TwoDay Method® Market Research: Report on IRH Experience, Evidence, and Recommendations; and Interviews with Stakeholders, Donors, and Possible Future Collaborators

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Submitted June 2010
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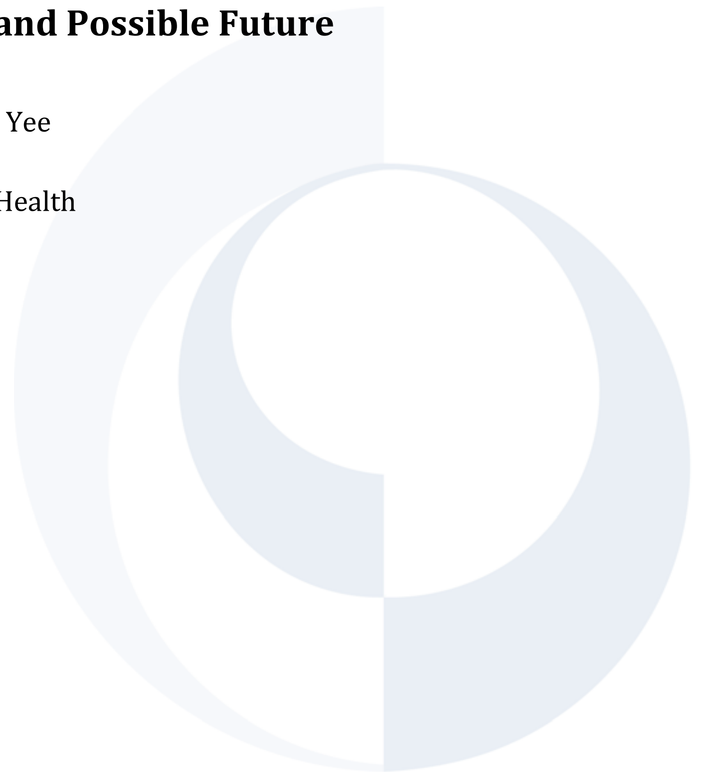

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Recommended Citation:
Aumack Yee, Kimberly. June 2010. TwoDay Method® Market Research: Report on IRH Experience, Evidence, and Recommenations; and Interviews with Stakeholders, Donors, and Possible Future Collaborators. Washington, D.C.: Institute for Reproductive Health, Georgetown University for the U.S. Agency for International Development (USAID).

The Institute for Reproductive Health (IRH) is part of the Georgetown University Medical Center, an internationally recognized academic medical center with a three-part mission of research, teaching and patient care. IRH is a leading technical resource and learning center committed to developing and increasing the availability of effective, easy-to-use, fertility awareness-based methods (FAM) of family planning.

IRH was awarded the 5-year Fertility Awareness-Based Methods (FAM) Project by the United States Agency for International Development (USAID) in September 2007. This 5-year project aims to increase access and use of FAM within a broad range of service delivery programs using systems-oriented scaling up approaches.

This publication was made possible through support provided by the United States Agency for International Development (USAID) under the terms of the Cooperative Agreement No. GPO-A-00-07-00003-00. The contents of this document do not necessarily reflect the views or policies of USAID or Georgetown University.

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Acronyms

AFLF	African Family Life Federation
AIDS	Acquired Immunodeficiency Syndrome
BIP	Basic Infertile Pattern
BV	Bacterial Vaginosis
CA	Contracting Agency
CBO	Community-Based Organization
DRC	Democratic Republic of Congo
DHS	Demographic Health Surveys
DHHS	Department of Health and Human Services
EC	Emergency Contraception
ECP	Emergency Contraception Pills
FA	Fertility Awareness
FAM	Fertility Awareness Method
FBO	Faith-Based Organization
FCG/FGM	Female Genital Cutting/Mutilation
FP	Family Planning
HER-C	Highly Effective Reversible Contraception
HIV	Human Immunodeficiency Virus
IEC	Information, Education and Communication
IRH	Institute for Reproductive Health, Georgetown University
KIT	Knowledge Improvement Tool
LAM	Lactational Amenorrhea Method
LARC	Long-Acting Reversible Contraception
MOH	Ministry of Health
NFP	Natural Family Planning
NIH	National Institutes for Health
NGO	Nongovernmental Organization
OPA	Office of Population Affairs
OR	Operations Research
RH	Reproductive Health
RSH	Reproductive and Sexual Health
SDM	Standard Days Method
STI	Sexually Transmitted Infection
TA	Technical Assistance
TDM	TwoDay Method
US	United States
USAID	United States Agency for International Development

TwoDay Method Market Research: Report on IRH Experience, Evidence, and Recommendations; and Interviews with Stakeholders, Donors, and Possible Future Collaborators

Executive Summary

Background

The TwoDay Method® (TDM) is an effective, fertility awareness method of family planning developed and tested by the Institute for Reproductive Health at Georgetown University (IRH). This simple method, based on a woman's naturally occurring signs of fertility, involves a woman checking her cervical secretions on a daily basis to identify the fertile days of her menstrual cycle. To avoid pregnancy with this method, the woman and her partner use a barrier method or abstain if she notices any secretions today OR noticed any secretions yesterday.

Following a research-to-practice model, IRH first established the theoretical basis for the TDM, then tested it in a multi-country clinical trial, and conducted small introduction studies to further test the method in service delivery settings. Results indicate that the TDM is 96% effective with correct use and about 86% in typical use. Clients describe the method as easy-to-use and providers report it is easy to teach others to use. Study results are further described in peer-reviewed journals and international guidance documents. Tested program and training materials as well as prototype tools for clients, providers and outreach are also available.

To further develop and test the TDM, and respond to programmatic needs for a non-commodity method of family planning, IRH conducted a market research project to:

> Part 1— Review IRH experience with TDM through staff interviews, synthesize TDM evidence as reported in scientific articles and reports, identify any gaps in TDM resources, and summarize findings and recommendations for future TDM activities
>
> Part 2— Analyze the potential for increasing awareness, availability and access to the TDM, identify opportunities and challenges for integrating the TDM into programs, and synthesize opinion research (phone surveys) with stakeholders, funders and potential collaborators regarding the feasibility and viability of integrating the TDM

The findings are summarized in this two-part report as well as in supporting documents developed in conjunction with this report to highlight details regarding key next steps.

Summary of Findings for Part 1: Report on IRH Experience, Evidence and Recommendations

While the TDM is too new and experience is too limited to assess the demand, IRH staff and consultants indicated that the potential for TDM was great, given the resources. Barriers to TDM integration include lack of awareness or information about the method, a funding focus on long-

acting reversible contraception, limited resources, negative assumptions or initial impressions of providers and policy-makers, and concern about client and/or partner motivation and its affect on efficacy. Lessons learned include: 1) the need for multi-level advocacy and Information, Education and Communication (IEC) at the community, provider, and policy levels; 2) the relevance of behavior change theories and strategies, especially with regard to couple communication and negotiation during the fertile days; 3) the usefulness of a communication tool (like CycleBeads) that the client can leave with, in her hand; and 4) the benefit of building on the successes and lessons learned from IRH's significant work on all aspects of the SDM.

The TDM is easy to teach and learn at any time of the menstrual cycle. Most women have observed their secretions before ever receiving instruction in the TDM, but have not previously associated their secretions with fertility. Although the current TDM service delivery model works well and has been well-tested, there is strong support for evaluating ways to adapt, streamline or simplify different aspects of program integration including training, job aids, client educational materials, reminder options and other tools to different settings (including non-family planning and non-facility-based settings.) While a follow-up visit is not necessary for accurate use of the TDM, providers stressed the importance of support to clients during the early months of learning the method.

Research priorities include a focus on operations research, in particular pilot studies that further test the integration of the TDM into different service delivery systems, with different levels of staff and local adaptations. There is also a need to further assess how to diffuse TDM information including the identification of local words, images and conceptual approaches for raising awareness and teaching the method to different target audiences. The need for more research on the bridge from LAM to FAM, couple dynamics, and gender issues was described. There are many opportunities to integrate the TDM into a variety of ongoing IRH activities, and the relevance of a wide variety of new technologies to future TDM work was noted by many.

Summary of Findings for Part 2: Report on Interviews with Stakeholders, Donors and Possible Future Collaborators

In many areas, the responses of stakeholders, donors and possible collaborators reinforced the findings from part 1 of this project. For example the potential of the TDM to address unmet need for family planning, expand choice and empower women and girls with a simplified fertility awareness method that also teaches individuals about normal, healthy body changes was described by many. The benefit of a non-commodity method, especially in resource-constrained and remote areas, was also stressed.

Regarding challenges to TDM integration, some interviewees voiced concern about partner involvement and potential impact on efficacy, cultural taboos regarding touching the genital area, confusion with other vaginal secretions including infection, bacterial vaginosis, arousal fluids, etc.

and the potential impact of female genital cutting (FGC) and use of desiccants in some regions, especially in Africa. Programmatic and funding constraints were also described as a barrier to TDM integration in light of the need for quality training and client education with staffing resource constraints. The broader challenge of moving initiatives from guidelines at the policy level to program implementation was also discussed.

Interviewees described a wide variety of organizations and approaches appropriate for TDM integration including those focused on family planning, general fertility awareness, youth-focused fertility awareness, parents of adolescents, faith-based projects, existing Standard Days Method® (SDM), Lactational Amenorrhea Method (LAM) and/or sexually transmitted disease (STI/HIV) education and services, community and facility-based programs including those not currently offering family planning, breastfeeding and postpartum programs, women's empowerment, human rights, efforts to end FGC, microenterprise, literacy and other sectors. When integrating the TDM into non-family planning programs, the need for collaboration and referral to local organizations offering a wide-range of family planning options as well as services for other areas of reproductive health including STI/HIV/AIDS) and prenatal care was stressed. Although many described the importance of youth learning about fertility awareness and the role of secretions, the need for age-appropriate messages and buy-in from parents, schools, service providers and the community was described as challenging and critical.

Efforts to position the TDM should include a multi-faceted approach to increase visibility and credibility of the method with specific, targeted approaches for the policy, provider and community levels. Many interviewees suggested additional operations research and advocacy research as key strategies to increase the evidence and publicize the results. Recognizing significant funding limitations, opportunities to collaborate with other organizations to further research and advocacy activities were stressed along with the possibility of exploring woman-to-women networks, like La Leche League, and eventually moving to a direct-to-consumer approach with the TDM.

Recommendations

In reviewing the findings, the following themes appear to be central to future TDM work: simplification, expansion, integration and collaboration. While these themes overlap, the recommendations that emerged from the findings are summarized under these categories.

Simplification

- Conduct operations research to further simplify how the method is offered, approaches to remembering the fertile days, and ways to fine-tune service delivery. Include pilot studies with larger numbers, different areas of focus and different geographic areas (like what was done with the SDM). Add to the evidence base and publish additional articles in peer-review journals.

- Test adaptations of the TDM approach including simplified client and provider tools for different local texts, especially with low-literacy populations.
- Whenever possible strengthen existing tools, rather than create new tools.
- Conduct advocacy and marketing research and seek simple, easy-to-remember words and images to associate with the TDM and to counter bias and negative perceptions about the method as well as concern by some that the method and related activities reflect a moral agenda they do not agree with.
- Capture the voice of satisfied, successful TDM users.
- Design and test a simplified, two-hour TDM provider training for compatibility with existing in-service training formats, and a further simplified informational version for conference presentations.
- Explore possibilities for offering the TDM through woman-to-woman networks as well as opportunities for direct-to-consumer application.
- Capitalize on new technologies like mobile phones, internet applications, webinars, blogs, etc. to include the TDM and key messages in a variety of ways as well as link with reputable, far-reaching sites.

<u>Integration</u>

- Seek a wide range of opportunities to integrate fertility awareness information and the basics of TDM as "facts-for-life" that are important for all women, men and youth in the general population. This can be through the health sector, education including colleges, facility and community-based programs, microenterprise, etc. Lay the groundwork to achieve buy-in at all levels, especially when working with youth-focused programs.
- Build on the successes and lessons learned through previous SDM and LAM research, project activities, and networks with past collaborating organizations. Integrate the TDM into programs that currently offer the SDM.
- With new TDM projects create linkages with organizations and programs focused on multi-method family planning and broader reproductive health areas including STI/HIV/AIDS, maternal and child health, etc. to both support the integration of TDM and to reinforce opportunities for women to segue into other needed health services.
- With TDM method instruction, continue to incorporate how to use the selected barrier method if one will be used, information about the TDM not protecting against of STIs including HIV/AIDS (and referral if needed), and support for the partner's role in effective methods use.
- Use inclusive language for counseling and IEC that is consistent with (does not appear to contradict) other public health messages or other health concerns.
- Continue to integrate the TDM into state-of-the art publications, policy documents and national guidelines and work to bring the method from the policy stage to program implementation. Create talking points for in-country partners to discuss the TDM with policy makers and gate keepers.

- Contact editors and authors of key medical textbooks for training physicians, nurses, etc. to incorporate fertility awareness in general, and the TDM in particular, into textbooks and curricula for training medical professionals.
- Seek additional ways to integrate the TDM into a variety of other, ongoing IRH projects and activities.

Collaboration

- Continue expert consultations and seek opportunities to collaborate with other researchers to gather and analyze data regarding:
  - the prevalence and potential impact of non-ovulatory secretions (BV, STIs) for women from different geographical regions and for women with different conditions (like FGC and use of desiccants)
  - the secretions of post-partum and breastfeeding women to discover a quicker/easier bridge to the TDM
  - the secretions of women with a non-changing, basic infertile pattern and premenopausal women with irregular cycles
  - the possible impact of learning and using fertility awareness information, including the TDM, on the empowerment of women and girls
  - behavior change processes, male involvement and gender equity issues to further inform TDM counseling, reminder materials, IEC and service delivery
- Collaborate with faith-based organizations and other NFP groups interested in offering the TDM. Facilitate modification of TDM materials to incorporate the philosophical perspective of faith-based groups and invite them to participate in pilot studies or to contribute data and experiences helpful to TDM expansion.
- Seek collaboration and lessons learned from new family planning projects (e.g. FHI/PROGRESS) bringing hormonal methods like the injection and implant to remote areas through health extension workers (HEWs). Seek other lessons learned from other projects that employ human resources task-shifting for systems strengthening.
- Seek additional funding from organizations like the Office of Population Affairs (OPA), National Institutes for Health (NIH), Gates Foundation and Packard Foundation. Conduct an occasional mini-TDM presentation for key staff at the USAID office.
- Keep those interviewed for this project in the loop for future collaboration; send E-Blast and other updates to maintain connections.

Future IRH Studies on the TDM

In January 2010 IRH staff met to discuss preliminary findings and recommendations from the market research project, explore the IRH vision for future TDM work, and determine priorities for the next phase of research pertaining to this method. As a result, two pilot studies have been designed and site selection and study protocols are being finalized.

One study includes offering the TDM through community-based workers who have not previously offered methods of family planning. The purpose of this study is to determine the methods or tools needed to offer the TDM to women and couples with low-literacy skills, and the feasibility and effect of using this approach to integrate the TDM into a community-based program. The study will probably be conducted in the Democratic Republic of Congo (DRC) and Guatemala.

The other pilot study includes integrating the TDM into a service delivery system that already offers the Standard Days Method® (SDM) using CycleBeads®. The purpose of this study is to determine the feasibility and effect of integrating the TwoDay Method into the family planning method mix, especially in facilities where the Standard Days Method (SDM) is already offered routinely.

> "See where (you) have come…Took the method (TDM) from nothing to evidence-based…Here it is! Now, positioning and marketing will be the next set of challenges." - (International TA organization interviewee from the phone survey)

TwoDay Method® (TDM) Market Research Part 1: Report on IRH Experience, Evidence, and Recommendations

1. Introduction

The TwoDay Method® (TDM) is a simple and effective natural method of family planning developed and tested by the Institute for Reproductive Health (IRH) at Georgetown University. In order to complete development and testing of this innovation and to design a plan to generate and respond to programmatic demand for the TDM, information is needed on IRH experience, evidence and recommendations for future TDM activities. Information is also needed on international service delivery organizations, donors, and individuals who may be interested in incorporating the TDM into their work. In addition, information on the type of evidence, tools, and materials they require is also needed.

This section of the report documents Part 1 of the TDM market research project by compiling and synthesizing IRH experience, evidence, and recommendations for future TDM activities.

The purpose of part 1 of this report is to:

- Synthesize existing experience and evidence of TDM research and service delivery
- Update the list of TDM resources including a description of each available resource
- Identify gaps and/or recommendations to modify IEC, client education, training, and service provider materials and resources
- Summarize interviews with key IRH staff, former staff, and consultants directly involved in TDM projects
- Highlight lessons learned and recommendations from previous TDM studies (as well as SDM experiences) which may help guide future TDM activities and introduction plans
- Identify key stakeholders and experts to interview for the market assessment protocol

2. Methods

To compile part 1 of this report, the following methods were employed:

2.1 TDM Journal Articles and IRH Project Reports

All peer-reviewed journal articles on the TDM as well as all TDM project-specific reports were reviewed. A list and description of these journal articles and reports is included in the references for this report and in Annex A: TDM Resources. Findings and conclusions were noted and later discussed with key IRH staff during scheduled interviews. Key points from these interviews along with highlights of findings from the TDM journal articles and reports have been summarized by major themes in the results section of this report.

