In response to questions about calculation of FABM effectiveness, please see: <a href="http://chelseapolis.com/blog/understanding-effectiveness-estimates-for-fertility-awareness-based-methods-of-contraception">http://chelseapolis.com/blog/understanding-effectiveness-estimates-for-fertility-awareness-based-methods-of-contraception</a>

Roopan Gill: I am wondering where the evidence for waiting 6 months post miscarriage/ abortion is coming from? We know that we do not need to advise woman to wait after a miscarriage particularly if they wish to try again and six months is quite significant.

#### **Devon McKenzie:**

I wanted to chime in about the question on the recommendation to wait six months after an abortion or miscarriage before trying to conceive again. The WHO recommendation stems from a study in Latin America that looked at maternal and perinatal outcomes among women whose previous pregnancy ended in abortion. However, the study did not differentiate between safe abortion, unsafe abortion, or spontaneous abortion.

Research in the U.K. and the U.S. since then has actually found better outcomes for those who don't delay trying to conceive after a miscarriage – a study in Scotland showed that women who conceived again within six months were less likely to have another miscarriage or ectopic pregnancy compared to women who got pregnant between six and 12 months, and a recent study by the NIH found that couples trying to conceive within three months of an early pregnancy loss had similar or greater odds of having a live birth than those who waited longer.

The WHO report notes that the Latin America study may not be generalizable and recommends additional research. Similarly, the findings from the U.S. and U.K. may not be as applicable for low- and middle-income countries. Nonetheless, I do think those studies suggest a need to interpret the WHO recommendation "with some qualifications," as the WHO put it. If a woman is healthy and emotionally ready to try again after a loss before 20 weeks, it may not be necessary to wait a full six months to try again.

Trying to conceive soon after a pregnancy loss may increase chances of live birth: NIH study finds no reason for delaying pregnancy attempts after a loss without complications. Couples who attempt to conceive within three months after losing an early pregnancy, defined as less than 20 weeks gestation, have the same chances, if not greater, of achieving a live birth than those who wait for three months or more, according to a National Institutes of Health study.

This finding, published [January 2016] in Obstetrics & Gynecology, questions traditional advice that couples should wait at least three months after a loss before attempting a new pregnancy. The World Health Organization, for example, recommends waiting a minimum of six months between a pregnancy loss and a subsequent attempt.

Report of a WHO Technical Consultation on Birth Spacing

Recommendation for spacing after an abortion

After a miscarriage or induced abortion, the recommended minimum interval to next pregnancy is at least six months in order to reduce risks of adverse maternal and perinatal outcomes.

#### Caveat

This recommendation for post-abortion pregnancy intervals is based on one study in Latin America, using hospital records for 258,108 women delivering singleton infants whose previous pregnancy ended in abortion. Because this study was the only one available on this scale, it was considered important to use these data, with some qualifications. Abortion events in the study included a mixture of three types – safe abortion, unsafe abortion and spontaneous pregnancy loss (miscarriage), and the relative proportions of each of these types were unknown. The sample was from public hospitals in Latin America only, with much of the data coming from two countries (Argentina and Uruguay). Thus, the results may be neither generalizable within the region nor to other regions, which have different legal and service contexts and conditions. Additional research is recommended to clarify these findings.

RCOG statement on 'Women don't need to delay getting pregnant after miscarriage'

A paper published in the BMJ [August 2010] looks at the effect of interpregnancy interval on outcomes of pregnancy after miscarriage. Researchers found that women who conceive within six months of an initial miscarriage have the best chance of having a healthy pregnancy with the lowest complication rates.

Current World Health Organization (WHO) guidelines recommend that women who experience a miscarriage should wait at least six months before getting pregnant again. Researchers say this may need to be reviewed.

The researchers reviewed the data of over 30,000 women who attended Scottish hospitals between 1981 and 2000. The participants all had a miscarriage in their first pregnancy and subsequently had another pregnancy. The results showed that women who conceived again within six months were less likely to have another miscarriage, termination of pregnancy or ectopic pregnancy compared to women who got pregnant between six and 12 months after their initial miscarriage.

