

GLOBAL HEALTH

Innovation Insight Series



Photo courtesy of Cycle Technologies

CycleBeads is a natural family planning tool based on the Standard Days Method

CYCLEBEADS I: Building Acceptance for a Simple Idea

WASHINGTON, DC

ESTABLISHED 2002

VICTORIA JENNINGS, INVENTOR

LESLIE HEYER, FOUNDER,
CYCLE TECHNOLOGIES

THE PROBLEM/SOLUTION SPACE

Unplanned pregnancy impacts not only women of childbearing age and their families, but the countries around the world where they live. The problem contributes to overpopulation, rising poverty levels, and increased maternal and infant mortality. Nearly 1.5 billion women are of childbearing age (between 15 and 45 years old); and during most of these years they do not wish to become pregnant.¹ Even with worldwide advancements and the availability of medical and surgical contraception, as well as user-directed methods, unplanned pregnancy continues to be a problem. Each year, more than 80 million women in developing countries are affected by unplanned pregnancies due to their non-use of contraceptives or their use of ineffective birth control methods. This leads to 30

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million unplanned births, 40 million abortions, and 10 million miscarriages annually.² According to a report by the United Nations Population Fund and the Guttmacher Institute, providing safe access to modern family planning methods to all women with an unmet need would prevent 21 million unplanned births, 79,000 maternal deaths, and 1.1 million infant deaths per year in the developing world.³

Geographically, the annual incidence of unplanned pregnancy varies greatly depending on the quality of health care and the economic status of a country. Accordingly, the highest rates are in sub-Saharan Africa and parts of Asia. In these regions, it is culturally more common for women to marry young,⁴ and medical and surgical contraceptive solutions are not always accepted or readily available due to economic, political, and religious restrictions. Natural contraception alternatives exist, but they are often poorly understood or perceived as cumbersome and too complex. For example, some methods

require extensive user training, as well as symptom tracking and the calculation of mathematical equations to achieve high success rates. As a result, they are not always practiced correctly or consistently and their effectiveness is compromised.

ABOUT CYCLEBEADS AND THE STANDARD DAYS METHOD

To help address the issue of unplanned pregnancy and maternal mortality in the developing world, Victoria Jennings, a researcher at the University of Georgetown’s Institute for Reproductive Health (IRH), recognized the need for an intuitive, natural contraception method that could meet the needs of families that chose

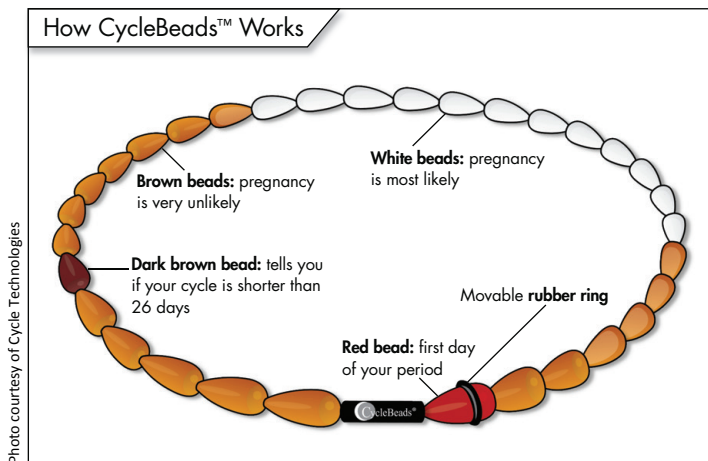


Photo courtesy of Cycle Technologies

CycleBeads was designed to be simple and easy to use

not to use medical or surgical alternatives. “Those of us involved in the innovation—with decades of field experience in global health and family planning issues—were well aware of the potential demand for something that is a very simple, fertility awareness-based solution,” she recalled.⁵

IRH developed the Standard Days Method (SDM), a simple natural family planning system that could be implemented in all countries and cultures across the globe. Researchers studied thousands of menstrual cycles and concluded that most women’s cycles were 26 to 32 days. In approximately 89 percent of cycles studied, ovulation most often occurred within (plus or minus) three days of mid-cycle. By avoiding unprotected intercourse between the 8th and 19th days of their menstrual cycles, women could significantly reduce their likelihood of getting pregnant.⁶