2.2. TDM Client Education, Training, and Service Delivery Materials

All TDM client education, training, and service delivery materials were reviewed in English, Spanish and French. This includes client card, provider cue card, job aids package with initial and follow-up checklists, training manuals, posters, brochures, flyers, and other materials developed and tested for TDM projects to date. The international policy and norms documents that currently include the TDM were also reviewed. A description of these materials, along with material-specific recommendations/considerations for future modifications or use, is included in Annex A. In addition, a summary of key points is included in the results section of this report.

2.3 Interviews with IRH Staff and Consultants

Following a review of all TDM documents and materials, interviews were conducted with 12 IRH staff, former staff, and consultants with direct experience in TDM research, client education, training, and service delivery. The following individuals were interviewed by phone or Skype: Victoria Jennings, Rebecka Lundgren, Jeannette Cachan, Irit Sinai, Arsene Binanga (DRC), Marie Mukabatsinda (Rwanda), Marcos Arevalo, Monica Marini, Marco Antonio Basualdo Ibañez (Peru), Rosario/Charo Panfichi (Peru), Judith Diaz (Peru), and Lidia Mazariegos (Guatemala).

The interview questionnaire is included in Annex B. The interviews lasted approximately 45 minutes to an hour, as probing questions were added depending on the experience and expertise of the interviewee. This questionnaire was also translated and specifically tailored for interviews with field staff in Peru, Guatemala, Rwanda, and DRC, for discussing project-specific field experiences in greater detail. Dina Abi-Rached assisted with French translation during the interviews regarding Rwanda and DRC. The interviews with staff in Latin America were conducted in Spanish. Meredith Puleio was also interviewed regarding her experience including the TDM during conference exhibit booth discussions. The results of the interviews are summarized below.

3. Results

The following is a synthesis of the review and analysis of: 1) TDM journal articles and project reports; 2) TDM client education, training, and service delivery materials; and 3) interviews with IRH staff and consultants. The results are summarized below in relation to the main topics discussed in the interviews.

3.1 Demand for TDM

Most interviewees reported that there is not enough experience to assess the demand for TDM. In general providers, clients, and policy makers do not know about the TDM.

Although interviewees reported a need for effective, natural methods with no side effects, it was not known whether women would prefer a symptoms-based method like the TDM or a calendar-based method. Interviewees spoke very positively about the TDM as a method option for women and couples. "The potential demand is big, if given the resources."

More women can potentially use the TDM (when compared to the SDM) since there is no cycle length criteria. Very few TDM study participants were excluded because of too many or too few days of secretions (1)[1]. In contrast, many more women were excluded from the SDM studies because of cycles outside the 26 to 32 day range. Since the TDM follows the naturally occurring fertility signs in a woman's body, this appears to be very assuring to many women.

In Guatemala a particular demand for natural methods in the rural areas was described, where women and couples have limited or no experience with family planning and do not want to use other methods. "The TDM (and natural methods in general) do not take away from other family planning methods (as some providers are concerned about) but open the door to greater access to the array of family planning methods and services." Other interviewees also described the potential demand for the TDM among women who do not want to use hormonal methods (or are unable to); however programs should be careful not to accentuate client concern about hormones.

In Peru the Demographic and Health Survey (DHS) indicated that 22% of family planning users follow withdrawal or periodic abstinence, but with limited knowledge of the fertile days. In the "TDM Quick-Start" study in Peru 1.3% of new users to family planning in Lima selected the TDM, and 2.9% in Piura (2).

It was noted that future efforts to increase awareness and the demand for the TDM should also include plans to provide the necessary supplies and project infrastructure to address a newly created demand. Many field staff also reported the need for TDM projects to be fully funded and supported through system-wide integration.

3.2 Barriers to TDM Service Delivery

The most commonly cited barriers to TDM use and program implementation were: lack of awareness of the method, provider bias against natural methods in general, as well as the TDM being the least known, least understood of the FAM options, and limited funding available for the TDM.

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[1]See the references at the end of this report for a numerical list of journal articles and IRH project reports referenced in this document.

USAID funding for family planning is currently focused on other new methods, in particular long-acting reversible contraception (LARC) and especially new implants and community-based distribution of injectable contraceptives. “Efforts to integrate two or more new methods can be a drain on program time and resources.” Additional efforts to incorporate a FAM (like the TDM) have not been a high priority, and the TDM has a higher pregnancy rate when compared to LARC.

IRH current work includes scaling up the SDM as well as LAM activities. With limited resources, allocating time and energy for TDM work has been challenging. Some interviewees were concerned that programs may be reluctant, or find it difficult, to offer more than one FAM. Others stressed the need for IRH to diversify and not be perceived as a “one-method organization”.

All interviewees described provider bias as a significant barrier to FAM efforts in general and the TDM in particular. However, once providers were well-trained to offer the TDM, they did so with confidence, enthusiasm, skill, and within the context of informed consent. Colleagues of trained providers (those who had some awareness of the TDM but no direct experience or training in the method) expressed concern that women would be unable or unwilling to check secretions, concern about efficacy, and fear that FAM/TDM might lure clients from more effective options, or play on the concerns some clients have regarding hormonal methods. While the provider biases and concerns are not evidence based, they are real and pervasive and efforts to change provider attitudes have been challenging. “Sadly NFP is the last wheel on the car.”

With the SDM, clients can foresee and plan ahead for the “fixed” 12-day fertile window. With the TDM, however, clients cannot accurately predict when the fertile days will begin (when the woman first observes her secretions) or when the fertile days will end (after two days in a row without secretions). This will vary for different women and within different cycles of the same woman. With the TDM the fertile window may be longer or shorter than 12 days; this was usually between 11 -15 days long, with a mean of 13 days (3). The unpredictable variability of the fertile window may be a challenge for some couples in terms of negotiating the fertile days, especially when first learning to use the method (3).

3.3 Lessons Learned

Interviewees stated the following as important lessons learned: 1) the need for multi-level advocacy and IEC at the community, provider, and policy levels; 2) the relevance of behavior change theories and strategies, especially with regard to couple communication and negotiation during the fertile days; and 3) usefulness of a communication tool (like CycleBeads) that the client can take with her.

In general, integration of the TDM into family planning services in Peru was very well received. However, it was much easier to integrate the TDM in Piura, which is a more provincial area; there was less staff turnover, more institutional and provider support for natural methods even before the study began, a provider culture that was more accepting, and basically "more fertile ground." In contrast, Lima is a big city with a more complex family planning service delivery system. There were more reservations among staff in Lima, less administrative support, more "pushing" of hormonal methods, more staff turnover, and little previous experience with a "counseling-focused" method.

Suggested strategies for integration of the TDM include creating a solid NFP/FAM-positive approach to Ministries of Health and key national organizations that would include the SDM, TDM and LAM as a package. The inclusion of peer-reviewed journal articles and other context-specific evidence for the inclusion of these methods in policies, norms and programs was stressed by many interviewees. Efforts to integrate the TDM into schools of nursing and obstetrics were also instrumental in Peru.

Pilot projects and introduction studies need follow-up and support over time to fully integrate the new innovation. Support is also needed at key, opportune times to coincide with nation-wide activities for updating and revising family planning norms, policies, training, and materials to help reinforce sustainability efforts.

Previous IRH work in the SDM including personnel contacts, past studies, approaches tested, materials developed and other SDM activities have "opened the road, cleared the path" which facilitates TDM projects. With the various iterations of the SDM materials, they have been simplified over time and often served as models for future TDM materials. TDM services also have the potential to compliment well with programs offering the SDM and/or LAM.

Early on there was concern that women would not want to check their secretions or possibly touch themselves (although touching is not required to use the method). However, "Women don't mind doing this." It is not viewed in a sexual way and is different in different cultures. "People aren't grossed out about secretions."

3.4 Service Delivery

All interviewees reported that the TDM is easy to teach and learn, and easy to implement into programs (a few added, not as easy as the SDM). Some suggested that the TDM can be offered to supplement SDM or LAM projects as an added option for women, capitalizing on current IRH efforts in scaling up the SDM and where there is existing logistical and programmatic support. (Preliminary data from the Mali project on integrating both the LAM and SDM into health services will soon be available.) Other interviewees stressed that

the TDM should not only be viewed as an "add on" for those not eligible for the SDM, but rather positioned as a viable method for any woman interested in a fertility awareness-based method (FAM).

With correct use the TDM has a first year pregnancy rate of 3.5 and a typical use rate of 13.7 (4). This is a slightly lower first year pregnancy rate for correct use when compared with the SDM, but a slightly higher rate for typical use. This may be because the TDM follows a woman's naturally occurring fertility signs, but it may not be quite as simple to teach, learn or use. Results of the Peru Quick-Start study determined that the TDM can be offered at any time of the woman's menstrual cycle (5). Providers need to understand the menstrual cycle well and adjust counseling to highlight what the woman will be observing based on the phase of her respective cycle (6).

3.4.1 Simplification

Although interviewees felt the current service delivery model worked and was well-tested, they supported the idea of evaluating ways to simplify different aspects of service delivery including training, tools and job aids, and the method recording system. For integration into future programs the message from many was "Keep it simple."

When asked about their perspective regarding simplifying the recording of secretions, almost all interviewees supported testing this idea. In Guatemala most families have a "free promotional calendar in the home and this could be used to record secretions." In Peru a simplified, minimal recording could be tested, although the interviewees have had limited experience working in the rural areas. In Rwanda the idea of testing a simplified recording system was supported as "some women and men are not able to read or write." All agreed that there was a need for a carnet or card that the client left with, that would include information on what the method is and how to use it. One person felt that there was no need to simplify the counseling model or recording approach, only a need to simplify the training.

Another person cautioned that attempts to simplify should not "take away too much" at the expense of reducing comprehension or skills. Some felt that a woman needed to record secretions the entire cycle, especially during the learning phase, to understand her pattern. Others were open to testing a recording system that did not include daily recording of secretions. In the Peru "Quick-Start" study half of the clients interviewed indicated that within three to six months of learning the TDM they could have stopped recording, as they were able to determine whether a given day was fertile or not (7,8).

See Annex C: "Ideas for Testing TDM Recording Options," for a examples of simplified recording systems for possible testing.

There was reluctance to create a "gadget" like CycleBeads for marking/remembering the fertile days when using the TDM, as interviewees reported problems with procuring and distributing supplies as a barrier to SDM integration. With the TDM there is the advantage of offering a "non-commodity" method. For Peru, client education materials "need to be adapted for integration at the Ministry level, and cheap to produce."

3.4.2 Group Teaching

While sensitization and "awareness raising" about the TDM can and is done in groups, most field-based interviewees considered individual or couple instruction of TDM to be more appropriate than group teaching, especially because of the sensitive nature of talking about sex, sexuality, and couple relations. The individual (or couple-focused) counseling model fits within the family planning service delivery system as well as community-based distribution of family planning methods as women are typically counseled about family planning methods as an individual (or couple) and not in a group. However, the TDM lends itself to group teaching more than the SDM as there is no eligibility criteria for cycle length, and "everyone is on the same page."

3.4.3 Follow-up

During the efficacy study 96.4% of participants had no problem detecting secretions at one month (9). For this reason, many IRH staff considered follow-up to be a non-issue for effective TDM use, especially since many family planning programs have women come back for follow-up anyway, as follow-up is required for other methods and/or other health-related reasons. During the efficacy study the participants were visited three or more times during the first month to review the woman's diary card and techniques for checking secretions, which may have contributed to accurate detection of secretions at one month after method instruction.

In the Peru "Quick-Start" study, the percentage who reported occasional trouble detecting secretions was higher after the first cycle than after the fourth cycle. About 2/3 of study participants completed seven cycles of method use (10). This and anecdotal information from the Peruvian study team suggests that a follow-up visit may contribute to correct use. During interviews with the Peruvian team the importance and benefits of follow-up were described as supporting correct method use, addressing partner issues, checking on other health issues, clients wanting the connection, lack of counseling experience among providers, and a way to fit with the protocol of other methods that require follow-up.

3.5 Client Education and Counseling

In Peru, the client education and counseling approach was well-liked and supported, and took about 30 minutes per client. As a result of the Peru experience, an existing graphic on

the TDM client card is being adapted to show when secretions occur in reference to the entire menstrual cycle. The card will then serve as both a client card and provider cue card. "This decreases the number of job aids, facilitates training, and reduces printing costs."

The importance of the learning phase, and teaching women to pay close attention and notice secretions from when they first start was stressed by interviewees, as well as the need to counsel regarding the partner's support of the method and negotiation about the fertile days. The need for both partners to have a "strong intention to avoid pregnancy" was stated as a factor in successful use of the method.

Many field staff reported that women had observed and knew about their secretions, but did not have experience talking about this nor an understanding of the link between secretions and their fertility. In Guatemala, the importance of teaching women to see their secretions first, and then pay attention to what they feel throughout the day, was stressed.

Although most users had no problem with avoiding unprotected sex on fertile days, for woman who had unprotected sex on a fertile day, the most common reason was the husband insisted (11). After three cycles of experience with the TDM, users report less occasional difficulties with identifying secretions (12) and couples adjusted sexual behavior to accommodate the method and increase correct use.

In rural Guatemala women often did not wear underwear or use toilet paper. Although not required for the method, some husbands became involved by buying toilet paper for their wives to use. Women could easily distinguish between urine, which just looked "wet", and secretions which had a "shiny" appearance.

Women with previous experience with barrier methods, withdrawal, or NFP were twice as likely to use a back-up method to having unprotected sex (13). Also given the high incidence of bacterial vaginosis noted in the Peru study, the need to tell clients to return if they notice unhealthy secretions was stressed.

The findings described above point to the benefit of discussing with TDM clients about the use of barrier methods during the fertile time, partner support and negotiation regarding fertile days, and identification and follow-up for clients who may experience unhealthy secretions. See Annex A: SDM Resources for a list of all the client educational materials and minor suggestions for material-specific revisions based on an assessment of findings from the research projects, TDM materials, and interviews.

3.6 Training

A comprehensive, six-hour TDM provider training was conducted for the "Quick-Start" study in Peru. Detailed training materials are available for replication of this training in English, Spanish and French. This TDM provider training includes practice activities with all the TDM tools and educational materials, as well as a written test and practice counseling at the end of the session. A 20 slide PPT presentation is also available to provide an overview of the method.

Supervisory reports from Peru indicated that providers were able to provide quality counseling post training. The KIT was described as an excellent tool for provider assessment (JD). In addition, refresher training or supervisory visits were later recommended to remind providers to offer the TDM at any time of the woman's menstrual cycle, and to tell clients when to return for follow-up, what to do if unhealthy secretions were observed, and that the TDM does not protect against STIs. "The provider needs to be sure, convinced, and well-trained to take the method to the client."

The need to increase TDM awareness and support among other staff (those not trained as TDM providers) was identified during the "Quick-Start" study in Peru. A standard TDM orientation training for all staff may increase support for integration of the method as a valid option for women, address broader provider bias, and encourage referral of interested clients to the trained TDM providers. (See Annex A: TDM Resources for specific suggestions.)

Many staff interviewed stressed the need for a short (approximately two-hour) TDM provider training to integrate into existing training programs within the context of informed consent. In Peru, national training updates for all methods were three days, and are being reduced to 1 and ½ days. There is a need for a shorter, more simplified TDM training and an accepted training protocol for the TDM at the Ministry level in Peru. The Ministry is also supporting skills-based online training courses, and it would be ideal to integrate the TDM into these trainings.

If TDM service delivery or tools are simplified, then "future training should be designed around the simplified approach or tool." Other interviewees appreciated the need to shorten TDM provider training but also stressed their experience that providers needed more time to improve counseling skills and address how to discuss couple issues with the method. Providers are often not trained in counseling, "They just give a shot as it's easier and faster."

Many commented that providers who observed their own secretions became convinced about the specifics of the method and this experience helped them describe secretions and

how to observe and record them. "They became believers…were fascinated." However, self-observation of secretions was optional, not a requirement of the training.

Some interviewees voiced concern about the possible break down in the quality of future training, following a cascade of trainings to the most remote areas. "By the time training reaches some of these areas, the quality can be compromised."

3.7 Research Priorities

Interviewees suggested that the focus be on small, mini-studies that support integration of the TDM into services. The importance of further "testing the TDM in programs before any scaling up" was stressed. In Guatemala the importance of selection criteria for study participants was stressed along with the need to test target audience knowledge and beliefs about fertility, secretions, etc. at the beginning of any project. The reality of fiscal constraints and the need to form viable partnerships with other organizations to expand possible TDM research efforts was also discussed.

The following emerged as suggested areas of study for future research:

- Who can offer the TDM? (Community-based providers? Instructors of other symptoms-based methods like Billings OM? SDM or LAM providers? Successful users, Others?)
- How to offer the TDM? (How to simplify? What are the best images and language to share the messages? Conduct qualitative studies to assess how to teach the method easily and effectively)
- Where to offer the TDM? (Offering the TDM at the field level, with community-based programs? Other?)
- How to integrate the TDM into programs? (How can it be simplified? What if women stop charting?)
- How to diffuse TDM information? (How to get the word out? Approaches to raising awareness and changing attitudes among community members, providers, policy makers, etc. within the context of significant bias, barrier analysis?)
- How to transition from LAM to TDM?
- Test different versions of the KIT for different service delivery models and different needs
- Assess couple issues, the male perspective
- Assess direct to consumer projects (with minimal help from providers)
- Explore SMS texting and web-based, internet opportunities

Following up women for a long time is costly. As a result, opportunities to look at method continuation from a retrospective study were suggested.