Dr Tony Falconer (President-elect) said: "This paper suggests it is appropriate to conceive within six months of a miscarriage which is at variant to WHO advice. "If you wish to be pregnant, trying again soon, whenever you feel physically and emotionally ready, does not increase your risk of miscarrying next time. It may be worth taking this opportunity to talk to your GP about anything you can do to prepare for a pregnancy."

Amylynn Smith: The 24% is a lumping of methods and the methods have different effectiveness rates. You touched on that. Isn't it true that they aren't using the Rhythm method because most persons have not actually read the Rhuythm method text....they just track the days of bleeding and count days 'x' number of days to identify a time of fertiltiy that might be something they heard from goolge or their friend

The comments above are unclear and not framed as a specific question, which complicates the ability to provide a useful response. Please feel free to contact the presenter directly (<a href="mailto:cpolis@guttmacher.org">cpolis@guttmacher.org</a>), or read her blog on this topic: <a href="http://chelseapolis.com/blog/understanding-effectiveness-estimates-for-fertility-awareness-based-methods-of-contraception">http://chelseapolis.com/blog/understanding-effectiveness-estimates-for-fertility-awareness-based-methods-of-contraception</a>

Amylynn Smith: Where can we find research/information about 'healthy spacing' (i.e. what is the science to support the 2 year spacing as being ideal)?

From the citations below, a two year interval between one birth and the beginning of a new pregnancy, results in a birth-to-birth interval of about 3 years. The data below show that birth-to-birth intervals of 3 to 5 years are optimal for healthiest outcomes. The papers by Rutstein (2008) and Rutstein and Winters (2014) present the evidence of the impact of spacing on mortality.

Here is a link to a video produced by the WV HTSP project:

http://wvi.org/video/healthy-timing-and-spacing-pregnancy-and-family-planning-kenya

# Cindy Uttley--Samaritan's Purse: Does anyone have experience using FABM in emergency settings?

No research studies have been conducted on this topic. However, IRH is aware of some instances where humanitarian organizations have used CycleBeads in their programs, including UNHCR and Mercy Corp. In the Democratic Republic of Congo, a country with prolonged conflict, FAM use is particularly high. Finally, FAM has the potential to be easily accessible via mobile phone apps or traditional provider counseling considering they are information-based methods. Further exploration of this is an important next step.

Adrienne, could you please type the citation for the 2008 & 2014 studies you mentioned? Thank you.

**DF]**Further Evidence of the Effects of Preceding Birth ... - The DHS Program

https://dhsprogram.com/pubs/pdf/WP41/WP41.pdf

by SO Rutstein - 2008 - Cited by 1 - Related articles

2008 No. 41. Shea O. Rutstein. Further Evidence of the Effects of Preceding Birth Intervals on Neonatal, Infant, and Under-Five-Years Mortality and Nutritional Status in Developing Countries: Evidence from the Demographic and Health Surveys. September 2008. This document was produced for review by the United States ...

## [PDF]The Effects of Fertility Behavior on Child Survival ... - The DHS Program

### https://dhsprogram.com/pubs/pdf/AS37/AS37.pdf

Shea Rutstein and Rebecca Winter of ICF International. ... Corresponding author: Shea Rutstein, International Health and Development, ICF International, 530 ...... 2008). In recent years, multi-country studies have sought to identify the optimal birth interval for child survival. Rutstein (2005 and 2008) found that for neonatal.

### [PDF]DHS WORKING PAPERS

pdf.usaid.gov/pdf\_docs/Pnadm649.pdf

by SO Rutstein - 2008 - <u>Cited by 1</u> - <u>Related articles</u>

2008 No. 41. Shea O. Rutstein. Further Evidence of the Effects of Preceding Birth Intervals on Neonatal, Infant, and Under-Five-Years Mortality and Nutritional Status in Developing Countries: Evidence from the Demographic and Health Surveys. September 2008. This document was produced for review by the United States ...