Along with developing the SDM approach, Jennings wanted a way to make the practice easily understandable and accessible to women. As a result, she and her team created CycleBeads to provide a visual, tangible tool to help women follow the method. CycleBeads is a color-coded string of beads that represents a woman’s menstrual cycle and allows her to monitor her cycle and manage her fertility. The first day of her menstrual cycle, the woman moves the rubber ring onto the red bead and notes the day on a calen-

dar. Daily, she moves the ring forward, directed by arrows in the chain. Anytime the band is on the red or colored beads, the user has a low risk of pregnancy; but when she moves the band to a white glow-in-the-dark bead (days 8 through 19), she has a high likelihood of pregnancy if she engages in intercourse without protection.⁷

In clinical trials conducted by IRH, SDM used in conjunction with CycleBeads was shown to be 95 percent effective in preventing pregnancy when practiced correctly.⁸ “Though not quite as effective as hormone methods or IUD implants, it is equal to if not more effective than other user-directed methods, like condoms or diaphragms,” said Leslie Heyer, founder of Cycle Technologies, who partnered with Jennings’ team and licensed the rights to bring CycleBeads to market. Cycle Technologies was responsible for worldwide manufacturing, quality, sales, and distribution of the product, while IRH remained involved in helping pilot and roll out the technology in emerging markets. The company hoped to reach users in developing countries where drug and surgical options were limited or unacceptable, as well as developed countries where women wanted effective, non-invasive birth control and proactive family planning tools.

ONE CHALLENGE: BUILDING ACCEPTANCE FOR A SIMPLE IDEA

When Cycle Technologies and IRH introduced CycleBeads into the complex world of reproductive health, it met with some resistance. As Jennings explained, “There have been decades of focus on what are referred to as permanent and long-acting methods of

family planning—trying to get people in the developing world to have sterilization, IUDs, more recently Depo-Provera, birth control pills, and so forth. The space has been very doctor-focused, very medicine-focused. So the idea of a family planning method that allows women to do something very simple to understand and control their own fertility was extremely challenging. It had to be done very carefully.”

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Established stakeholders in the reproductive health field, especially pharmaceutical companies and manufacturers of other birth control products, had a vested interest in maintaining the status quo. As a result, some sought to

create roadblocks for the CycleBeads by seeking to discredit its effectiveness. “I didn’t realize the strength of some of these companies and the influence they have on procurement processes in various countries and the long-term connections that they have with people in the Ministries of Health,” Jennings noted.

It was also important to bolster CycleBeads’ credibility and to demonstrate that this product actually provided a way to bring more women into the family planning process rather than merely compete for existing customers of other birth control methods. “CycleBeads addresses the needs of women and couples that are otherwise not met by existing methods,” Jennings said. For example, in Mali, West Africa, women were reluctant to adopt traditional birth control methods. According to Jennings, they had misconceptions about hormones and they faced religious issues related to the use of other, more invasive family planning methods. CycleBeads could provide a safe, culturally acceptable, and effective method to women who otherwise might do without birth control.

THE SOLUTION: ESTABLISHING CREDIBILITY THROUGH EVIDENCE AND STAKEHOLDER ENGAGEMENT

To validate the effectiveness of SDM and CycleBeads, IRH dedicated itself to conducting exhaustive clinical and field-based studies. The results of these tests consistently confirmed the +95 percent efficacy rate for the method and the product, when used in combination. Importantly, these studies also demonstrated that the approach was an effective catalyst for bringing new customers to the practice of family planning. “There has been a huge amount of evidence-gathering which shows that this is a viable product,” Jennings noted.

The approach that IRH took to planning and executing these tests created a base of knowledge that could also help the Institute and Cycle Technologies overcome stakeholder resistance. Initially, when conducting its preliminary peer-reviewed scientific

studies, IRH directly involved key opinion leaders from the field. “We engaged with the people who are well known to be experts in clinical trials of contraceptive methods,” Jennings recalled. “We involved them in designing the studies, interpreting the results, and then disseminating that information to the scientific audiences in the global health community who needed to be aware.”