3.8 Possible Areas of Focus

3.8.1 Community-Based Programs

Interviewees felt the TDM may be uniquely suited for introduction into community-based programs. These programs often serve populations in marginalized, rural areas with a high unmet need for family planning. Work in Guatemala with Mayan women and couples suggest that FAM methods in general, and the TDM in particular, provide an important family planning option for families that do not want to use other methods. In addition this provides an "open door" for introduction and access to other health programs and services. With a community-based program, "there is not a need to focus on family planning per se, unless this compliments the program". The importance of having a "no-cost" approach, "not even a bag" was stressed. "Take natural methods to the farthest out places…where others don't go."

3.8.2 Breastfeeding and Postpartum Women

Breastfeeding and postpartum women can use the TDM if they have had four periods since their baby was born and meet the other selection criteria. About 40.5% of participants in the efficacy study were still breastfeeding at admission. However, based on the findings of the journal article on the application of simple FAMs to breastfeeding women, only about 25% of these women would be able to begin using SDM/TDM on their fourth cycle postpartum; the others would need to wait longer to establish cycle regularity (14). TDM users could possibly start earlier but would experience many more fertile days than women with regular cycles and would require more days of abstaining or using a barrier method like condoms (13). Also, this study reports that 50% of the women who hadn't had a period by six months (no longer covered by LAM) had extensive mucus patches—secretions 80% of the days. For breastfeeding women who may be interested in using the TDM, many would need to use an alternate method for some time before being eligible for the TDM.

Interviews with IRH staff reflect the need and desire to better serve breastfeeding woman with a natural method option and/or a bridge from LAM to the TDM. In Guatemala, the high motivation of postpartum women to avoid pregnancy after a recent birth was described as well as their desire for a natural option, especially when breastfeeding. In Rwanda, DRC, Peru and Guatemala field-based interviewees stated that breastfeeding women wanted to use the TDM but had not yet met the criteria. Rwandan and DRC providers previously trained in Billings thought the TDM should be applicable before four periods. Work in finding a calculation and/or combined calculation and secretion observation for the postpartum/breastfeeding woman has proved to be too complicated for program implementation. However, IRH is currently working on a "Bridge to the SDM" client card which may be able to be modified for use with TDM.

IRH staff mentioned "we don't know what happens to secretions postpartum and post hormonal method use." However, staff is also concerned about using limited resources on the postpartum/breastfeeding interface. "Researchers have tried, money has been spent, but there is no magic bullet for breastfeeding and postpartum women."

3.8.3 Faith-Based Organizations (FBOs)

Working with FBOs there is built in acceptance and promotion of natural methods. However, instead of addressing provider bias against natural methods, there is the possible need to address provider bias against other modern methods of family planning. Some interviewees felt increased work with FBOs would give short-term visibility but in the long term could be problematic if the method was primarily associated with a church group. "It's risky…..could bring down the method." Others felt this was not a major risk or concern as FBOs are available and good opportunities for possible linkages and program support, especially in times of fiscal constraints, and this would not be a unilateral focus. However, efforts to collaborate with Ministries of Health in Peru were reported to have greater potential impact at the country level than work with FBOs.

Billings OM instructors in Rwanda and DRC have been trained in the TDM. Focus groups were held with these providers, most of whom observed their own secretions to "test" the method. Although providers report that the TDM is easy to understand and use, and approved of the client materials, most had not yet offered the method to clients. Whether previous experience teaching the Billings OM method enhances or over-complicates a provider's ability to offer quality TDM client education is not known (15).

In Guatemala the Anglican Church, as well as the Catholic Church, may provide openings for increasing access to the TDM (and SDM). Since these methods do not require touching one's self, this is seen as a positive aspect.

3.8.4 Adolescents

The TDM lends itself even more to fertility awareness education than the SDM. Although the relevance and importance of TDM information as a fertility awareness tool for adolescents was stressed, the "ability to attract an interested funder may be challenging."Key messages about healthy secretions, their role in fertility, the ability to control one's fertility, the value of partner communication, and the value of talking with a health care provider about one's reproductive health fit well within the themes of adolescent health, human rights, and women's empowerment. Young girls could learn to notice secretions before the onset of menses and recognize their significance in terms of "fertility literacy" for their entire reproductive years. No suggestions for possible funding were provided.

In Peru the unintended pregnancy rate of teens was reported as high, and TDM messages could be added to the fifth year of secondary education which is when many schools include a family life curriculum (JD). The need to test the TDM as a family planning method in programs was viewed as a priority over fertility awareness education for adolescents.

3.8.5 Early Detection of Syndromatic STIs

Many IRH staff indicated that a study on using the TDM to support early detection of syndromatic STIs would need to be too large and costly to be feasible, and this is not of interest to USAID or the scientific community. (VJ, RL, JC, MA) Providers at conferences and in programs have voiced concern that women would not be able to differentiate between healthy and unhealthy secretions. In the Peru study, the importance of reminding women to return if they observed unhealthy secretions was noted. This message could also be incorporated into the client card. In Guatemala, it was reported that many indigenous men and women would "see a curandero or self-treat" rather than report a possible STI to a health provider.

3.8.6 SMS Texting and Web-Based Applications

The possibility of offering the TDM through SMS texting was explored briefly with interviewees. The TDM could be taught and/or complemented with a simple program for the individual to enter whether or not she has secretions on a daily basis, and the program would calculate whether a given day is fertile or not. There is no need to reset the calculation each cycle to adjust to first day of menses. Instead, self-contained software that answers the various questions and keeps track of today and yesterday would suffice. There would be no need to pay to send or receive a separate text message, unless it was a daily question about secretion status. In Guatemala and Peru the high use of cell phones was noted. However interviewees commented that usage was probably less in the more marginalized, rural areas.

There is also an increased use of the internet, especially in Peru, including low cost internet cafés available to the public with technical support. There are also increased opportunities for online training of providers at the different health posts.

3.8.7 Planning a Pregnancy

Couples can increase their chance of achieving pregnancy by simply timing intercourse on days with noticeable secretions (16). However, research in this area is not a high priority for IRH. "To study the impact of TDM on planning a pregnancy, one would need to study the time to pregnancy with and without the additional knowledge about targeting days with secretions." Since about 85 out of 100 women get pregnant within a year if no method of contraception is used, "who would fund a study like this?" Perhaps an infertility group

would be interested in looking at the extent to which using secretions to target intercourse helps sub-fertile couples achieve pregnancy. This was not described as a priority.

3.8.8 TDM as an Expansion of SDM Programs versus TDM-Specific Focused Approach

Although it is ideal to test the TDM in isolation, limited resources and the eventual reality that the method would probably be offered in conjunction with other FAMs through informed choice, or for women who cannot use the SDM because of cycle length, may dictate offering the TDM where the SDM has already been offered.

3.9 Positioning the TDM

In discussing suggestions for positioning the TDM, interviewees stressed the importance of finding out what resonates with different target groups.

3.9.1 Confusion with the Name "TwoDay Method"

Many interviewees articulated concern about the name "TwoDay" method, and had encountered confusion regarding this name, especially when community members and others misinterpreted the name to mean that a woman only needs to protect herself for two days. One person also mentioned possible confusion with the method Today Sponge.

Some interviewees suggested testing and possibly finding a better name for the method. A few proposed following a process similar to the one used to determine the name for the Standard Days Method. This included asking each IRH staff member to come up with ten possible names, discuss these, and test the preferred options. Another staff suggested hiring a marketing consultant with a fresh vision to help determine the best name for the method.

Concern about confusion with the acronyms SDM and TDM (especially if programs were offering both methods) was also expressed. One suggestion is to always write and say **2Day Method** so as not to confuse the TDM with the SDM.

3.9.2 Finding Words and Images to Describe Secretions

The need to find images,visuals and words to promote the concept of a method based on observation of secretions in a clear and meaningful way was expressed. In Rwanda it was hard to find the right word to describe secretions in the local language, there was a term for "movement of liquid coming out" but this was awkward and challenging to describe. In Peru, providers often described secretions in the following way:

When we are sad, our eyes cry tears
When we are sick with a cold, we have a runny nose (mucus)
When a woman is fertile/can get pregnant, she has vaginal secretions

Although interviewees reported that women often knew about and had observed their secretions, the women did not know how these secretions related to fertility. In Guatemala, during initial needs assessment they determined that women knew and observed menses, as well as healthy and unhealthy secretions. However in most countries women and the public were not familiar with talking about secretions in common, everyday language. Also, women did not mind looking at and even touching their secretions.

Suggestions for marketing included looking at how pregnancy test marketing has been done, connecting urine tests with pregnancy detection, and eliciting those with marketing expertise to help find the best messages for talking about secretions.

3.9.3 Increased Integration of the TDM at IRH

Suggestions were also made to more fully incorporate the TDM into IRH materials, conference presentations, exhibit booth discussions, available briefs, etc. to more fully highlight and incorporate the TDM into IRH ongoing marketing and publications. Other suggestions for "getting the word out" include creating a press kit, video, and concrete strategies for marketing and presenting the TDM to the public, potential providers, contract agencies, other organizations, and policy makers.

3.9.4 Local Involvement and Input into Testing of Messages, Materials, and Approaches

A Nicaraguan group created a report on strategies for positioning the TDM along with sample promotional and educational materials. The report of areas to consider as well as prototype materials may serve as samples (JC). Field staff shared the need for messages and materials to always be locally tested and carefully adapted for the target audience. The need to do rapid field testing and revisions at an early stage was also stressed.

3.9.5 Alternative Venues

In Peru, for example, there are a growing number of independent health food and health product stores. Some of these enterprises offer acupuncture and other health services. This may be "another venue for offering the TDM and other FAM." However, private sector collaboration probably has less, broad-reaching impact than efforts through the public sector.

3.10 Areas of IRH Strength and Linkages

The experience and expertise of staff at IRH is a definite strength and asset for future TDM work. Previous IRH work in the areas of the SDM, LAM and other natural methods has been significant. In addition, having had a medical doctor and international researcher on the IRH staff to champion the FAM methods dispassionately within the context of medical education, evidence-based research, and high level international conferences and meetings

with the professional medical community was very helpful. The need to continue to have a MD/medical director affiliated with the TDM efforts was also expressed.

The following organizations were discussed regarding possible linkages and collaboration:

FHI has many resources, but a lot of commitments at the moment. FHI is also involved in a high-profile, multi-country SMS texting project called Mobile4RH. The possibility of integrating fertility awareness, TDM (as well as other FAMs) into this project could be one way to capitalize on existing projects.

Population Council has integrated the TDM (and SDM and LAM) into their Balanced Counseling strategy materials. There may be opportunities to capture TDM data there.

Catholic Relief Services is an interesting partner. Collaboration has resulted in some creative adjustments, for example using words other than "reproductive health" in a job description.

Centro para la Educación en la Vida Familiar (CEVIFA) in Honduras may be a very good partner, working in conjunction with Maria Elena DeQuan.

Another possible partner would be with the new Project K (knowledge) for Health with JHPIEGO.
IRH staff suggested that the stakeholders to be interviewed for part 2 of this report should include people who "know something about the TDM" in order to provide effective input and guidance.

4. Discussion

The TDM is an effective, **"non-commodity" method** for pregnancy prevention. Although no commodity is required (which is preferred because there is no cost, no procurement, and no dissemination) it is important to package a client card to provide key messages as a memory aid for clients and to have a "take-home" product that lends credibility to the method and can be shared with the woman and her partner as a communication tool. This client card also serves to reinforce the key messages for provider training. This client card can be produced locally, adapted with locally-tested images and terminology, and printed on paper at a very low cost.

The importance of **local input** into efforts to position and communicate the method within the community (and to providers and decision makers) is critical to finding the language and images that will resonate with the target audience, addressing potential barriers, and

raising awareness and possible acceptance of the method. In addition to testing words, terminology and images, it is important to test the best **conceptual approach** or approaches for communicating accurate and meaningful messages.

Having been successfully introduced into family planning services in Peru, the TDM is ready for future integration into a variety of possible programs. The need to test **integration of this method into community-based, field projects** is a logical next step. With a community focus, opportunities to further **simplify** training, client educational materials, and other service delivery materials may enable the method to be more widely disseminated within a population not often served by facility-based health service systems.

TDM provider training and other integration efforts should not focus on a "stand alone" strategy. Rather, the TDM should be **integrated into established training** programs, updates, continuing education, conferences, systems-based venues for sustainability over time, and integration into well-established, ongoing programs.

For future projects (especially with a simplified or community-based approach) it may be advisable to continue to assess the cost/benefit of **follow-up or linkages** to other services and information. This may include facilitating access to appropriate services and/or information which may arise as a result of using the TDM. (For example, what to do if one notices unhealthy secretions, has questions or concern about the method, needs access to other family planning or health services, could benefit from empowerment projects or other services.)

Although **breastfeeding and postpartum women** currently need to wait until they experience four periods to begin the TDM, there is a need for an alternative natural method or bridge to the TDM at an earlier point in time. However, research efforts so far have not encountered a recommended solution that can be easily implemented into programs. Work with the "SDM Bridge" should be assessed for possible early application to the TDM.

Efforts to **position the TDM** need to consider the significant provider bias, lack of institutional will and funding, and challenges inherent to creating messages about observation of vaginal secretions— a topic that women, couples, providers, and policy makers typically do not discuss. At the same time there are opportunities to build on past accomplishments of including the TDM in policy and norms such as the WHO method eligibility criteria, Family Planning: A global guidebook for providers, Balanced Counseling Strategy: A toolkit for providers, and Contraceptive Technology, 19th revised edition as well as the potential benefits of a free, universally applicable, information-based method.

5. Conclusion

The TDM has the potential to be a non-commodity, information-based method that is freely available to ALL women from adolescence throughout their reproductive life. Women typically notice their vaginal secretions on their own, with no instruction, but they do not recognize the significance of these secretions in terms of the power to control their fertility. However, the very simple messages for family planning and women's empowerment are: 1) pay attention and note your secretions every day; 2) each day with secretions is a day you can get pregnant; 3) each day following a day with secretions you can also get pregnant; 4) once you have two days in a row with no secretions you cannot get pregnant (no secretions today, and no secretions yesterday).

The main barriers to providing access to this basic information and a universal family planning method option include:

- Lack of information and awareness of the method
- Provider bias regarding efficacy and client ability/desire to use the method
- Low priority and little funding within institutions and organizations with the potential to integrate the method

Part 2 of the market assessment report addresses possible competition regarding methods and resources, and the results of opinion research on the perceived feasibility and viability of adding the TDM to a variety of possible programs.

Upon completion of the market assessment, the results were analyzed and discussed at a meeting with IRH staff and USAID CTO to guide efforts to introduce the TDM innovation into future projects and activities.

TwoDay Method® (TDM) Market Research Part 2: Report on Interviews with Stakeholders, Donors and Possible Future Collaborators

1. Introduction and Objectives

In order to supplement the information gathered in TwoDay Method Market Research Part 1: Report on IRH Experience, Evidence and Recommendations, information was needed on international service delivery organizations, donors, and individuals who may be interested in incorporating the TDM into their work along with the type of evidence, tools, and materials they need to do this. This section of the report documents the results of an opinion survey of stakeholders and donors to assess the market potential for the TDM, identify recommendations for IRH TDM activities and identify opportunities for collaboration on TDM projects in the future. The objectives of part 2 of the market research project were to:

- Analyze the potential for increasing awareness, availability and access to the TDM
- Identify and assess the opportunities, challenges, and competition for the TDM within family planning and other programs, including NFP-specific programs
- Synthesize opinion research (phone survey of key stake holders and possible funders) on the feasibility and perceived viability of integrating the TDM into a variety of programs and services
- Summarize IRH experience, TDM evidence and results from the opinion surveys to propose future direction for TDM research and project activities

2. Intervention

The following research questions were addressed through the results of the opinion survey:

- What types of organizations would be/are interested in the TDM?
- What are important considerations regarding different approaches for different organizations and settings? (FP, FBO, NFP, women's groups, community-based providers, programs with existing SDM services, etc.)
- What individuals, donors, and technical assistance agencies would be/are interested in championing and/or supporting TDM integration at the international and country level?
- What do key stake holders find appealing (or not) about the TDM?
- How should the TDM be positioned with regard to the different family planning options in general? FAM options in particular, especially the SDM and LAM?
- What donor or multilateral agencies may be/are interested in funding larger scale introduction studies? What level of resources might they be willing to commit?
- What type of support would interested organizations need to introduce the TDM?

- What evidence and materials do stakeholders and programs need to decide whether and how to introduce the TDM?

3. Definition of Boundaries

Opinion research was conducted through individual telephone (or Skype) interviews with key representatives of the following groups: USAID, other donors and foundations, international technical assistance agencies, experts in the field of family planning/ reproductive health, community-based organizations, faith-based organizations, NFP groups, universities conducting FAM research, US family planning providers and IRH field staff or consultants with expertise in the TDM, SDM or LAM (who were not been interviewed for part 1 of this project.) Selection criteria included individuals with previous knowledge and/or experience with the TDM, national and/or international expertise in their field, and a recommendation from IRH staff. Most of the interviewees were in a position to potentially integrate or support the integration of the TDM into some aspect of their work (project activities, research, funding, training, materials development, service delivery, etc.) Although all were knowledgeable about the TDM, most did not have previous direct experience with the method.