## [PDF]Making the Demographic and Health Surveys Wealth Index Comparable

https://www.iussp.org/sites/default/files/.../ComparativeWealth-DRAFT-IUSSP.pdf

by SO Rutstein - <u>Cited by 38</u> - <u>Related articles</u>

Aug 31, 2013 - Making the Demographic and Health. Surveys Wealth Index Comparable. '5\$)7. Shea O.Rutstein. Sarah Staveteig. ICF International. Measure DHS. Calverton, Maryland, USA ..... (Rutstein 2008) to allow for differing item weightings in each area and for urban and rural specific analyses. Currently, the DHS ...

Laura Robson: I'm interested to hear what exactly Dr Polis means when she refers to the "rhythm method"? How are fertile days determined by "rhythm" users? I find "rhythm" is often used as a fairly vague term for calendar-based FABMs (not including SDM / CycleBeads of course) without clarity on how fertile days are determined (calculations? guesswork? algorithms / apps?) and this makes it very difficult to make sense of method effectiveness.

The term "rhythm" is indeed used in a variable manner. The actual rhythm method has specific rules which involve keeping record of your last 6 menstrual cycles, finding the longest and shortest of those cycles, subtracting 18 from the number of days in your shortest cycle (to find the first fertile day in your current cycle), subtracting 11 from the number of days in your longest cycle (to find the last fertile day in your current cycle), and avoiding unprotected sex from the first to the last days identified as fertile. Some women who identify as a "rhythm" user may not be using these formal rules, which are not commonly taught anymore.

If you have specific question regarding how surveys capture which method survey participants are using, you can refer to survey documentation or reach out to Dr. Polis for assistance (<a href="mailto:cpolis@quttmacher.org">cpolis@quttmacher.org</a>).

For all presenters: Another question - what role do you think female-controlled non-hormonal methods (e.g. the Caya diaphragm developed by PATH) have to play in relation to FABMs in low-resource settings where women using CycleBeads may have difficulty negotiating abstinence or condom use during the fertile time?

According to the many studies conducted on SDM and TwoDay Method, couples use both abstinence and barrier methods to avoid unprotected sex on fertile days. It is up to the couple how they decide to manage the fertile days. Couples who desire to use newer methods like the diaphragm should be encouraged so. Further exploration of this is an important next step.

FAM is unlikely to be a good option for women who are unable to negotiate with their partner about when to have sex. In fact, during the counseling for both SDM and TwoDay Method, an important screening criterion for method use is a woman's ability to avoid unprotected sex on the fertile days. This should be discussed as part of the counseling session. However, it is important to note that when a woman has access to information and to a visual tool like CycleBeads, it can be much easier for her to talk with her husband about managing their fertile days.

A Mullen: Further to the 24% failure, do not the efficacy studies on the methods bear more weight?

As described in the presentation and in this blog (<a href="http://chelseapolis.com/blog/understanding-effectiveness-estimates-for-fertility-awareness-based-methods-of-contraception">http://chelseapolis.com/blog/understanding-effectiveness-estimates-for-fertility-awareness-based-methods-of-contraception</a>), contraceptive effectiveness estimates from large surveys (like NSFG) and prospective studies each have different advantages and disadvantages.

All effectiveness estimates should be considered in light of the strengths and limitations of the data and study designs from which they are derived. For example, effectiveness estimates from large national surveys may suffer from analytic constraints (which may lead to "lumping") or from data limitations stemming from issues such as recall bias. Effectiveness estimates from some prospective clinical studies may not be widely generalizable, and can also be impacted by the fact that participants in some studies may have regular contact with study investigators - which can impact on how well they use the method, and the the effectiveness rate estimated from that study.

We hope our upcoming systematic review, which will summarize the best available evidence from prospective studies, will help to provide clear information about what we know and do not know regarding effectiveness rates derived from that type of study design.

In sum, <u>both</u> types of estimates can contribute important information, and it is essential that those estimates be used and interpreted appropriately.

