using this method for the next three months? 1) _____ Yes ➔ **Skip to 26** 2) _____ No
23	Why not? **(Mark only one answer)** 1) _____ Became pregnant ➔ **Skip to #26**

	2) _____ Desires pregnancy ➔ **Skip to #26** 3) _____ Two or more cycles out of range (irregular cycles) 4) _____ Concerned about effectiveness 5) _____ Partner concerned about effectiveness 6) _____ It doesn't protect against STIs. 7) _____ Separated from partner/Doesn't have frequent/regular sexual relations 8) _____ Husband disapproves of method 9) _____ Difficult to use/Don't understand well enough 10) _____ Too many days to avoid sex during fertile days 11) _____ Lost CycleBeads 12) _____ Other _____
24	Do you plan to use (are you using) another method to avoid becoming pregnant? 1) _____ Yes 2) _____ No ➔ **Skip to #26**
25	What method do you plan to use (are you using)? **(mark all mentioned)** 1)_____ Male sterilization 2)_____ Female sterilization 3)_____ Pill 4)_____ Patch 5)_____ NuvaRing 6)_____ IUD (Mirena or ParaGard 7)_____ Depo/Injection 8)_____ Implanon 9)_____ Condom 10) _____ Female condom 11) _____ Diaphragm 12) _____ Foam/Jelly 13) _____ Withdrawal (pulling out) 14) _____ Natural Family Planning 15) _____ Rhythm Method 16) _____ Other: _____
26	INTERVIEWER: check cover page of form **If this is follow up 12 check here:** ☐ ➔ **SKIP TO #36** **If this is 3 or 6 check here:** ☐ ➔ **CONTINUE**

27	Is it easy or difficult for you to remember to move the black ring of your CycleBeads every day? 1) _____ Easy 2) _____ Difficult ➔ Why? _____
28	Is it easy or difficult for your husband/partner to cooperate in using the method? 1) _____ Easy 2) _____ Difficult ➔ Why? _____
29	Is it easy or difficult for you to manage the fertile days? 1) _____ Easy 2) _____ Difficult ➔ Why? _____
30	Is it easy or difficult for you to remember to mark the calendar on the first day of your period? 1) _____ Easy 2) _____ Difficult ➔ Why? _____
31	Is it useful for you to mark the first day of your period on the calendar? 1) _____ Yes 2) _____ No ➔ In what way? _____
32	Did you mark the first day of your period on the calendar every month? 1) _____ Yes ➔ **Skip to #34** 2) _____ No
33	Why didn't you mark the calendar every month? (**Mark only one response**) 1) _____ I forgot 2) _____ I was confused and didn't know what to do 3) _____ I don't have a calendar 4) _____ Other: _____
34	During your white bead days, did you use another method? 1) _____ Yes 2) _____ No ➔ **Skip to #36**

35	Which method did you use? **(mark all mentioned)** 1) _____ Condom 2) _____ Female condom 3) _____ Diaphragm 4) _____ Foam/Jelly 5) _____ Withdrawal (pulling out) 6) _____ Natural Family Planning 7) _____ Rhythm Method 8) _____ Other: _____
36	INTERVIEWER: Check response to #23. If answer is '**1) Became pregnant**', check here ☐ **➔Continue to #37** If did not answer 23 or did not become pregnant: **If this is follow up 12 check here:** ☐ **➔ SKIP TO #43** **If this is 3 or 6 check here:** ☐ **➔ END INTERVIEW** **➔Thank respondent for her time and remind her that you will call her in a few months to speak with her again. If she does not wish to be contacted again, mark here** ☐ **Offer her incentive and verify address.**

Pregnancy module

37	Were you using CycleBeads to prevent pregnancy when you became pregnant? 1) _____ Yes **➔ Skip to #39** 2) _____ No

38	Why did you stop using CycleBeads? (**Mark only one response**) 1) _____ Desired pregnancy ➔ **Skip to# 42** 2) _____ Two or more cycles out of range 3) _____ It doesn't protect against STIs. 4) _____ Didn't have frequent/regular sexual relations 5) _____ Husband opposed 6) _____ Difficult to use/Don't understand well enough 7) _____ Not effective/fear of pregnancy 8) _____ Other _____
39	During your last menstrual cycle before you got pregnant, was there ever a day when you had unprotected sex knowing that your CycleBeads were on a white bead (fertile) day? 1) _____ Yes 2) _____ No
40	During your last menstrual cycle before you got pregnant, was there ever a day when you had unprotected sex and later realized that your CycleBeads were on a white bead (fertile) day? 1) _____ Yes 2) _____ No
41	During your last menstrual cycle before you got pregnant, did your husband/partner insist on having unprotected sex even though you were experiencing a white bead (fertile) day? 1) _____ Yes 2) _____ No
42	**END INTERVIEW** **Thank her for her participation and let her know that you will not be contacting her again.** **Offer incentive and verify address.**

Partner communication module

43	Can you let your husband/partner know when you want to have sex? (**Interviewer: Read options)** 1) _____ Always 2) _____ Sometimes 3) _____ Never 4) _____ Don't know
44	Can you let your husband/partner know when you **don't** want to have sex? (**Interviewer: Read options)** 1) _____ Always 2) _____ Sometimes 3) _____ Never 4) _____ Don't know
45	Does your husband/partner take into account how you feel when he wants to have sex? **(Interviewer: Read options)** 1) _____ Always 2) _____ Sometimes 3) _____ Never 4) _____ Don't know
46	Who makes the decision to prevent a pregnancy? 1) _____ Husband/partner 2) _____ Myself 3) _____ Both 4) _____ Other

47	Do you feel comfortable talking with your husband/partner about preventing a pregnancy? 1) _____ Yes 2) _____ No 3) _____ Depends (explain _____)
48	When you and your husband/partner are together, do you feel embarrassed or talk very little about birth control? 1) _____ Yes 2) _____ No 3) _____ Depends (explain _____)
49	On days when you are concerned about getting pregnant, does your husband/partner become angry if you do not want to have sex? 1) _____ Always 2) _____ Sometimes 3) _____ Never 4) _____ Don't know
50	What about the days when you are not concerned about getting pregnant, does he get angry? 1) _____ Always 2) _____ Sometimes 3) _____ Never 4) _____ Don't know

N. List of presentations by IRH/GU

Dissemination venues for research results

Venue	Location	Format	Date
Nurse Practitioners in Women's Health Conference	Providence, RI	Poster	October 2009
American Public Health Association (APHA) Annual Meeting	Philadelphia, PA	Presentation	November 2009
Marquette University Natural Family Planning Conference	Milwaukee, WI	Paper, presentation and poster	June 2010
Title X Family Planning National Clinical Conference	St. Louis, MO	Poster	August 2010
APHA Annual Meeting	Denver, CO	Poster	November 2010
Title X Family Planning National Grantee Meeting	Miami, FL	Presentation	August 2011
Planned Parenthood Mar Monte-Modesto and Marin Community Clinics	Modesto and San Rafael, CA	Presentations	September 2011
JSI and Health Quarters	Boston, Lawrence, and Beverly, MA	Presentations	November 2011
Title X Family Planning National Clinical Conference	New Orleans, LA	Skills session and poster	Planned for August 2012
APHA Annual Meeting	San Francisco, CA	Presentation (pending acceptance)	Planned for November 2012