Each interview was kept to approximately 30 minutes, which was an effort to increase interviewee availability as well as to focus interview questions on major points of interest. Efforts were made to interview a representative group of individuals with insight into the potential feasibility and viability of adding the TDM to programs as a family planning option. While some individuals from US programs were interviewed, the focus was on international integration of the TDM, especially for resource-constrained communities typically served by USAID-funded projects. Separate documents have been prepared to describe potential future collaboration with interviewees, their organizations and other contacts.

4. Methodology and Process

The objectives and research questions for part 2 of the marketing research project were determined as a result of part 1, which was an analysis of TDM experience, evidence and recommendations from IRH staff and consultants who participated in the TDM clinical trial and/or TDM operations research projects. Once determined, the research questions for part 2 of this project provided a framework for drafting a questionnaire to be administered to stakeholders during the phone interviews. This questionnaire included five key questions and additional probing questions that were tested in simulated interviews before use. Part 1 of this project (IRH experience, evidence and recommendations) also facilitated

the development of a list of proposed interviewees, which was further reviewed by key IRH staff and expanded to reflect the desired breadth and depth of proposed contacts.

Forty-eight individuals were contacted via email and invited to participate in this telephone opinion survey. Thirty-two accepted and were then interviewed by phone or Skype using a tested, interview guide with open-ended questions. (See Annex D.) Prior to these interviews a data analysis plan was determined and a matrix for synthesizing interview results was drafted and tested. An individual matrix was used for reporting and coding responses to the questions for each interview. The responses were then synthesized and analyzed on a combined matrix. Additional contacts were made to seek increased information and guidance regarding cultural practices in some regions (especially in Africa) that may impact effective TDM use.

Preliminary results from both part 1 and part 2 of this project were presented at an IRH staff meeting in January 2010. Following this presentation there was a discussion of the IRH vision for TDM along with priorities for future TDM research and other activities. At that time the basic designs for two pilot studies of the TwoDay Method were proposed. Additional pending interviews were later conducted, analyzed and integrated into this report to further identify and document the focus, recommended actions and opportunities for collaboration on future TDM efforts.

5. Results of Interviews

5.1. Perceptions Regarding the TwoDay Method: Perceived Benefits

5.1.1. Unmet Need and Expanded Choice

Most interviewees had a positive impression regarding the potential integration of the TDM into a variety of programs. The potential to *decrease the unmet need for family planning in areas where nothing is used, yet pregnancy is not desired,* was seen as a benefit. The TDM was described by many as *"simple"* and *"effective"* and having *"no dependence on cycle length."* It is also *"appropriate for women that the SDM doesn't work for because of cycle range."* The value of a non-commodity method was also stressed, especially in resource-constrained areas and places where stock-outs of other methods are common.

"Need to stress informed choice."

"(It's a) woman's right to choose….not limit choice to LARC (long-acting reversible contraception)…"

"Many people don't want to add something to their bodies. Contraceptive prevalence is plateauing; we need more options."

"(It's) timely for the Philippines… birth control methods are no longer free in the country… family planning is transitioning to buying their own commodities."

"It's easy to use, (easy to) teach others to use."

There was an expressed desire by many to increase method options for women, honor a woman's right to choose, and recognize that some women want a method that has no side effects and does not affect their health. Others described that women switch methods, are in-between methods, or do not have their method available all the time.

5.1.2 Fertility Awareness and Empowerment

In addition to using the TDM as a family planning method, interviewees described the important benefit of *empowering women* through *knowledge about their bodies* recognizing that many women lack an understanding of their bodies and their fertility.

With fertility awareness and knowledge about her own naturally-occurring secretions, a woman has the potential to observe, understand and manage her fertility (in collaboration with her partner) as well as identify some signs of a possible reproductive health problem. With the TDM she has an autonomous method, based on her own observation and determination of fertile days to communicate with her partner. This was described as both beneficial for her in terms of personal control, but also challenging in that there was not a visual tool to share with her partner, confirming and validating her assessment.

> "Girls education, right of passage… knowing how their bodies function is a wonderful thing."
>
> "(Starting with body changes and secretions, these are the) basic building blocks of sex education.... self-respect, healthy relationships."

5.1.3. Simple and Effective Method

Two faith-based organizations in the USA had well-established, classic NFP methods available to their members and felt their current NFP methods had higher efficacy, could be used by more women throughout the life cycle (including women who are breastfeeding or peri-menopausal) and were historically accepted by their members. However, the interviewees from NFP experienced faith-based organizations felt the TDM could be viewed as *"a simple method for casting a wider net."*

> "(The TDM) increases the common goal of making FAM/NFP more accessible and easy to use."

5.2. Perceptions Regarding the TwoDay Method: Perceived Challenges

5.2.1 Efficacy and Partner Involvement

Some interviewees, especially from US family planning programs, were more inspired by the TDM for its fertility awareness potential rather than its use as a family planning method. Efficacy of the method was described as a perceived challenge by interviewees from both US and international programs. Although the TDM efficacy trial indicates the method is about 96% effective in perfect use and 86% effective in typical use (similar to other non-hormonal, user-directed methods) it has a lower effectiveness rate when compared to the "top-tier" long-acting, reversible methods like IUDs, implants,

> "If it's not used correctly, (there is a) higher failure rate than other methods, not very forgiving."
>
> "The potential for perfect use is low."

injectables, oral contraceptives, etc. The need for partner support and participation for effective use was stressed, along with the need to recognize the amount of non-consensual sex and *that many women are not in control of their circumstances.* The need to include couple-related issues in the method counseling was stressed. Interviewees added that the TDM is new, not very well known, and for some was associated with the rhythm method and not considered a “modern” method.

> “Must be vigilant, motivated, (need the) will of the woman and couple to follow through.”
>
> “(There are) problems with misinformation. Fertility Awareness methods are not as reliable. (They are) highly dependent on motivation, timing and symptoms.”

5.2.2. Secretions

Another perceived challenge described by many interviewees was concern about observation and recognition of “any” secretions. Some interviewees doubted a woman’s ability and desire to observe her secretions. Others were concerned that there would be too many days with secretions or that a woman would confuse her secretion observation with a sexually transmitted infection, poor hygiene, and/or the presence of arousal fluid or semen. Two interviewees trained in the Billings Ovulation method and symptom-thermal methods discussed how the TDM would not work for women with a basic infertile pattern (BIP) and not work for breastfeeding women who had not yet experienced four periods post partum. This was described as an obstacle to universal use of the TDM. One interviewee was concerned that the possible influence of eating certain foods (theories of hot/cold foods with Chinese medicine), stress, exercise and weather might influence the presence of secretions. More commonly, the concern about secretions was related to potentially excessive number of days with secretions and confusion with non-ovulatory-type secretions.

> “There are a lot of secretions out there.”
>
> “Secretions… too vague, (there are) other types of secretions.”
>
> “Patients are confused about secretions. Some say, ‘I have it all the time.”
>
> “Hygiene is problematic, women don’t bathe often, don’t use under garments, use a hose, may not bathe for 2 weeks, may not change their panties for days.”

5.2.3 Program Implementation

While many interviewees indicated that the TDM is a much simplified version of other secretion-monitoring methods, a few considered it to still be too complex and bothersome from both a client and provider perspective. Some also stated it was not a high priority for programs.

> “If there is daily charting, how is this simplified?...Might as well teach the other secretion methods.”
>
> “Too much work, effort, why would anyone do it? (It’s) more complicated than CycleBeads” …. (It) won’t be accepted at the clinics as a true option. I know them.”

5.2.4 Cultural Taboos

Among interviews with both international stake holders and US-based individuals many expressed beliefs or judgments about whether women would be interested in checking their secretions. One interviewee mentioned the possibility of *gender dynamics if the provider is male and the clients are female*.

> "(There is a) cultural taboo with touching yourself below the belly button."
>
> "Women in Kenya don't like touching their private parts. "
>
> "Some feel if you touch your genitals, hair will grow on your hand."
>
> "(Women) are not ready to look down there. I don't even want to do that!"

Other opinions regarding obstacles to TDM integration expressed by interviewees include: emphasis on LARC funding priorities, need for sufficient training and capable staff to effectively counsel clients, and the amount of bias or negative assumptions among policy makers, administrators and providers (while interviewees mentioned that these biases or assumptions do not seem as apparent at the community level). A donor interviewee recommended that the TDM be carefully defined and described at any conference where it is presented, (before discussing the details of a given presentation) since attendees do not necessarily know what the TDM is and how the method is used. Many interviewees praised IRH for the rigor and quality of past FAM studies, while a few stressed that although the TDM is *"science-based, evidence-based, effective if used correctly….people write it off, even in the USAID office* (with) *our colleagues* (there is) *substantial bias."*

5.3 Different Organizations and Approaches for Integrating the TwoDay Method

Interviewees described a wide variety of organizations and approaches appropriate for TDM integration including those focused on family planning, general fertility awareness, youth-focused fertility awareness, parents of adolescents, faith-based projects, existing SDM and/or LAM programs, STI/HIV prevention efforts, community and facility-based programs, breastfeeding and postpartum programs, women's empowerment, microenterprise, literacy and other.

> "Introduction into guidelines is easy, but into programs is another story."
>
> "Focus on large family planning NGOs, community-based organizations and also women's empowerment."

Underlying issues, important to consider when planning TDM integration, were also discussed. For example, while the TDM (and other FAM methods) may be present in the national and organizational norms, integration into programs is slow and often non-existent. With a non-commodity, information-based method like the TDM, many said it was uniquely suited for community-based and women's empowerment programs. While offering the method in non-facility, non-family planning settings appears very doable and a way to address unmet need for family planning especially in remote and marginalized areas, care should be taken to ensure access to the medical infrastructure. Linking with the

medical system can provide support, referral opportunities, and help to avoid being perceived as "undermining" family planning efforts in a given area. Additionally, the need for buy-in from all levels (the community, providers, all levels of staff at an agency, policy level individuals, etc.) was stressed in order to facilitate TDM integration into programs. While offering the TDM does not require a follow-up visit, ongoing support and contact with new users may help them integrate this method into their lives and better address the male perspective.

"Move the method out of facility-based service delivery….. The level of TA is always underestimated. You need 2 to 3 years for training… sustainability…to make sure it is part of the system."

"(The TDM) requires follow-up, not to learn the method, it's easy to understand, but to have support and motivation, incorporating the new behavior…And, how to use condoms if they choose that…They need support."

"The Ministry of Health and governments (are) slow to champion (the TDM) because of the investment in training and counseling required (and because of) issues with perceived effectiveness…but if (they are) on board you have broad, sweeping integration… implementation.

5.3.1 Family Planning Programs

In many countries providers receive "points" or some incentive to recruit clients to specific family planning methods. However, with the TDM (and other FAM) this is not the case; there is no incentive. Additionally, with the time required for TDM or any FAM counseling (time that providers often do not spend when dispensing pills or giving an injection) this is another disincentive for providers to offer the TDM.

While most described the benefit of adding more method options for greater informed choice, some interviewees described challenges providers have with providing accurate information on all the many method options available, and were concerned about possible confusion of key messages.

"Our experience has been that people who start with natural methods often move on to other family planning methods."

"There is a lot of method switching. Position this as: before other methods, in between methods, and as a method itself. Facilitate switching in and out of TDM."

"Family planning organizations and workers are stressed with so many family planning methods…one more method!"

The "Balanced Counseling Strategy" (which includes the TDM and other FAM) was suggested as a technique for assessing and providing the key information needed to make an informed decision about all method options, including the TDM. Interviewees stated that many women *"do a lot of method switching"* and are dissatisfied with side effects associated with hormonal methods. A few interviewees stressed that rural, underserved areas would benefit from a non-commodity method, but added that the TDM/FAM should be integrated into all levels.

5.3.2 Fertility Awareness for Adults and Youth

Many interviewees applauded the fertility awareness aspect of the TDM…*teach about our bodies, sense of control, fantastic!* They indicated that fertility awareness information was lacking within the adult population in general, and with youth in particular. Many considered that the TDM included universal messages all women (and men) should know. However, some voiced caution in terms of youth-focused fertility awareness education.

> "University students have poor fertility awareness."
>
> "Fertility awareness helps women pay attention and learn about their bodies, note healthy and unhealthy secretions.
>
> "Good (adolescent) programs are lacking in most countries….need comprehensive, quality…there is hesitancy and pressure from conservative groups and parents….need multi-pronged approach with parents, policy makers, and teen-friendly services with monitoring and evaluation….how information on the indicators would improve behavior."
>
> "(It's) important for boys and girls to understand what happens….depends on how it is presented…how much information to give adolescents (it's a) deep hole to fall into."
>
> "Fertility awareness is ideal for all youth (but there are) the politics of abstinence-only and comprehensive sex education."
>
> Be cautious, careful, (there is the issue of) discouraging sexual activity…be very careful about this…knowing about the body is OK…(fertility awareness for youth) through schools, perhaps, but carefully."
>
> "Work with pre-adolescents before they are sexually active."
>
> "Never say 'family planning' (with youth)."
>
> "Youth fertility awareness, coupled with chastity values…youth would benefit from more comprehensive, classic OM/ST for more (detailed) information…they are not supposed to be having sex."
>
> "Teens are not interested in fertility awareness…people should know that secretions change….teens will misuse (the information) not pay attention."
>
> "Adolescents and parents want the information, aren't concerned about ramifications, but donors are."

There was concern about how much information to provide, and at what age. A variety of approaches were suggested including direct information to youth, school-based programs, addressing youth through parent education and/or combined youth and parent approaches along with the need to seek guidance from TA organizations that focus on youth. There was a wide variety of perspectives on youth and fertility awareness, as reflected in the sample of many different quotes above.

5.3.3 Faith-Based Organizations

In general, interviewees described both opportunities as well as the challenges of integrating the TDM into faith-based organizations (FBOs). The TDM is a simplified version of some of the secretion-

> "Within NFP groups (there is) skepticism regarding anything that is not their own… OM, Billings, Couple-to-Couple, Creighton."

based methods advocated and taught by some faith-based organizations, and is also consistent with their philosophical approach to planning and honoring families. Some interviewees described that many existing NFP programs were very loyal to the particular natural method they have long used, and were reluctant to test or integrate another type of NFP.

However, interviewees from FBOs described interest in collaborating with IRH to integrate the TDM in a variety of ways, including upcoming online NFP training affiliated with the US Bishop's Council. For FBOs, there is a need to adapt TDM materials and approaches to fit with the philosophical perspective of the group's faith. Often, this includes discussing abstinence during the fertile days (not barrier methods as an option), using the TDM to achieve pregnancy, and honoring the inclusion of children and family rather than focusing on limiting or spacing. One interviewee mentioned that FBO TDM training should be tailored to include *a sensitivity that ties training and client education to a personal reflection and internalization about how the subject matter impacts the individual personally and with regard to their faith.* For example, this could include reflection regarding the Koran for Muslim clients or the Bible for Christian clients. Some of the FBO programs follow system-wide standards which add more detail and time to method instruction, follow-up and training.

"(With) strained relations with church and family planning…. sometimes natural methods can be a bridge."

"FBOs (are) more pastoral. They like the idea of it (NFP) rather than have the ability and desire to make it available to people….not good at moving the method to the community."

Some interviewees implied that links with FBOs can increase the likelihood of identifying the TDM with religious organizations formally associated with the rhythm method (which is often viewed as ineffective by other groups), as well as associating the TDM with a *specific moral agenda* of some FBOs that is often opposed to approaches and philosophical underpinnings of mainstream family planning efforts and initiatives. Others, however, described the TDM as a common ground issue and an opportunity to address strained relations between FBOs and family planning organizations.

5.3.4 Community-Based Programs

Many interviewees said community-based programs were uniquely suited for offering the TDM. Several interviewees stressed the need to link community-based TDM efforts with the medical system or framework for access to medical care, "*a grassroots to facility link*." Another commented on an emphasis at WHO and within other organizations for *systems strengthening* and assessment of *human resource allocation*. There is a *"form of task-shifting to meet community needs… WHO task-shifting guidelines"* and TDM integration appears very timely, an "*exciting, good time to do this."*

Several interviewees suggested facilitating or creating women's support networks similar to the La Leche League model, a network of supportive women who help one another. *"Create avenues of information that don't require the government or Ministries of Health."* In working with community-based organizations or cooperatives, one interviewee stressed that a given project needs to not only benefit the individuals in the community, but also the whole cooperative as a group. The need to *incorporate elders and get their blessing* was also shared.

"The CHW (or community health worker) is a natural for this. They are there, at the bus stop."

"Incorporate TDM where women come together …income support, breastfeeding, attach health to income sustainability projects."

"The greatest need for a non-commodity method is rural NGOs….services are few and far between. There is great appeal here, but the TDM should be incorporated at all levels!"

"If using non-family planning workers…peer-to-peer, community-based, non-health….make sure family planning and health groups (in the area) don't think you are undermining their work. That would be terrible."

5.3.5 Woman's Empowerment

Many interviewees described fertility awareness, body awareness, partner communication and TDM as "self-empowerment" at the individual, personal level—an opportunity for a woman or girl to use self-knowledge and interpersonal communication to improve her status and well-being within an intimate or sexual relationship. It was described as having the potential to support gender equity and empowerment.

"Self-respect, knowledge, respect of one's own body…self-empowerment."

"CARE…(TDM) fits with the "I am powerful campaign."

"Knowing more about fertility, does it give women more control? Empower women? Change gender dynamics? Increase sexual consent?"