Similarly, when conducting field-based studies to further refine and validate its approach, IRH engaged well-established partners from the global health ecosystem. As Jennings explained, “We did a number of studies with partner organizations. We never went into the field and said, ‘We are going to identify a community for women, and we’re going to teach them this method and see how it goes.’ We always, always worked

through organizations that were already on the ground implementing things, be it the Ministry of Health of the country or an NGO like Save the Children or Doctors Without Borders. They know the setting well, and they can be your best friends if you do it right, and they can block it if you don’t, so I think that’s a really important aspect of it.”

Another benefit of this approach was that it allowed IRH and Cycle Technologies to create advocates for the product who were not directly affiliated with its development. As Jennings explained, they found these champions invaluable in building support for the product. “These are people who can take your message and deliver it in a credible manner to other stakeholders you need to have on board,” she noted.

In terms of directly addressing resistance, Heyer recommended “choosing your battles.” She advised that sometimes it was appropriate to react strongly in defense of one’s product, while in other situations, “perhaps you will decide to show no acknowledgement at all, as your attention to the resistance might bring undeserved attention to incorrect or biased opinions.”



Photo courtesy of the Institute for Reproductive Health, Georgetown University

Women in Africa watch a CycleBeads demonstration

Particularly with its early implementations, Jennings and Heyer also chose their geographies carefully to help mitigate potential resistance. “You need to go places where there are other organization that are actively working on issues that are relevant to what you’re trying to do so that you can have partners with resources to take something forward,” Jennings explained. Even though CycleBeads was simple and intuitive to use, “We recognized that we couldn’t simply distribute 500,000 sets of CycleBeads in a developing country and say, ‘do your best,’” she continued. For this reason, they took a “systems perspective” to their rollouts—carefully working to align financial support for procurement, advocates to create excitement about the innovation, and education to aid end-users in understanding the value of the product when implemented accurately.

Cycle Technologies was able to leverage IRH’s relationship with the U.S. Agency for International Development (USAID) for some of its first sales (USAID was a long-time funder of the Institute). “Early on, that relationship was extremely helpful in getting us started and building a strong customer base. Our first orders were from IRH itself and some of the other USAID organizations,” It wasn’t a huge number at that time, but enough that we could safely get the business off the ground,” recalled Heyer.

As of 2012, nongovernment organizations (NGOs) represented Cycle Technologies’ largest customer group, although it also had growing sales in the U.S. to individuals, healthcare providers, and retailers. “Our evidence collection and advocacy building are, by necessity, ongoing efforts,” said Jennings, and those efforts seemed to be paying off. According to Heyer, “CycleBeads’ technology has been used by programs in over 50 countries around the world since its inception in 2002, and is currently readily available in 30 countries, most of which are in the developing world.” To date, the product was most heavily used in Africa, although it was gaining traction in the U.S., Europe, and some Asian markets. ♦

NOTES

- 1 “Abortion: Worldwide Statistics,” Magnus Hirschfeld Archive for Sexology, http://www2.huberlin.de/sexology/ECE2/html/world_wide_statistics.html (June 19, 2012).
- 2 “Adding It Up: Costs and Benefits of Contraceptive Services—Estimates for 2012,” Guttmacher Institute and UNFPA, June 2012, <https://www.unfpa.org/webdav/site/global/shared/documents/publications/2012/AIU%20Paper%20-%20Estimates%20for%202012%20final.pdf> (August 14, 2012).
- 3 Ibid.
- 4 “Unplanned Pregnancy Statistics,” eHow-Mom, http://www.ehow.com/about_4611925_unplanned-pregnancy-statistics.html (June 19, 2012).
- 5 All quotations are from interviews conducted by the authors unless otherwise cited.
- 6 “Natural Family Planning: The Standard Days Method,” Natural-Family-Planning.Info, <http://www.natural-family-planning.info/standard-days-method.htm> (June 19, 2012).
- 7 About, CycleBeads.com, <http://www.cyclebeads.com/cyclebeads> (June 19, 2012).
- 8 “Natural Family Planning: The Standard Days Method,” op. cit.