Leslie Heyer: Can any of the presenters speak to the challenges of data collection on FABM use? We know for instance that there are major challenges with identifying if/when people are using modern FABM as they are often mis-identified as using rhythm method or classified as users of other methods if they are using other methods in conjunction with FABMs (i.e., condoms).

The first major challenge in documenting FAM use is the lack of indicators in HMIS service delivery records and national level surveys like DHS. It is important for all FAM options to be included alongside other methods in service delivery records like facility registers so that use can be reported. Furthermore, providers should have a clear definition of a FAM user. For example, an SDM user would be recorded if a set of CycleBeads was offered at the end of the counseling (once method eligibility through screening was verified) and for TwoDay Method if the pamphlet with method instructions and secretions recording card was given. SDM has now been included in DHS surveys as an "opt out" rather than "opt in" method, meaning that it will be the default to collect information on SDM. To remove it, country teams must elect to "opt out" of collecting information on SDM. Track20 has, in some cases, collected information on SDM as well. This is a step in the right direction. To avoid confusion between different natural methods, DHS surveys use prompts for the data collector to confirm use of SDM and LAM. DHS prompts include:

Standard Days Method.

PROBE: A woman uses a string of colored beads to know the days she can get pregnant. On the days she can get pregnant, she uses a condom or does not have sexual intercourse.

Lactational Amenorrhea Method (LAM).

PROBE: Up to six months after childbirth, before the menstrual period has returned, women use a method requiring frequent breastfeeding day and night.

However, not all data collection tools specify with this level of detail, and we still see very few countries choosing to collect this information on national surveys or via their HMIS. Often, designing tools to collect all necessary indicators and doing so accurately requires awareness of established indicators and advocacy by partners to integrate changes. With regard to the concern about dual method use, most surveys do collect information on both methods. It is during analysis that decisions are made about which method will be selected as the primary method used. This is dependent on the criteria used by those doing the analysis and their awareness of modern FAM options. These discrepancies should be kept in mind when interpreting results.

# Leigh Wynne: How can Missions and bi-laterals help get the cycle beads more available in public sector?

Missions can integrate the procurement of cycle beads into their programming, and ensure fertility awareness based methods are a part of their method mix. Integrating FABMs into calls for programs can be effective in motivating bilaterals to include them in their proposals and programs. Ensuring monitoring and evaluation indicators by method helps to substantiate the added value of FAMS into mission programming.

**Susan Otchere:** http://apps.who.int/iris/bitstream/10665/69855/1/WHO\_RHR\_07.1\_eng.pdf - WHO resource. You can point listeners to this resource, though published in 2005, the science hasn't changed (Pardon - on the question on waiting 6 months after a miscarriage)

Deborah Sitrin: Seems FABM may require even more counseling than other methods, in order to help women (couples) use correctly. Is that true? Do we know how long it takes to counsel for women to feel comfortable that she is correctly using these methods.

Since FAM options are information-based methods, providers teach clients how to use the method correctly as part of the counseling (in addition to completing screening for method eligibility). Providers also support the client in how to communicate with her partner to manage the fertile days. Several studies have shown that quality counseling is important for correct use and continuation. On the other hand, social marketing of CycleBeads through pharmacies and kiosks where the seller gives limited instruction to the client has also been successful (http://journals.sagepub.com/doi/abs/10.1177/1524500412450486).

Several studies have been conducted to assess the length of counseling in different settings. SDM counseling generally seems to fall into allotted timeframes for counseling within service

delivery guidelines. However, concern about the length of counseling session has been noted. In Peru, the average SDM counseling session was 23 minutes, in India it was 20 minutes, in Rwanda the average was 43 minutes (versus 38 minutes for pill counseling on average), and in Albania and Ethiopia researchers found that individual counseling sessions for SDM users required somewhat more time than other methods (León et al. 2006, León et al. 2007).

With the growing availability of smart phone apps like the CycleBeads app, we are seeing that there is an opportunity for women to learn about the method and how to use it without the involvement of a provider at all. This direct-to-consumer approach is being studied in several countries, and preliminary results are very promising.