"In gender work, transforming roles… bodily secretions haven't come up."

A few, however, questioned whether fertility awareness and the TDM would be empowering or not. In the past these interviewees had not seen a perceived need or witnessed a benefit from increased fertility awareness.

One interviewee commented about potential interest in the TDM within the *"reproductive justice and empowerment movements in the US."* These movements include grassroots, community-based frameworks for mobilizing individuals and communities (that have been disenfranchised, marginalized and oppressed) to challenge power inequalities at different levels of society to create structural change. According to this model, *"A woman's ability to exercise self-determination—including in her reproductive life—is impacted by power inequities inherent in our society's institutions, environment, economics and culture. Reproductive justice exists when*

"Change starts from the inside out…fueled by and brings along the most disenfranchised."

all people have the economic, social and political power and resources to make healthy decisions about our gender, bodies and sexuality for ourselves, our families and our communities." (Asian Communities for Reproductive Justice (ACRJ) and ACCESS 2009).

5.3.6 Breastfeeding, Post-Partum and Women with Persistent, Continuous Secretions

Many interviewees described the post partum and breastfeeding women as being particularly interested in FAM or TDM.

Many interviewees assumed the TDM could be used immediately following LAM, and were concerned when they realized there was not a reliable, easy-to-use FAM to bridge this time period. One interviewee suggested that the TDM could be expanded or built upon for special circumstances (with additional information as needed) to address the breastfeeding woman once she could no longer use LAM as well as other women with a basic, non-changing infertile secretion pattern (BIP). The suggestion was to incorporate a few additional messages in TDM provider training, for providers to teach women only as needed, about: 1) How to identify a basic infertile pattern (BIP) of secretions; and 2) How a woman with a BIP could ask herself a modified version of the two TDM questions for these special circumstances. For example:

> "Postpartum women often look for non-hormonal methods, no side-effects, doesn't hurt the child…(They) feel vulnerable during this time, often use condoms, withdrawal, Depo."
>
> "After LAM, many are on the injection (and) switch later to something else."

- Did I have a change in my basic infertile pattern of secretions today? Yes or No
- Did I have a change in my basic infertile pattern yesterday? Yes or No

Additional messages like these, however, would add complexity to TDM instruction and training, and have not been tested.

5.3.7 Client Education, Counseling and Provider Training

Many interviewees described the need for quality TDM training of providers to enable them to offer interested clients quality education and counseling on the TDM, and to promote partner involvement for effective method use. The need to address client and partner motivation, in some way, for effective method use was also described. The need to provide adequate

> "TDM training of providers…..make sure the provider is well connected back to the facility so TDM doesn't get a bad name, don't take short cuts with training."
>
> "Need funding support to train providers and work with couples…. carefully involve all stakeholders in a given area…to get buy-in to key messages and approaches…tough process."
>
> "Need a motivated partner…(and) need partner component in the FAM counseling."
>
> "More than just information… low lit materials, get them out there."
>
> "Collaborate with WHO more…..WHO logo on materials raises credibility."
>
> "Tools already exist, (there is) not at a need for more tools, strengthen existing tools…. beads, calendar….everyone has one."

instruction on barrier method use (if a barrier method will be used during the fertile time) was also stressed. Many interviewees stressed the need for quality, effective, low-literacy educational materials on the TDM. One interviewee said the focus should be on strengthening existing tools, rather than creating new ones. Regarding key messages, the need to expand messages to include "*lack of STI protection*" and the possibility of unhealthy secretions and/or too many days of secretions in a row was noted. The benefit of collaborating, with reputable organizations like WHO, for development and integration of TDM materials was stressed. Incorporation of well-known logos of reputable organizations on the materials lends credibility and confidence to both providers and clients.

"Need good tools to show people… more than pictures in a book, slippery substance to touch….to see what is being talked about."

"Must include 'NO HIV/STI protection' in the messages… (It is an) entry point for STI discussion."

5.4 Positioning the TwoDay Method and Raising Awareness

Some interviewees shared general suggestions for positioning the TDM and raising awareness about the method while others noted that this was not their area of expertise, and deferred to IRH expertise and experience in this area. In general many expressed that *positioning and marketing will be the next set of challenges.* The goal, as described by one interviewee, is to *"increase visibility, increase credibility of the method."* A variety of strategies were suggested to accomplish this, including the need for buy-in at all levels.

"When integrating TDM, any FAM, make sure there is buy-in at all levels, not just administration, not just with one person."

5.4.1 Suggested Strategies

- Identify concerns of the various target groups/ levels (community, providers, administrators, policy makers and donors). Systematically look at the different groups as well as different types of programs. Then, plan a multi-pronged, specific strategy for each group or level. Also create awareness among men and young college students.

- Conduct additional operations research, gain more evidence, and highlight findings in respected, peer-reviewed journals to convince donors, policy makers and providers.

"Keep efforts to raise awareness and acceptance at both levels. Community/ provider and administrative/ policy… although the administrative/ policy may show increased resistance, don't abandon work on both fronts"

"Need TDM ammunition, OR studies, evidence."

"Present data on community acceptance."

- Conduct advocacy research, and more marketing in general. Several interviewees voiced the need to better understand how to describe, talk about, and depict visually a method that deals with cervical secretions. Learn from other RH campaigns. For example, in the US with the availability of the emergency contraceptive pill (ECP), advertisers conducted significant marketing and consumer research with US women. Women said they, *"Didn't know they could get pregnant,"* and implied "*wishful thinking about avoiding pregnancy that was grounded in fear."* In this example, researchers heard the panic, urgency and fear described, and focused the ECP campaigns on themes like *"Be calm. Be in control. Be covered."* The ECP campaign eventually focused on the tagline *"Be in control."*

"Advocacy research is key….At the provider/policy level we haven't looked at this systematically….haven't done this research to understand how it relates to barriers in the minds of policy makers."

- Integrate fertility awareness education into all levels and all types of programs. Develop strategies for moving TDM and other FAM from national norms into the actual program level.

- Establish and/or support women-to-women networks.

With pills, women learn about it from friends, talk about them, buy and take them….this woman-to-woman network has an impact on scale.

"Woman-to-woman, like La Leche League."

- Do a "road show" for medical schools, nursing schools and midwifery schools. Include the TDM (and other FAM) in text books, PPT presentation, medical and nursing school curriculum, etc.

"MDs are hardest to change."

- Include the TDM in state-of-the-art materials. (The TDM is included in WHO Medical Eligibility Criteria, Contraceptive Technology, Family Planning: A Global Notebook for Providers, Balanced Counseling Strategy: A Toolkit for Providers, and in reputable websites like PPFA and the Mayo Clinic. However, there is minimal or no inclusion in the UK Medical Eligibility Criteria, WHO Decision-Making Tool for Providers and Clients, and some websites like CDC and ARHP.)

- Develop simple IEC and education/counseling materials. Make sure messages are clear and do not contradict other important reproductive health messages. Develop kits with key materials

"No other method has functioning of the method 'unprotected sex' as a message….subtlety of this…problematic. (Possible confusion with STI prevention messages)"

and talking points that can be tailored for the audience to raise awareness and counter resistance. For example, a simple sheet with talking points when addressing policy makers.

- Seek direct-to-consumer opportunities. Explore how much behavior change communication is needed to get and keep a successful user.

- Have expensive, glitzy TV commercials, radio spots, web resource, blog, classes on internet, (800) phone number. Have a contest to create the best radio spot, or best pster, etc. and a prize for winners. The challenge of designing media "*around secretions"* was also expressed.

- Include respected, credible and popular individuals as well as actors, opinion leaders, and other sources to facilitate broader adoption of a new method. "*We need the voice of successful users."*

- Build on SDM and LAM efforts and accomplishments. Incorporate the TDM into SDM programs for women with cycles that are too long or too short to use the SDM. Incorporate the TDM into more IRH activities (conference, articles, sub-projects, etc.)

- Partner with MOH, big NGOs, CBOs and respected advocates with influence and champions within a country. Position efforts as *an insider* so the innovation is <u>not</u> perceived as foreign or supplanted by an outsider.

- Get senior staff of USAID and contracting agencies (CAs) to advocate for inclusion of the method.

"Right message, right counseling, right time, right person"

"Need money and slick, cool commercial. Not your grandma's rhythm."

"…More than a humble brochure."

"The graphic with mucus stretched between fingers is gross…. it's on our fact sheet."

"Find agencies with a similar mission and priorities."

"Once TDM becomes part of the public sector programs, this should be the tipping point."

"There has been a shift in SDM awareness and acceptance (but it) took a lot of effort."

5.4.2 Factors Influencing Awareness and Positioning of the TwoDay Method

In developing strategies to position and raise awareness about the TDM, interviewees stressed the importance of appreciating the "climate" or "environment" that may support or hinder efforts to raise TDM awareness and availability. Some of the following points were mentioned earlier, but are summarized here for consideration regarding their potential impact on positioning the method. For example, in some areas with some groups or levels of staff, there is suspicion that FAM in general and TDM in particular are "anti-science" or without an evidence base. Some groups are also concerned about a "morality driven agenda" regarding FAM methods which have been (and continue to be) supported and promoted by FBOs with a specific moral perspective that may be against other FP methods. Some groups or individuals are also suspicious because IRH is part of a faith-based university and there was concern by a few interviewees that IRH may be advocating the philosophy of the faith-based institution. Within many family planning organizations and various funding institutions there is also a desire to promote long-acting reversible contraception (LARC) also called highly-effective, reversible contraception (HER-C) over family planning methods that are non-hormonal and user-directed. One interviewee also shared concern that condom users who switched to the TDM would reduce their overall condom use (to only during fertile days), and would potentially expose themselves and their partners to a greater risk of STIs including HIV.

> "Rejection (of the method) is not rational or systematic. (The method is) rejected out of hand. It doesn't get to the level of detail or analysis…just rejected."

On the other hand, there is also a climate of heightened interest among many women, men and the community in general for methods that do not have side effects, do not harm one's health and are only used when needed. The ecological nature of FAMs (including the TDM) is consistent with those who are interested in avoiding unnecessary drugs, chemicals or pesticides and who favor green movements and/or organic foods and products. "*Go green with the body.*" One interviewee recommended framing discussions about the TDM and FP in terms of spacing children rather than avoiding pregnancy, to increase sensitivity and respect for philosophical and religious beliefs of some groups.

Interviewees also discussed TDM key messages that could be linked with other health messages creating a common ground with other important health initiatives and/or activities. For example the TDM and healthy secretions could be incorporated into *"vital signs for women's health, good for the body, good for the whole person."* The TDM also fits with *"healthy sexuality"* messages that include *"the joy of sex"* in a positive way. As previously mentioned, the links

> "Once introduced, they (the community) will respond. The issue is getting information past the policy and provider bias."
>
> "Information is critical, but not the only piece to change attitudes and behaviors… How to challenge assumptions in a nice way."

with fertility awareness, puberty, life skills for youth, empowerment, gender equity, interpersonal communication and RH through the life cycle are also messages that link well with and reinforce the TDM messages.

Several interviewees also talked about how the TDM interfaces well with HIV/AIDS/STI work. Both STI prevention and effective TDM use need partner communication and negotiation. Paying attention to secretions on a daily basis, as one does with the TDM, may help a woman identify signs of unhealthy secretions early on, and know to seek medical care. Both the use of female condoms and the TwoDay Method involve awareness and ability to look at or touch the genital area, as well as negotiate method use with one's partner.

5.4.3 The TwoDay Method in Relation to the Standard Days Method®

Many interviewees indicated the benefit of building on past and current Standard Days Method® (SDM) efforts, contacts, research, and other SDM linkages to facilitate TDM introduction. The non-commodity aspect of the TDM was described as a benefit by many, yet the pros and cons of a non-commodity method in relation to the SDM were also discussed. (e.g. pros: no procurement, no material cost, accessible, free for use when needed especially in areas with stock-outs of other commodities or methods, women dependent for interpretation of symptoms, and cons: people like a gadget, the gadget lends legitimacy to the method, *if there is no "face" it's not perceived as a "real" method,* without the gadget there is no visual to show and discuss with men, need paper or some other material or approach to teach and remember the messages.)

> "Non-commodity is a good thing. Some women need to hide their (Cycle) beads….But you need even better negotiation skills if there is no tangible item like beads."
>
> "Add (the TDM) where there is traction….Build on SDM experience."

While many interviewees talked about the potential universal application of the TDM (as there is no cycle length requirement for its use and it enhances a woman's self-awareness of fertility indicators tied to her own body) others favored the SDM. Some interviewees said the TDM probably needs more teaching and training compared with the SDM, and indicated that the SDM would be of greater interest to multi-method programs, with the TDM viewed as an added component of SDM programs if the woman did not have 26 to 32 day cycles.

In some areas the existing SDM infrastructure has had significant challenges in handling the integration of SDM. As a result, field staff in India suggested waiting to integrate the TDM, until after the TDM is fully tested with introduction studies elsewhere. Although the TDM does not have a cycle length criteria, a few interviewees cautioned that care should be taken to assess if there is a high prevalence of continuous secretions, infections, or other

vaginal discharge in a given area before introducing the TDM. Concern about possible confusion of TDM and SDM messages was also voiced.

5.4.4 The Name: TwoDay Method

Most interviewees liked the name "TwoDay Method." It was described as *"catchy, made sense."* However, some said the name was confusing, sounded too much like the SDM and was misleading. These interviewees said that hearing the name "TwoDay Method" people assumed the woman only needed to protect herself from pregnancy for two days.

5.5 Considerations for the TwoDay Method in Africa

As with other secretion-based methods, the TDM reflects the woman's naturally occurring signs of fertility. In addition, there are current screening assessments for all women interested in the TDM to determine if they need to wait to start the method because of circumstances like: recent delivery, breastfeeding, recent use of a hormonal method of family planning, or recent miscarriage or abortion. WHO research on NFP that was reanalyzed when determining the theoretical basis of the TDM, European studies on cervical secretions, and the IRH clinical trial on the TDM, all indicate that most women have secretion patterns that are conducive to using the TDM. Of the 450 women in the IRH clinical trial only two participants were excluded for having less than five days of secretions and 27 were excluded for having more than 14 days of secretions (and referred for assessment of STIs or other health problems).

The WHO data analyzed for the TDM and the IRH TDM studies, however, were not conducted in countries in Africa. Although faith-based programs have long provided NFP services with secretion-based methods in Africa, there is very little research on secretion patterns of women in Africa where conditions like female genital cutting/mutilation[2] (FGC) and the use of desiccants (drying agents like powders or traditional leaves placed in the vagina for "dry sex") are prevalent in many areas. The extent, to which these factors may have an impact on secretion patterns and the use of TDM, is not well understood.

A quick review of the FGC literature was conducted along with interviews with individuals with experience conducting reproductive health research in Africa, and working with NFP secretion-based programs in Africa. Some recent studies on FGC have shown an increase in

[2]WHO has classified FGC into four types: Type I – partial or total removal of the clitoris, and/or prepuce (clitoridectomy), Type II – partial or total removal of the clitoris and the labia minora, with or without excision of the labia majora (excision), Type III – narrowing the vaginal opening with creation of a covering seal by cutting and repositioning the labia minora and/or the labia majora, with or without removal of the clitoris (infibulation), and Type IV – all other harmful procedures to the female genitalia for non-medical reasons, such as pricking, piercing, incising, scraping and cauterization. Global strategy to stop health-care providers from performing female genital mutilation UNFPA, UNICEF, UNHCR, UNIFEM, WHO, FIGO, ICN, WCPA, WMA, MWIA, World Health Organization 2010

bacterial vaginosis (BV) among women who have undergone this procedure. Also, the incidence of BV and other STIs is higher in some regions compared to others. Increased prevalence of BV, or STIs in general, may result in an increased number of days with secretions. For the TDM, this would be more of an acceptability issue than an efficacy issue.

FGC has also been linked to other women's health problems including increased fistulas from obstructed childbirth (resulting in ongoing leaking of urine and/or feces) which could possibly obscure or confuse secretion observations. If secretions are masked, or dried with desiccants, this could affect the woman's ability to determine whether or not she observed secretions on a given day, and possibly impact the effectiveness of the method for her.

Regarding the use of desiccants, one informant commented:

> *"The question of drying agent is spoken about with the women and the teachers of the programme in Kinshasa. The coordinator thinks that the product could have an influence on mucus, and that also the leaves which were also used long ago (less now) give infection. The effect has not been studied in a scientific way.*
>
> *They have encountered women using 'leaves' to dry their vagina, and observed that those women had vaginal infections ……when the women understand that they are having infections with the leaves, they stopped that practice…..For the product (drying powder placed in the vagina) they explain this to the wife, that the drying agent could have an effect on the mucus…..and usually the women abandon the practice…those practices were more used long ago…the young couples abandoned those practices in town."*

The use of desiccants, as well as the prevalence of BV, has also been linked to increased transmission of HIV. This further emphasizes the need to link family planning efforts to STI/HIV prevention, testing and services.

Further research on the TDM in African countries, and ongoing consultation with those conducting related reproductive health research with women in Africa, is needed to better understand these factors, examine whether there is an impact on TDM use and to help determine if/which adaptations may be indicated when integrating the TDM into programs in specific regions and/or countries in Africa.

5.6 Research and Recommendations

Interviewees described the research priorities to be operations research, advocacy research, determining a better bridge from LAM to TDM, further assessing partner issues and addressing women with *persistent, regular discharge.* A few interviewees suggested studying secretion patterns in different countries and sub-groups to assess secretion variability and collect more information on the percentage of the population who can use the TDM. Two individuals recommended more research on whether or not fertility awareness is empowering to women and/or youth. One individual stated that the goal of future TDM research should be to "*integrate the TDM into service delivery in sustainable ways and establish evidence-based data for policy*."

> "Conduct more OR, like (what was) done with SDM, (use) program examples with large numbers. (Possible research questions include:)
>
> - Who can offer it?
> - How?
> - What materials do you need?
> - What amount and type of training is needed?
> - How do you deal with problems?
> - What does it take to offer the TDM?
> - What is the experience of users?"
>
> "Possibly do a choice study:
>
> - Who's interested?
> - (Is this) substituting rather than growing CPR?
> - SDM vs TDM
> - Are programs interested in integrating (the TDM)?
> - Who is attracted to this method?
> - Do they stay with it?"
>
> "(I suggest) OR with community-based organizations… programs with rural, illiterate women, not wearing panties… culture not used to touching oneself."

In terms of operations research suggestions included: studies to further simplify the method and/or the reminder approach, *adaptability, pre-introduction as was done with SDM, program examples with larger numbers, and pilot studies* with different areas of focus. Specific areas of interest raised by interviewees include looking at: simplification vs. effectiveness especially for "non-charting approaches", offering the TDM with different levels of providers including community-based distributors (*like with the family planning Depo model*) using peer promoters as method counselors, task-shifting away from a facility-based delivery system to a community-based system, looking at different training models as well as *cheap educational materials* and local adaptations of materials and approaches, identifying any areas of confusion among TDM users, offering the method in a variety of settings with different groups including different ethnic groups, across educational levels, different levels of hygiene and cleanliness, and expanding the TDM into a broader, fertility awareness context that includes links with STI/HIV prevention, healthy and unhealthy secretions, as well as the family planning link, and how the TDM user might transition to other methods. Another interviewee suggested conducting *qualitative research where SDM has a foothold.*

A few researchers involved in US-based university programs suggested: 1) an effectiveness and acceptability study in the US; 2) a randomized clinical trial comparing the TDM to the Creighton method; and 3) a US study that includes TDM (or SDM) with one group *using a barrier method during the fertile time and another one group abstaining, cluster randomly and assess efficacy*.

Other suggestions included keeping a strong focus on monitoring successful users, including learning more about whether TDM users continue charting and how to get messages to partners and involve men. One person recommended looking at *outcomes beyond knowledge to autonomy, decision-making, self esteem and efficacy.*

Many interviewees recommended advocacy research to determine better and more effective means of advocacy. Suggestions included *multi-dimensional scaling, barrier analysis of providers and policy makers, hearing from the voice of successful users* and studying *what people want for family planning, what do people say about this (TDM)? Which method would they choose? Why? Explore concerns about side effects? Assess issues with partner involvement. Which messages work best? We need advocacy research…How to get information out there?*

"How much information… behavior change…communication is needed to:

- Get a good user?
- Keep an effective user?
- Is it always provider interaction?
- What can you do with mass media, broader information sharing effects?
- Is secretion checking odd or difficult for some cultures?"

Other recommendations include exploring options for direct-to-consumer marketing, looking at behavior change studies, creating supportive networks, addressing the issue of lack of funding for TDM work and the need to capitalize on good timing opportunities, (for example increasing efforts for integration of the TDM when countries are revising national family planning norms and policies.)

5.6.1 Innovative Technologies

While many interviewees described the tremendous potential for linking with and utilizing innovative technologies, there were few specific suggestions for how to do this. One recommendation is to link with the FHI mobile phone study. Data could be collected on knowledge of fertility awareness, shifting or increase in knowledge, ability to control one's fertility with this knowledge, etc. One interviewee had incorporated cell phone use when following up newly trained TDM instructors. Interviewees encouraged IRH to explore all potential technology opportunities including the use of cell phones, I phones, twitter, SMS texting, online training, blog support, web-based education, phone referrals and links with clinics and services, innovative ways to answer questions and provide follow-up.

6. Discussion

The discussion below responds to the research questions described in part 2, page 19,of this report, and is based on a summary of the results of the interviews with stake holders, donors, IRH staff, and future collaborators as well as evidence from peer review journals and IRH research.

6.1 What types of organizations would be/are interested in the TDM?

Based on conversations with interviewees it appears that a wide variety of types of organizations are potentially interested in the TDM both as a method of family planning and as part of broader fertility awareness education effort. This includes organizations focused on multi-method family planning, NFP-only and faith-based approaches, SDM-experienced groups, general reproductive health including STI/HIV prevention and care, community-based programs including those dedicated to women's empowerment, literacy, microenterprise, youth education, support to breastfeeding and post partum women, and other areas. TDM information, along with support and referral for other services, are also well-suited for integration into emerging new technologies (including SMS texting) which may also open opportunities for a direct-to-consumer approach.

As a "non-commodity" method the TDM appears to be uniquely suited for resource-constrained areas, especially areas with a community-based infrastructure able to provide minimal counseling to interested women and couples. However, interviewees stressed that the TDM should not be targeted toward specific groups, but rather incorporated at all levels "not be put in a box."

With limited resources for global reproductive health as well as the FAM project, efforts should be made to capitalize on existing linkages and targeted research to maximize traction and outcomes. For example, organizations with existing SDM services, can add the TDM for clients interested in the SDM but excluded because of cycle length.

A separate document describes the interest generated from the phone survey and possible collaboration with interviewees and their contacts. Interest may be stronger on the international level where there is a greater unmet need for family planning, and different opportunities to address provider bias. However a US presence for the TDM would also help establish credibility for world-wide efforts.

6.2 What are important considerations regarding different approaches for different organizations and settings?

Local adaptations of TDM messages and service delivery approaches need to be tailored to different organizations and settings where the method is offered. This includes words,

images and concepts used for talking about the TDM, remembering the fertile days, and communicating this with one's partner. Further testing, simplification and dissemination of prototype materials may facilitate TDM integration into a variety of future programs. Linking the TDM with the mission and overall objectives of an organization places the method within the guiding framework of an organization.

While the TDM efficacy study, WHO NFP study and other studies of secretion-based FAM methods indicate that the TDM can be used by most women, (in the efficacy study most cycles had 10 to 14 days of secretions and over 96% of users had no problem detecting secretions at one month) there is concern among some providers that there may be too many days of secretions in some populations for the TDM to be an acceptable method. Some countries and sub-groups have a higher prevalence of bacterial vaginosis and other vaginal discharge than others, which may add to the total number of days per cycle with any secretions. In Peru, however, interested clients with signs of vaginal infection or continuous secretions were typically treated and then used the method successfully.

In some African countries, especially where FGC and the use of desiccants are wide-spread, the possible impact of these factors on the number of days of secretions and the use of the TDM has not yet been studied. While these factors are challenging and complex, they also exist in populations with unmet need for family planning and often limited access to family planning commodities. For this reason the benefit of a non-commodity method option like the TDM may be particularly relevant. Additionally, opportunities to partner with groups working to end the practice of FGC may reinforce and foster common goals in terms of efforts to increase fertility awareness, empowerment of women and girls, and gender equity.

For integration of the TDM into organizations not connected with health facilities, it is important to create linkages and referrals to health providers, as needed. This is important so as not to be perceived as undermining other family planning efforts in the area, and also to enable women and couples with problems like vaginal infections or health-related questions to seek medical advice or treatment as needed.

Some interviewees suggested that the TDM could be used before, in-between or after having used a different method of family planning, or when an individual's preferred method was out of stock. However, with the current TDM protocol a woman who recently used a hormonal method needs to wait until her last three periods have been about a month apart before starting the TDM, and a breastfeeding or postpartum woman needs to wait until she has had four periods post partum, with the last two periods about a month apart. This makes the TDM less suitable for intermittent use during hormonally method stock outs.

Different strategies for different organizations and settings include identifying common messages, approaches or themes that resonate with other services the organization provides as well as the TDM. For example both STI/HIV prevention and the TDM require partner communication and negotiation. Both benefit from an awareness of signs of healthy and unhealthy secretions. Successful use of the female condom to reduce the risk of STIs/HIV and prevent pregnancy involves the ability to look at and touch the genital area, as does checking secretions for use of the TDM.

For groups interested in incorporating TDM messages into fertility awareness education for youth, many interviewees cautioned that the approach be designed as age-appropriate, adapted to the culture, and address the possible concerns of all stake holders including parents, teachers, administrators, health providers, religious leaders, etc.

6.3 What individuals, donors, and technical assistance agencies would be/are interested in championing and/or supporting TDM integration at the international and country level?

See the separate document "Interviewee Suggestions for Potential TDM Collaboration and Possible Action Items" for answers to this question.

6.4 What do key stakeholders find appealing (or not) about the TDM?

In terms of appealing qualities of the TDM, stakeholders find the addition of a new, effective family planning method with no side effects as an opportunity to expand method choice for women and couples and also address an unmet need for family planning, especially among those who have not used a method before yet wish to space or limit births. Another appealing factor is that the TDM is tied to a woman's naturally occurring signs of fertility, and does not have a cycle length criteria for effective use. It can also be used to expand SDM services to include women with cycles that are too long or too short to use the SDM. The TDM appeals to stakeholders because it is cheap, does not require procurement and distribution of a commodity, is easy-to-use, and easy to teach others to use. Many stakeholders also found the potential for fertility awareness and woman's empowerment to be appealing. Some stakeholders found the TDM to be a "green" method, ecologically appealing in that it was natural and did not negatively impact the woman's health or the environment.

Regarding less appealing aspects of the method, stakeholders indicated that the availability of a variety of more effective methods of family planning (in both perfect and typical use) make the TDM less appealing. Since effective use of the TDM is linked with partner support and his "co-use" of the method, and because of the reality of non-consensual sex for many

women, these aspects also made the method less appealing as did concern about couples reducing STI/HIV protection by reducing condom use to only the fertile days.

While recognizing the value of good reproductive health counseling, less appealing aspects of the TDM include the need for training and client counseling/education to integrate the method, as well as the lack of funding and/or human resources to accomplish this. Some stakeholders indicated "method overload" because the TDM added to the number of methods providers need to understand well in order to offer them appropriately. Other unappealing aspects of the TDM include perceptions among some providers about cultural taboos in their communities around touching or paying attention to one's genital area, issues regarding feminine hygiene and bathing, high prevalence of vaginal infection in some locations, and the possibility of confusing cervical secretions with vaginal infections, semen or arousal fluids. Other unappealing factors include seeing the TDM as linked with the rhythm method and being part of faith-based, moral agenda they disagreed with.

6.5 How should the TDM be positioned with regard to the different family planning options in general? FAM options in particular, especially the SDM and LAM?

With regard to different family planning methods, the TDM should be positioned within the context of informed choice. Family planning method counseling should be client-centered, focused on the client's choice of method, personal and health considerations, partner's role (or not), accurate information, discussion of past method experiences, beliefs and desires, support for effective method use, and the opportunity to change methods if unsatisfied.

In terms of FAM options, the TDM should be able to be added to existing SDM programs either as an additional, separate FAM option or phased in— first as a method for those who were initially interested in the SDM, do not meet the cycle length criteria for the SDM, but would still like to use a FAM. However, research regarding this and whether there is confusion of messages when adding another FAM to a service delivery system is just beginning in Africa. Lessons learned from this pilot study should be very helpful in terms of facilitating the future integration of the TDM into services that already provide the SDM. Whether the TDM is offered separately or together with the SDM, discussion about how the couple will protect themselves during the fertile time should include how to use their chosen barrier method and/or how to be successful using abstinence during the fertile days.

If integrating the TDM into NFP-only FBOs, with previous experience with secretion-based methods, care should be taken to identify how the TDM will interface with other NFP methods offered by the FBO that include detailed interpretation of characteristics of the secretions, and have more rules and charting than is involved with the TDM. When integrating the TDM into FBOs, there may be a need to incorporate additional topics (like

family life or abstinence) to address the FBO philosophical approach. Pilot studies with experienced NFP providers in Rwanda and the DRC found the NFP providers were able to understand and use the TDM materials easily. The African Federation of Family Life (AFFL) programs were recently contacted to see if there was interest in integrating the TDM into any of their programs.

Positioning the TDM with regard to LAM is more challenging. Currently there is no easy "bridge" from LAM to either the SDM or TDM. In the article *Application of Simple Fertility Awareness- Based Method of Family Planning to Breastfeeding Women* (Fertility and Sterility, 2003) 73% of breastfeeding women would not meet the SDM criteria in the early post partum period because they would not have 26-32 day cycles. Of breastfeeding women who had not had a period by 6 months after their babies were born (no longer covered by LAM) 50% had extensive mucus patches or continuous days of secretions for 80% of the days. The current protocol for the TDM requires that a woman have 4 periods post partum before starting the TDM. As a result, most women using LAM need to first transition to a family planning method other than the SDM or TDM. Additional research is needed to determine how to best serve women interested in transitioning from LAM to a FAM. Lessons learned from LAM research, especially in the area of behavior change and support networks for breastfeeding may be applicable to future TDM services.

6.6 What donor or multilateral agencies may be/are interested in funding larger scale introduction studies? What level of resources might they be willing to commit?

The stakeholders interviewed during the phone survey did not have detailed recommendations for donor or multilateral agencies interested in funding larger scale introduction studies. Specific suggestions for small-scale collaboration were suggested. (See the supplemental document.) Most agreed that national and international family planning funding efforts were focused on LARC. Some staff from international TA organizations described having received additional funding for special projects from the Packard and/or Gates Foundations. US-based opportunities for funding may come from OPA or NIH grants.

Other opportunities for funding support include integration and collaboration on research that targets other areas. For example, large-scale adolescent pregnancy prevention funding opportunities in the US may provide an opportunity to weave in and test fertility awareness education. Or, male involvement projects and gender equity work may be stretched to include a sub-project that integrates the TDM. Maintaining strong relations with USAID-funded CAs to collaborate on existing projects funded by USAID, like the FHI mobile phone project in Kenya, may provide opportunities to support future research incorporating fertility awareness, the TDM and other IRH priorities. The timing of activities and efforts can be crucial, for example, incorporating the TDM into country-wide norms at

the precise time when national guidelines are being updated, or creating a partnership with another organization to prepare a proposal for a unique, time-sensitive funding opportunity.

6.7 What type of support would interested organizations need to introduce the TDM?

The support needed to introduce the TDM depends on the type of organization, amount of institutional expertise they have, and opportunities for support and collaboration with other organizations. For example, an international TA organization would benefit from content information on the TDM, lessons learned from the TDM efficacy study and operations research to date, prototype materials, and training curriculum used to support integration of the TDM into other organizations. However, a field project or community-based organization with minimal resources and funding would need additional support and TA to train staff, adapt any materials for the local context, raise awareness with the local community and providers, introduce the method, and also provide follow-up, ongoing support and TA until the method is fully integrated into the system. For larger, well-functioning systems, plans to integrate the TDM training with regularly scheduled updates on other methods or other services is an ideal way to facilitate integration of the TDM so it is consistent with and reinforced by system-wide updates for integration of other new methods or services.

Organizations interested in introducing the TDM should seek buy-in at all levels of the organization, gain community support and raise awareness around the potential benefits of integrating the TDM as well as strive to counter possible provider bias and other types of resistance that might challenge or slow down the integration of the method.

6.8 What evidence and materials do stakeholders and programs need to decide whether and how to introduce the TDM?

Stakeholders and programs need more evidence; they need the results of additional pilot studies, operations research and introduction studies as was done with the SDM. They need examples of how the TDM can be further simplified and adapted to the local context. They need advocacy research, and a better understanding of how to raise awareness about the TDM and position the method with regard to the community, providers, administrators and policy makers. They need talking points, with country-specific data indicating that the TDM efforts are valid and relevant to their local community.

7. Conclusion

Summarizing the findings of the phone survey as well as the findings from interviews with IRH staff, evidence from the TDM research studies, and IRH staff recommendations, three

themes emerge as central to future TDM work. These are simplification, integration and collaboration.

The TDM is a much simplified, easy-to-use FAM when compared to other secretion-based FAM. However, further **simplification** and fine-tuning of how the method is offered may increase access to the method by a much broader base of potentially interested users. Operations research and advocacy research on this method are in the infancy stages. Pilot studies are needed to test adaptations of the TDM approach and reminder materials for different local contexts. Opportunities to further simplify the client education and reminder materials, provider tools, and fine tune the integration into services are timely and will increase evidence and experience with the TDM. Simplification or fine tuning and streamlining efforts may also provide insight into possibilities for a direct-to-consumer approach for the TDM.

Many interviewees described the importance of integrating the TDM into existing services and avenues for increasing awareness and providing counseling/education on the method. This includes **integration** into a wide range of existing programs, existing training systems, existing provider tools, existing norms and guidelines, medical and nursing schools, reproductive health blogs and websites, and other existing systems. One interviewee said, “The mantra should be integration, integration, integration.” Efforts to integrate the TDM should include strategies to address significant provider bias and lack of awareness of the TDM as an effective method option for women and couples. The basic fertility awareness information included in the TDM is also important to the general population, especially given the general lack of fertility awareness information worldwide. Integration of information about secretions, fertility and the TDM into reproductive health and family life programs for all youth, women and men may increase personal awareness of indicators of reproductive health and fertility which could be useful to know and possibly empowering throughout their reproductive years. Increased integration of TDM into IRH activities was also suggested by interviewees.

With funding and human resource constraints, as well as the synergistic opportunity to build on the work of other institutions, **collaboration** is important in order to expand and enhance future TDM efforts. For example, additional research on ways to provide a bridge from LAM to the TDM, or additional TDM instructions for the postpartum or breastfeeding woman, would be very costly. However, through collaboration with other organizations currently collecting data on secretion patterns and breastfeeding women, new information relevant to the TDM may be discovered. A multi-pronged approach to future collaboration with key individuals and organizations could include increased TDM visibility in state-of-the-art materials, collaboration on research projects that may include a subproject on the TDM and/or to collect secretions data, behavior change studies, gender equity work,

women-to-women networks, support to support networks, youth programs and new technologies. As stated by the director of one international TA organization, *"See where (you) have come…took the method from nothing to evidence-based…here it is! Now, positioning and marketing will be the next set of challenges."*

Next Steps

A TDM meeting was held at IRH on January 12, 2010 which included discussion of the preliminary results of the phone survey of stakeholders, previous interviews with IRH staff, TDM research-based evidence, and other input. Following this meeting IRH initiated the planning phase for two new pilot studies on the TDM: 1) to determine the methods or tools needed to offer the TDM to women and couples with low-literacy skills and the feasibility and effect of using this approach to integrate the TDM into a community-based program; and 2) to determine the feasibility and effect of integrating the TwoDay Method into the family planning method mix, especially in facilities where the Standard Days Method (SDM) is already offered routinely. Once these studies are completed, the results (along with inter-agency collaboration on other TDM projects) should provide important evidence and experience on the TDM, support replication of lessons learned, and make the method more accessible and available for interested women and couples.

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“Summary of Findings of Interviews with TwoDay Method Clients and Providers in Lima and Piura” July, 2007

Part 2

Global strategy to stop health-care providers from performing female genital mutilation UNFPA, UNICEF, UNHCR, UNIFEM, WHO, FIGO, ICN, WCPA, WMA, MWIA, World Health Organization 2010

Annex A: TDM Resources

TITLE	DESCRIPTION	ENGLISH	SPANISH	FRENCH	RECOMMENDATIONS/CONSIDERATIONS
			POLICY & NORMS		
WHO Medical Eligibility Criteria	This evidence-based international document provides guidance regarding "who" can use family planning methods safely (including TDM). It helps providers determine when to accept (A), exercise caution (C), or delay (D) the use of a particular method.	WHO web page			Actively seek opportunities to include the TDM in policy and country norms including WHO Family Planning Decision-Making tool, WHO Selected Practice Recommendation for Contraceptive Use, future revisions of the UK Eligibility Criteria, Peruvian national norms, and other state-of-the-art documents.
Family Planning: A global guidebook for providers (WHO, USAID, Johns Hopkins)	This handbook for family planning providers helps them assist clients choosing a method, support effective use, and address clients' problems. It includes a chapter on FAM and 1 page on the TDM.	WHO web page			
Contraceptive Technology, 19th revised edition (Hatcher, et al)	This text for USA clinicians providing family planning/reproductive and sexual health services details medical practice recommendations for all methods. The chapter on FAMs includes the TDM.	Ardent Media			
The Balanced Counseling Strategy: A toolkit for family planning service providers (Federico Leon, et al Population Council)	Integrates the TDM along with other methods for a systematic counseling approach. The toolkit includes a trainer's guide, DVD, client educational pamphlets, and laminated cards to share with clients.	Population Council			

TITLE	DESCRIPTION	ENGLISH	SPANISH	FRENCH	RECOMMENDATIONS/CONSIDERATIONS
TDM TRAINING MANUALS AND TOOLS					
TwoDay Method of Family Planning: A training for service providers Level for health care professionals	The training manual includes 10 activities for preparing providers to offer the TDM. During this 5 ½ to 6 hour training there are practice activities with all the TDM tools and educational materials as well as a final written test and practice counseling session. A 20 slide PPT is also available to provide an overview of the method.	Manual - ENG Manual- Eng Modified for faith-based providers PPT presentation	Manual - SPA PPT presentation	Manual - FR PPT presentation	This is a comprehensive, well-designed training. Peruvian providers and data collection staff recommend periodic refresher trainings and/or individualized support through supervisory visits. To train low-literacy, community-based workers additional modifications would need to be made. A separate, training orientation for non-TDM providers may help address provider bias. The need for a simple (2-hour?) training that can be integrated into existing training programs or updates has been expressed. However, the subsequent need for additional modules, to cover and/or practice other important areas (including counseling) has been suggested by Peruvian trainers.
Participant Notebook Level of health care professionals	This notebook includes all the handouts and materials to be read and used by the participants during training.	Notebook - ENG	Notebook - SPA	Notebook - FR	Depending on the participant audience, some of the notebook handouts may need to be adapted for the local context.
TDM COUNSELING TOOLS					
Client Card	Serves as memory aid for the client.	Link to Client Card - ENG	Link to Client Card - SPA	Link to Client Card - FR	IRH is making a few additions so the client card may also serve as a provider job aid when counseling on the method. Additional changes to consider include

					simplifying some terminology, modifying the graphic image to reflect the secretion pattern in relation to menses, and including a message to return to the provider if unhealthy secretions are noticed, and that the TDM does not protect against STIs. Consider testing/creating a low-literacy card that does not include interpreting and marking symbols.
Client Card (vertical panel)	Same	**Client "Vertical Panel" - ENG**	C**lient "Vertical Panel" - SPA**	**Client "Vertical Panel" - FR**	Having a few different, tested prototypes of the client card available may enable programs to more easily make context-specific adaptations to better meet the needs of their clientele. For replication and sustainability programs often need a low-cost version of the client cards and job aids (less color, less pages, not laminated)
Provider Job Aids Packet for Counseling Clients	Similar to the SDM job aids packet, this includes the initial and follow-up visit checklists, instructions for use and FAQs.	**Provider Packet - ENG**	**Provider Packet - SPA**	**Provider Packet - FR**	As the TDM is integrated into future programs, include project-specific job aids as samples. Revise English version of the "Instructions for Use" to include the ability to start the TDM anytime during the cycle. Possibly revised FAQ response for secretion recording and incorporate the LAM criteria into the response to the question on breastfeeding.
Provider Cue Card	A tool to help providers counsel women interested in the TDM.	**Provider Cue Card - ENG**	**Provider Cue Card-SPA**	**Provider Cue Card - FR**	Providers in the Peru study report they would be able to use the client card, rather than the cue card, when counseling clients. This would reduce printing and lamination costs.

Initial Visit Checklist	A provider tool with algorithm for determining if and when a woman and her partner can use the TDM.	**Initial Screening Card - ENG**	**Initial Screening Card - SPA**	**Initial Screening Card - FR**	Providers report using the screening checklists for the first few clients, then they do not need this tool. Consider combining the key information on the initial visit checklist and any important information on the cue card (not already on the client card) to create one, simplified job aid. This simplified job aid could be used in combination with the client card.
Follow-up Checklist	A provider tool with algorithm to assess correct method use, and address any issues or questions.	**Follow-Up Screening Card - ENG**	**Follow-Up Screening Card - SPA**	**Follow-Up Screening Card - FR**	Although research suggests that women can learn the TDM in one visit, TDM field staff emphasizes the benefits of follow-up.
TDM KIT	Tool for evaluating TDM provider knowledge, complete with list of questions to determine whether providers know the content information needed to provide accurate TDM counseling.	TDM KIT ENG	**TDM KIT-SPA**		This supervisory tool for evaluating the knowledge of TDM providers could also be modified and used for: 1) role play practice during training as an outline of points to cover and assess for; and 2) skills observation during a supervisory visit.
TDM PROMOTIONAL MATERIALS					
Banners	The promotional materials listed in this section were developed by a Nicaraguan marketing group following a report on strategies for positioning the TDM as a natural and effective family planning method.		Manta 1 Manta 2		The positioning strategies identified in the Nicaraguan report may be used to help identify key strategies and prototype materials that may tested and adapted for other countries and sub-groups. Support context-specific strategies for positioning the method and development of promotional materials designed for the local context.

TITLE	DESCRIPTION	ENGLISH	SPANISH	FRENCH	RECOMMENDATIONS/CONSIDERATIONS
Fliers			Flier Side A Flier Side B Flier Side B3		Peruvian providers recommend fliers, posters, street banners, radio announcements, and promotional campaigns such as health fairs as effective options for informing the public about the TDM.
Brochures			Brochure A Brochure B		
Posters			Bicycle 1 Bicycle 2 University 1 University 2		
Logos			Logo MDD 1 (vertical) Logo MDD 2 (vertical) Logo MDD 3 (vertical) Logo MDD 2 Logo MDD 3 Logo MDD 4		

TITLE	DESCRIPTION	ENGLISH		SPANISH	FRENCH
TDM MATERIALS FROM PERU					
Afiche Universidad (Poster)	The Peruvian promotional and educational materials listed below were tested and modified from the sample materials developed by the Nicaraguan marketing group.		Afiche MDD University		Discussions with Peruvian field staff emphasize the need to develop and use promotional/educational materials that resonate with the target community. This may require additional testing and local materials development, especially for large, system-wide integration.
Manta (Banner)			Manta MDD		
Brochures			MDD Brochure A MDD Brochure B		
Volante (Flier)			Volante MDD Parque A Volante MDD Parque B		
TDM DISSEMINATION—MEDIA ARTICLES					
Press Releases "'TwoDay' method helps women avoid pregnancy" Reuters Health, 10/26/04	Highlights the results of the efficacy study and quotes Dr. Marcos Arevalo regarding the effectiveness and ease of use.	Article Link			
"Getting pregnant could be as easy as 1, 2!" Pregnancy & Baby 4/19/2006	Highlights basic information about the TDM, analysis of the European Study of Daily Fecndability, and quotes Dr. David Dunson on method effectiveness.	Article Link			

TITLE	DESCRIPTION	ENGLISH	SPANISH	FRENCH	RECOMMENDATIONS/CONSIDERATIONS
"New kid on the block?" news.inq7.net 5-9-2006	Focuses on the Philippine experience with the TDM, with some off-beat humor. Challenges with abstinence are included along with support for inclusion of the TDM and other NFP/FAM as a FP option.	**Article Link**			
"'TwoDay' Method Helps Women Avoid Pregnancy" Prevent Disease[1].com 4-19-2006	Describes the TDM, efficacy study results and has quotes from Marcos Arevalo, similar to the Reuters Health article.	Article Link			
"Efficacy of the new TwoDay Method of family planning" Fertility and Sterility 10/2004	Documents the results of the efficacy study (Guatemala, Peru, Philippines). The first year pregnancy rate is 3.5 with correct use and 13.7 when all cycles and all pregnancies are included. The method is easy to teach, learn and use.	Abstract link			
"A New Algorithm to Identify the Fertile Time of the Menstrual Cycle" Contraception 1999	Reports on the analysis of a large data set from the WHO NFP study to determine the potential effectiveness of the TDM algorithm. Results suggest that the TDM can be an effective, simplified method.	Article link			

TITLE	DESCRIPTION	ENGLISH	SPANISH	FRENCH	RECOMMENDATIONS/CONSIDERATIONS
"Further analysis on the theoretical effectiveness of the TwoDay Method of Family Planning" Contraception 2001	Validates the theoretical effectiveness of the TDM by administering the same analysis of the previous study to a data set from the Italian Ovulation Method center. Results confirm that the TDM can be highly effective in helping a woman identify the fertile days of her cycle.	Abstract Link			
"It's all in the timing: coital frequency and fertility awareness-based methods of family planning" Biosocial Science 2005	Data from the TDM and SDM clinical trials was analyzed to determine the frequency and timing of intercourse during the cycle, and the determinants of coital frequency. Results suggest that coital frequency increases with consecutive cycles of use, while the frequency of intercourse during the fertile window and menses decreases.	Abstract Link			
"Application of simple fertility awareness based methods of family planning to breastfeeding women" Fertility and Sterility 2003	An original data set from FHI was reanalyzed to determine the potential efficacy of the SDM and TDM among breastfeeding women. There is still a need to find a more appropriate FAM for the early post partum period.				

TITLE	DESCRIPTION	ENGLISH	SPANISH	FRENCH	RECOMMENDATIONS/CONSIDERATIONS
“Fertility Awareness-Based Methods of Family Planning: Predictors of Correct Use” International Family Planning Perspectives 2006	Quantitative and qualitative data from SDM and TDM efficacy studies was used to compare characteristics of women who did and did not use the method correctly. No clear profile emerged of clients for whom these methods would be inappropriate. However the importance of helping clients overcome potential difficulties in managing the fertile days was stressed.				
“TwoDay Method a Quick-Start Approach” (pending journal publication)	The Peru study compared offering the TDM within the first 7 days of the menstrual cycle with offering the method at any point in the woman’s menstrual cycle. The results indicate that there are no significant differences in correct use, continuation, or acceptability between women who were counseled at different points of the cycle.				
“Fertility Awareness-Based Methods: Another Option for Family Planning” J Am Board Fam Med 2009	Presents a summary of current FAMs including the TDM and comments that the US physician knowledge on these methods is often incomplete. Suggestions for useful educational materials are also included.				

TITLE	DESCRIPTION	ENGLISH	SPANISH	FRENCH	RECOMMENDATIONS/CONSIDERATIONS
		IRH Project Reports			
"Offering the TwoDay Method within Family Planning Services in Peru" February 2008	This study is the first in introducing the TDM into regular RH/FP service delivery. It tested the feasibility of offering the TDM at any time during the menstrual cycle along with protocols, training curriculum, client materials and job aids supporting the integration. The approach had very positive results.				

Annex B: TDM Interview Questionnaire for IRH Staff and Consultants

Name: ___________________________________
Date: ___________________________________
Time: ___________________________________

IRH Staff Interviews Regarding TDM

The purpose of the IRH staff interviews is to:

- Synthesize existing experience and evidence of TDM service delivery
- Identify gaps and/or recommendations to modify IEC, client education, training, and service provider materials and resources
- Complement lessons learned and recommendations from previous TDM studies which may help guide TDM future activities and introduction plans
- Identify key stakeholders and experts to interview for the market assessment protocol

Current IRH staff interviewed:

- Victoria Jennings
- Rebecka Lundgren
- Jeannette Cachan
- Irit Sinai
- Marie Makabatsinda
- Arsene Binanga
- Meredith Puleio (only one question)

Former staff to interview:	Marcos Arevalo, Monica Marini
From the Peru experience:	Marco Antonio Basualdo Ibañez, Rosario(Charo) Panfichi, Judith Diaz
From Guatemala:	Lidia Mazariegos

Other key informants suggested, but not interviewed because of time constraints or lack of contact information:

- Mitos Rivera (Interview scheduled, but postponed. Could be included in market assessment interviews)
- Mary Finnegan (Boston Archdiocese) May be included in market assessment interviews
- Beth Yaeger
- Patti or Irma (Peruvian project staff)

Interview Questions

General Questions

1. How would you describe the **need/demand** for the TDM in the country/countries where you work?

2. How has the TDM been **perceived by clients, providers, policy makers** in the country/countries? (Initially? Over time?)

3. How would you describe the interest in the TDM by **conference participants**? (Only ask this question of Meredith and/or Magaly.)

4. From your work with the TDM what are some of the **key lessons learned** that should be incorporated into future TDM activities?

5. What do you perceive to be the **main challenges** to increasing **TDM awareness**, **method use, and an organization's ability to incorporate the TDM** as a method option?

6. What do you perceive to be the **linkages, areas of strength** (within IRH and/or networks/connections beyond IRH) to build on for future work in TDM?

7. When thinking about **SDM experiences**, are there lessons learned that would apply to TDM activities, introductions studies, or scale up?

8. Who are the **stakeholders/key individuals** (donors, TA agencies, experts in the field, key FP/RH service providers) who should be interviewed for their guidance regarding future TDM activities, research, capacity building, and IEC/training activities, as part of an overall market assessment (country specific and world-wide perspective)?

Research

1. What are the **high priority areas to research** regarding the TDM? What are the most important research questions?

2. In contemplating "TDM **mini-research projects**" with assessment and follow-up for about 6 months (to help something happen and document it) what would you recommend?

3. What factors should help **guide TDM future** research and project support? Why?

   Probe regarding how important it is to:

- Integrate into **FP service delivery** organizations
- Expand beyond FP organizations to **other areas like women's empowerment**, education of girls/women/general education, micro-enterprise, other?

- Link **with FBOs**
- Link with organizations experienced with **NFP/Billings/Ovulation methods**
- Identify opportunities for **SMS/Texting, web education**, innovative technologies
- Incorporate a **fertility awareness** approach….universal message of using secretions to plan or prevent pregnancy, ability to recognize abnormal secretions and need for RH care (with a **SMS/text/web** connected model, for **adolescent** programs? Other?)
- Address **community-based vs clinic-based** distribution factors (maximize cost/benefit with level of staff, individual vs group instruction, simplification of key messages)
- Link with/expand from **existing SDM projects**/service delivery
- Offer the **TDM in areas where the SDM** is not present
- Addressing the need of **Breastfeeding and Postpartum** women
- Other?

4. What are opportunities for TDM **funding beyond USAID?** (International and US-based)

5. What opportunities are there for **collaboration and TA with CAs** and other organizations?

TDM Service Delivery (From your experience….)

1. How would you describe the **effectiveness/appropriateness** (include any suggestions for revisions) of the following TDM materials:

- Client Card
- Initial Visit Screening Card
- Provider Job Aids packet* (follow-up screening card, cue card…)
- TDM KIT

2. Are there any **gaps or needs** for additional TDM materials? (Additional ideas for adapting the client card so it can also serve as a provider job aid.)

3. Do you have any suggestions for **simplifying TDM service delivery**? (Eligibility criteria? Charting? Job aids? Follow-up? Other?)

4. For basic service delivery, how important is it to have initial clients **complete a daily chart** with the various symbols to record their observations vs. instructing them to **check every day, but only chart secretions** on the days they occur (marking a calendar, for example, only on the days of secretions)? Is there a need for a "**no-chart" TDM counseling model**?

5. **IRH instructions** tell users to ask themselves if they note secretions today, and if they noted secretions yesterday. If the answer to either question is yes, they should use condoms or abstain that day. If the answer to both questions is no, they may have unprotected sex that day. (Thinking about today and yesterday)

WHO instructions (Family Planning: A Global Handbook for Providers pg. 242) tell users to avoid sex or use condoms on each day with secretions and on each day following a day with secretions. Couples can have unprotected sex once the woman has two dry days (days without secretions of any type) (Thinking about today and tomorrow)

Over time have **providers evolved a simplified way of teaching TDM clients** to determine the fertile time in the field? What conceptual approach is easiest to teach and easiest for people in the community to learn and remember the information?

6. Some TDM clients have said they could **stop charting** once they know the TDM well and have had experience using it for a few months. Does this have any implications for the service delivery model? (Explain.)

7. From your experience, is a **TDM follow-up** visit required/desired? How does this fit with most service delivery systems? (Check with **Marcos and Judith** about their protocol, experience, and recommendations regarding follow-up visits based on the Peru study.)

8. From your experience, how **easy or difficult** is it for providers to integrate the TDM into ongoing service delivery programs? (How well does TDM combine with other programs including family planning, STI prevention, overall fertility awareness, preconception/infertility, other areas?)

9. What is your perception of the current TDM counseling model? (For those with **direct service delivery experience** like staff involved in the **Peru OR study**)

   How do providers perceive the counseling process? the materials?

- Based on experiences and lessons learned, do you have any suggestions for modifying/streamlining the counseling model? (Could the counseling be less than 15 minutes?)
- Are there any recommended changes/additions/deletions to content information? Educational approach? Areas to emphasize?
- Are there opportunities/possibilities for group teaching of TDM?What are the most common reasons for follow-up/return TDM visits? (Unusual secretions, secretions for too many days, other?)

10. Do you have any thoughts/recommendations regarding community-based distribution of the TDM?

TDM Staff Training (From your experience…)

1. What are some of the lessons learned from TDM training activities?

2. What suggestions do you have for designing a 2-hour TDM provider training that could be integrated into existing service delivery training programs?

3. Do you have other recommendations for future TDM training? Probe regarding:

- Need for additional training materials? Alternate training plans (USA vs international focus)? Training different levels of staff? Indications or models for follow-up training?
- Need for brief TDM orientation/awareness raising training for all staff/volunteers vs. service delivery training for those who will offer the TDM?
- Need to identify key messages for TDM training?
- Need for prototype PPT presentation model?Need/how to best position the TDM within the context of informed choice? Male involvement?

4. How much time is needed to train staff to counsel women/couples on the TDM? (How much time for training is available in most situations?)

TDM Informational Materials/Positioning the Method/Outreach

1. What are the most cost effective/relevant ways to **help position the TDM**? Probe regarding:

- Quick market research before initiating new projects
- Use of new and/or modifications to existing materials (flyers, brochures, posters, radio scripts, PSAs, video and audio sound bites, health fairs, movie theaters, local businesses, TDM web page, etc.)
- Activities and training to incorporate outreach staff and proposed outreach efforts
- Use of creative/new technologies

2. What are the key **obstacles to acceptance of TDM** as a method option? Probe regarding:

- Lack of awareness/information
- Issue of possible negative association with touching/seeing cervical secretions
- Bias/concern regarding method effectiveness
- Previous bad experience with FAB methods
- Climate of family planning promotion of long-acting reversible methods?
- Time and money needed to incorporate something new
- Low priority
- Western medical model
- Other?

3. Do you have any **additional thoughts, ideas** regarding TDM activities, research, training, IEC or other areas to support future introduction studies and scale up of the TDM?

Annex C: Testing TDM Recording Options

Testing TDM Recording Options

Background and Rationale:
Women using the TwoDay Method (TDM) can accurately identify the fertile days of their menstrual cycle and use the method effectively. The current client educational materials have been well-tested and are well-liked by both providers and clients.

To date the TDM research has largely been conducted in clinic-based service delivery systems, and there is interest in expanding the TDM to community-based programs. This provides a unique opportunity to test other strategies that are appropriate for providers and clients in community-based programs. For example, alternate TDM recording options that require less record keeping may be needed for particular audiences including groups with lower literacy.

The TDM is a "non-commodity" method. There is no need for programs to procure and disseminate a particular "gadget" or supply in order to integrate and continue offering the TDM. For this reason, alternate TDM recording options should not rely on a new "gadget" or supply that could be a barrier to TDM integration. Rather, an alternate recording option would ideally require minimal or no additional tools.

Although the initial learning phase is different than the phase of competent use, 50% of TDM clients interviewed in the Peru study reported that they could stop recording after a few months (3 to 6 month range) of using the TDM. These women indicated that over time they were able to determine whether a given day was fertile or not without consulting their documentation of secretions.

The use of an alternate system for keeping track of secretions (that does not require daily recording or charting) has not yet been studied.

Goal:
Determine whether clients who choose the TwoDay Method (TDM) can successfully use an alternate system to correctly keep track of the fertile days.

Option 1: Minimal Recording on a Monthly Calendar

Objective:
Test a TDM recording option that instructs the woman to use a monthly calendar to record only days of secretions AND the two days after the secretions go away.

Key Questions:
During the learning phase:

- Can a woman learn and use the TDM correctly by only recording days with secretions and the two days after these secretions go away?

- Does a woman remember to check her secretions every day if she does not record them on a daily basis? (Or, is she more likely to forget to check her secretions?)

- Does a woman or the couple need to see a daily documentation of the secretion pattern?

Instructions for Minimal Recording on a Monthly Calendar
Use the information on the new TDM client card to provide standard method instructions on what the method is, how it works, what secretions are like, and how to tell if you have secretions.

Instead of describing how to mark and interpret the symbols on the chart of the client card, teach the woman to mark a monthly calendar as described below.

1. Each day pay attention to your secretions, especially in the afternoon and evening, by looking, touching, or feeling.

2. Every night before going to bed, remember if you had any secretions that day.

3. If yes, put a mark on the calendar for that day. *(Show how to do this with a sample calendar, see below.)* Once secretions stop, mark the first day with NO secretions with a number 1, and mark the second day in a row with NO secretions with the number 2. For all other days with no secretions, including days of menstruation, leave the calendar blank.

JUNE						
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
					1	2
3	4 √	5 √	6 √	7 √	8 √	9 √
10 √	11 √	12 √	13 **1**	14 **2**	15	16
17	18	19	20	21	22	23

(In the example above the fertile days begin on June 4th and end the night of June 14th.)

4. You can get pregnant:
   - On any day with secretions. (These are all the days with the check marks on the calendar.)
     AND
   - On the first and second day after secretions stop. (These are the days marked 1 and 2 on the calendar.)
     Or, use WHO wording from FP Global Handbook. "You can get pregnant on each day with secretions and the day following a day with secretions". The couple can have unprotected sex again after the woman has had 2 dry days (days without any secretions of any type) in a row. (There is a need to test the best wording to describe the fertile days with this recording option.)

   To prevent pregnancy abstain from sex or use a condom on these days.

5. If there were no secretions today, AND no secretions yesterday (two consecutive days with no noticeable secretions) the chance of pregnancy is very low. You can have unprotected sex on these days.

Materials Required

Revised client card
Monthly calendar
Pencil or other marker

Possible Steps for Testing Option 1

- Conduct formative research to select a minimal recording approach most suited to the target audience
- Determine, review and revise initial instruction messages
- Quick test messages for clarity and comprehension
- Finalize instruction messages and create mock-ups (if needed) to test this recording option with X # of women (barrier method users or non-sexually active women)
- Pilot with 1-to-1 instruction of a few women who agree to use the TDM with this recording option to track their secretions for a few months (and who will keep a diary or agree to speak with an interviewer about their experience and ability to check secretions and record as instructed)
- Conduct a focus group of providers to get their input
- Make modifications, as indicated
- Document findings

Alternate Approach

If calendars are not a desirable recording mechanism, other approaches may be used to document the fertile days. For example, another option would be to instruct women to use a piece of charcoal or pencil and make a mark on a stone, paper, or piece of wood to remember her fertile days. The most appropriate recording option would be determined during the formative research.

Option 2: Found Object as a Memory Aid (Two Stones)

Objective:

Test a TDM tracking option that helps a woman remember the days she can get pregnant with a common "found object" like two stones, or two kernels of corn (not a supply or gadget that needs to be purchased) and does not require recording secretions on a daily basis.

Key Questions

During the learning phase:

- Can a woman use the TDM accurately by learning/internalizing that any day with secretions is a fertile day, without actually recording or documenting these days with secretions? (The woman would only use a memory aid to remember the day secretions are no longer present, and the next day, and possibly the start of secretions.)

- Does a woman remember to check her secretions every day if she does not record them on a daily basis? (Or, is she more likely to forget to check her secretions?)

- Does a woman or the couple need to see a daily documentation of the secretion pattern?

Instructions for Using a Found Object as a Memory Aid
Use the messages on the new TDM client card to provide standard method instructions on what the method is, how it works, what secretions are like, and how to tell if you have secretions.

Instead of describing how to mark and interpret the symbols on the chart of the client card, teach the woman to use a found object like two stones, or two kernels of corn to keep track of and remember the days she can get pregnant. (This option is designed for local adaptation, so programs can use a found object that is relevant and available in their area. This could be two stones in a bag, two kernels of corn on a shelf, two sticks stuck into the ground or any other found memory aid. See below for a description using the example of two stones in a bag)

1. Every day pay attention to your secretions, especially in the afternoon and evening by looking, touching, or feeling.

2. Every night before going to bed, remember if you had any secretions that day.

3. If yes, put a stone in a bag. (Note: this example describes a stone in a bag, but the found object could be modified in many different ways for local adaptation.)

4. The next night before going to bed, if you had any secretions that day, put a second stone in the bag.

5. You can get pregnant on ANY day with secretions. (These are days when there is a stone(s) in the bag.)

6. Keep checking your secretions every day, especially in the afternoon and evening. (You don't need to add more stones to the bag. The two stones will remind you that you can get pregnant.)

7. Once the secretions go away, and there are NO secretions all day long, take one stone out of the bag before going to bed.

8. The next night, if there were NO secretions all day long, take the second stone out of the bag.

9. When there are NO stones in the bag, pregnancy is very unlikely. This means NO secretions today and NO secretions yesterday.

10. Once secretions start again (not menstrual bleeding) put a stone back in the bag. Remember, you can get pregnant on any day with secretions and on the two days after secretions go away. If you noticed any secretions today OR yesterday, you can get pregnant today. (The words and any visuals used to describe the fertile days, in relation to the "found object memory aid," need to be tested with the target

audience.)

Materials Required

- Revised client card
- Found object (like two stones in a bag, or two kernels of corn in a drawer)

Possible Steps for Testing Option 2

- Conduct formative research to select a found object or other reminder approach most suited to the target audience
- Determine, review and revise initial instruction messages to be used with this reminder approach
- Quick test messages for clarity and comprehension
- Test whether it is best to mark the beginning of the fertile days with a found object, OR if women can just remember and internalize that they can get pregnant on ANY day with secretions. If so, there is a possibility of testing the use of the found object only to mark the two days in a row when secretions go away.
- Finalize instruction messages and create mock-ups to test this tracking option with X # of women (barrier method users or non-sexually active women)
- Pilot with 1-to-1 instruction of a few women who will use the TDM and agree to use this tracking option to pay attention to their secretions for a few months (and who keep a diary or agree to be interviewed about their experience, ability to check secretions daily, and use the memory aid as instructed)
- Conduct a focus group of providers to get their input
- Make modifications, as indicated
- Document findings

Annex D: Market Assessment Interview Questionnaire for Stakeholders & Donors

Market Assessment Interview Questionnaire For Stakeholders and Donors[3]

Introduction
Thank you for participating in this interview. Your answers to the questions will help IRH determine the feasibility and viability of integrating the TwoDay method into a variety of programs and services.

As you know…
The TwoDay method is a natural, effective method of family planning with no side effects. This symptoms-based method helps a woman identify the days of her menstrual cycle she can get pregnant by checking her secretions. A woman can get pregnant today if she had secretions today OR yesterday. (Or…any day a woman has secretions is a day she can get pregnant. Each day following a day with secretions she can also get pregnant. Once she has NO secretions for two days in a row— no secretions today and no secretions yesterday—there is very little chance of pregnancy.)

The TwoDay Method does not require interpreting quality of secretions as in other cervical secretion methods like the Billings Method or Sympto-Thermal Method.

With correct use, the TwoDay method has a first year pregnancy rate of 3.5 and with typical use a rate of 13.7. (State effectiveness more simply depending on interviewee…less than 4 out of 100 women get pregnant when using the method correctly for a year) This "non-commodity" method can be used by most women regardless of cycle length, and when used correctly is more than 96% effective.

Questions

1. What is your **impression/opinion** of the TwoDay method as a family planning option for women and couples?

   Describe your **experiences** regarding this method (or natural methods or information-based messages with action item for clients/community).

   What are the **benefits/**potential benefits of integrating this method?

   What are the **challenges/obstacles/problems**/ or potential challenges with integrating this method?

2. What types of **organizations** would be **most interested in/able to integrate the TwoDay method** into their programs or services?

   Probe regarding family planning groups, FBOs, NFP groups, programs with existing SDM or LAM services, community-based programs, women's empowerment, literacy, micro-enterprise, other, etc.

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[3] This questionnaire is geared for policy/stakeholders and donors. For specific recommendations for TDM programmatic activities see part 1 of this report and the part 1 questionnaire.

What **different approaches** would you suggest for **different organizations?** (Tailor to their experiences/what approaches have or have not worked with something *like* this?)

What **different approaches** would you suggest for **different target audiences**? Who is their target? What program implementation approaches work with this target?

3. Field programs have reported challenges with lack of awareness about the TwoDay method as well as provider and institutional bias against fertility awareness methods including the TwoDay method. How do you recommend **positioning** the TwoDay method and **raising awareness** about this option?

   How should information about the TwoDay method be diffused/suggestions for **getting the word out**?

   Probe regarding positioning and diffusion to the **community, providers, administrators, and policy makers**.

   How should the TwoDay method be positioned with regard to the Standard Days Method (**SDM**) and Lactational Amenorrhea Method (**LAM**)?

   What is your opinion regarding the **name** "TwoDay" method?

4. Would you/your organization be interested in **championing/supporting** the integration of the TwoDay method at the international or country level?

   If YES, how?

   If NO, explain.

   Would you (or another organization you recommend) be interested in funding TwoDay method **introduction studies**?

   What **level of resources or support** would you be willing to commit?

   Who (list of names) would you recommend that could help with these efforts?

   What **type of support/assistance/evidence/materials** would your organization need to position and introduce the TwoDay method?

5. What additional **suggestions or recommendations** do you have for integrating the TwoDay method into programs and services?

   Are there **specific activities** or steps you recommend?

   Are there **research priorities** you would recommend?

   What do you think of suggestions for supporting TwoDay method services through **SDM/Texting, web education or innovative technologies**? Any specific suggestions or advice about this?

   Is there anyone else that you **recommend that I interview**?

Annex E: Matrix for TDM Opinion Survey Documentation

Matrix for TwoDay Method (TDM) Opinion Survey Documentation

Name of Interviewee________________________ Date_________

Name of Interviewer_________________________ Phone Number__________________

Organization_______________________________

Instructions: When administering the Market Assessment Interview Questionnaire, please use the matrix below to document answers to the questions. Complete one form per interview. Thank you.

Main Question	Probing Points			Other
1. General impression of the TDM	Experiences with TDM	Benefits of TDM	Challenges/problems	
2. Organizations that may be interested in the TDM	• FP • FBOs • NFP • SDM/LAM • Community-based • Women's empowerment • Literacy • Other	Approaches for different organizations	Approaches for different target audiences	

Main Question	Probing Points			Other
3. How to raise awareness/position the TDM	• Community • Providers • Administrators • Policy makers	Considerations for positioning the TDM with: SDM LAM Other	Impression of the name? TwoDay Method ☐ Like ☐ Dislike 2Day Method ☐ Like ☐ Dislike TDM ☐ Like ☐ Dislike Any concerns/suggestions	
4. Champion/supporter of TDM integration? International level ☐ Yes ☐ No National level ☐ Yes ☐ No	Can/will fund introduction studies ☐ Yes ☐ No Explain	Resources and support willing to commit -Funding or programmatic integration -Names of people to be involved	Assistance or support needed from: -IRH -Other	
5. Additional suggestions or recommendations	Specific activities	Research priorities	Innovative technologies -SDM texting -Web-based education -Other	

Record additional comments below: