SEEKING THE NEXT LEVEL OF MIDLIFE CARE FOR WOMEN

This article is based on an interview by Richard Ireland, publisher of The Ireland Report. It aptly illustrates how persistence, an incredible level of research, foresight to look to the next level of women's health, investment of physicians early on, networking, and sharing knowledge and results openly, has enabled Deb Soholt and her colleagues to become true market makers in midlife health. At the Midlife Care for Women clinic, Deb Soholt, Director of Women's Health at Avera McKennan Hospital and University Health Center in Sioux Falls, SD, is taking a new approach to hormonal therapy for midlife women, one that just may move hormone replacement therapy to a new level of care.

"When I began work for Avera McKennan in 1992, we were transitioning to a tertiary level of care. We began with a traditional definition of women's services, e.g., OB, GYN, surgical GYN, NICU, Pediatrics, and PICU. For the next seven years, we developed a variety of different hospital-based programs, particularly around the childbearing years. We felt that it was strategically important to build this market first in order to capture the NICU business which, of course, leads to Peds and on to women and their families, creating an interconnected system of care."

Once this foundation was in place, Soholt began looking to the next level of women's health. "I had spent the last 15 years focused on inpatient care, and I was ready for a new assignment. So three years ago I approached our CEO and Senior Vice President of Patient Care suggesting that we look at the future of women's health, to anticipate the next level of healthcare services that would build business in a different way. I requested a budget, time and appropriate space to figure out what our next approach should be.

"We think the health payment system is eventually going to shift to incentives for prevention and wellness care. Of course, not everyone agrees and it will certainly take awhile, but we are already seeing positive signs. Health plans are gradually recognizing the long-term benefit and impact of wellness on future utilization and their bottom line.

"What I discussed with my CEO was that every other market for women is a carve-out market. Some women will have babies and some women won't. Some women will have osteoporosis and some women won't – but every woman has hormonal issues, simply by being female. So this was about thinking of a woman beyond reproduction, or beyond hysterectomy. This was very different thinking for our hospital."

DEMOGRAPHICS

When Soholt looked at area demographics, it was very clear that she needed to be targeting midlife women. This was also clear from national efforts coming from The Office of Women's Health, The North American Menopause Society, The Jacobs Institute of Women's Health, The Congress on Women's Health & Gender-Based Medicine and others. Additionally, new research was coming to the front, such as the PEPI study trial, HERS study and Women's Health Initiative. "It was an exciting time to watch the evolution of thought as a new level of women's

health care was emerging. Now, of course, everyone is discovering the midlife baby boomer and gender-based medicine is rapidly gaining acceptance across the U.S. ”

Soholt was absolutely convinced that she needed to target middle-class women who can afford the service. “I have been appropriately challenged to expand this to community health centers and hopefully, this will happen in the near future. Lower income women have so many issues to deal with that some of their hormonal transitions are not always a high priority. However, I also had to be very clear that in the first couple of years, as much as I felt compassion for this important group, we needed to go after the group that could afford to pay out-of-pocket and/or had insurance coverage. Our demographics show that our primary market is white, middle-class women. To make it financially, this is the group we needed to target. And until we got them, we could not do an adequate job of serving other groups. There just wouldn’t have been enough revenue, and it would have been over for a clinic-based women’s health initiative.”

Her presentation was positively received and Soholt was given the go ahead to develop a program. “This was really a wonderful, marvelous leap of faith on the part my administration. Basically, I said that baby boomer women changed everything about childbearing and were now moving into their perimenopause and menopause life stage. Boomers changed everything about having a baby – initiated LDRPs, put partners back in the delivery rooms, revitalized breastfeeding and signed up for all the childbirth education classes. Now they are moving into their mid-40s/mid-50s and are going to be looking at midlife health services with the same level of involvement and interest,” continues Soholt.

In addition to market research with midlife women, Soholt spent nearly three months talking with experts all over the world, searching the literature, reading reports from the Jacobs Institute of Women’s Health, North American Menopause Society, and the National Institutes of Health, and attending relevant conferences on women’s health. She worked hard to invest physicians in the process early on and included key doctors in site visits to clinics and hospitals that were doing exemplary work in midlife health. They also attended conferences on gender-based medicine and programs offered by the North American Menopause Society. The idea was to create an ongoing conversation to build support and to develop an effective business model for the proposed clinic/community-based effort. “We’ve read and read. I work with an amazing group of people who are ever curious – truly continuous learners. And at the same time we were involved in exhaustive study, we began treating women.”

INTEGRATING BIOIDENTICALS

Soholt explains, “Our market research data told us that even though 75 percent of the women were very satisfied with their primary providers, if we built an integrated program that addressed their hormonal health, their midlife transitions, their personal risk factors, and helped them with their health choices, they would actually switch providers. So based on what we learned, and are learning, the obvious direction was to take a new and more effective approach to hormonal therapy, namely bio-identicals.

“The reason we use the bio-identical approach is that it refers to developing hormonal therapy that matches a woman’s exact chemical makeup of her body. We don’t use the word natural

because it tends to confuse people with herbals; they think we're referring to over-the-counter products of a natural food store. Bio-identical means natural to a woman's body and it is made in a compounding pharmacy by prescription only."

First, a women's health nurse practitioner was hired to lead the clinical direction, develop practice protocols, collaborate with physician partners and assist in "getting the word out" to women in the community. In the beginning of program implementation, the pharmaceutical component was missing. Soholt worked with their pharmacy director to develop a business plan, but at that time no one really knew much about compounding bio-identical prescriptions and no one on staff had that expertise. Pharmacists within the organization were contacted to see if interest could be generated. One pharmacist was very excited about what Soholt and her colleagues wanted to do. Funding was carved out to cover the pharmacist's time to learn about the concept of individualized bio-identical hormone therapy and the aspects of compounding. This led to another pharmacist taking the lead in actual compounding, while a role as consulting women's health pharmacist was defined for the other. The key, of course, was to get everyone educated, on the same page, and, where necessary, certified.

INDIVIDUALIZED TREATMENT

Physicians tended to look at Soholt's project on developing a bio-identical approach to hormone replacement therapy with a bit of skepticism. It was moving beyond one-size-fits-all HRT, and individualizing which was uncharted ground from a research perspective. Her philosophy was to examine everything in the research literature no matter how far out it seemed at the time. The idea was to be open and critically think about what they were learning. "It's been about bringing in new knowledge to what we were trying to do, and linking with experts to take us to the next level of learning. Physicians that are on the cutting edge of the bio-identical approach to hormonal therapy have been on our campus to help move thought. Although somewhat controversial, our physicians have been very responsive, and after 2 ½ years of actively treating women in our clinic, we now know that there isn't one woman that is alike," states Soholt. "We do a variety of things in the clinic – primary well-woman care that includes physicals, lab testing, diagnostics such as mammograms and dexascans, hormone replacement therapy, and hormone consultations. Our women's health nurse practitioner works as a consultant with primary care physicians (Family Practice, Internal Medicine, OB/GYN) for their client's individualized hormonal needs. Our women's health pharmacist works directly with primary providers to help them do the right thing when individualizing hormone therapy. Her role is interconnected with the compounding pharmacy, with revenues funding the position.

"We look at the whole woman. We don't do any kind of work in hormone therapy until we understand what her risks are for osteoporosis, heart disease, breast cancer and so on. We look at age appropriate lab profiles, such as cholesterol, triglycerides, thyroid, glucose, etc., and take into account her familial risk factors. Of course we also sort out what her health goals are for the long haul, and discuss choices that she can make to improve her overall health which typically includes new decisions about food and movement.

"Our goal in any type of hormone therapy is to give the least amount to bring the women into her balance. In order to do that, we use saliva testing as a diagnostic tool." Saliva testing provides

information about the three different types of estrogens – estradiol, estrone, estriol – along with progesterone, testosterone, DHEA. "Women who are cycling, for instance, and are in their 40s having hormonal transitions and they can't figure out what's going on with their bodies. Through saliva testing, we can determine if there are certain times of the month a woman may need supplementation. Our compounding pharmacy will create the appropriate supplement and delivery mechanism, such as a topical cream, vaginal cream, capsule or drops, etc. What is prescribed depends on the individual woman, her symptoms and which hormone is out of balance when."

Many times we can help women understand that they are in a hormonal transition time just by asking whether or not they are sleeping through the night. The first hormone to drop off in perimenopause is progesterone, the calming hormone. "When women aren't sleeping because their hormones are out of balance, then they become stressed. The stress causes their adrenals to respond, releasing more cortisol and then DHEA responds. The sex hormones are all so interconnected that one thing leads to another. Much of our work is helping women understand their own unique, rhythmic hormonal patterns. They know they have cycled during their entire adult life, but why? How? Without this basic understanding, it's hard for them to isolate what is particular to them. We want to change this knowing by having women come into the clinic, so they can understand the myriad of options that are available to them.
"We are starting to treat younger females. Our midlife mothers are bringing in their college-bound daughters. That was something we hadn't really planned on! They want their daughters to understand their bodies as well as they do now at 45, to understand their monthly cycle and what their body messages are – in order to make good health choices. Because of the demand, it looks like we are going to need to develop a companion program for young women. This will be a bit of a challenge because we don't want them to feel daunted about coming into a midlife clinic." The clinic's oldest client is 80 and the youngest is 12. And interestingly, there are women in the 20-30 year age group that are using the clinic as well.

Soholt strongly believes that integration of women's services into other clinical programs will be the next major emphasis. Acknowledging a woman's perspective and gender differences, no matter where she is in the hospital (which department/service line) is essential. For example, Avera McKennan is developing a new diagnostic center that is taking into account a women's health pathway, i.e. gender specific to women. For orthopedics, they will look at how a bone health program integrates with the physical fitness people for therapy.

INTERNAL RELATIONSHIP BUILDING

As our readers know all too well, it is the internal relationship building that is the primary focus and often the most challenging.

"The integrative model of having our nurse practitioner working with physicians, working with the pharmacist has been such a beautiful thing – to see how that has evolved. There is no reason that this can't work effectively on behalf of women with all the clinical specialties. Certainly there is skepticism to begin with. Most of my work is matrix work to other directors. For instance, with the compounding pharmacy, I needed a funded pharmacist and I don't even control that cost center. Our compounding pharmacy is managed by the director of pharmacy but

our pharmacist, even though she is paid from their budget, effectively reports to me. We have a great collaborative relationship.

“We are constantly moving forward looking for thought partners. For instance, we are excited to work with endocrinologists as our next real knowledge thinkers about all of the hormonal connections. I found some very enlightened endocrinologists that do a lot of thinking about the whole interconnectedness regarding diabetes. They are original thinkers and we’ll sit down and ask a lot of pithy questions. For example, insulin research ...when they were doing human subject research, they didn’t put every person on the same dosing of insulin. So if you don’t do the same dose on every person, why was the thinking that way using hormone therapy…if everyone is truly individual?

GENDER-BASED THINKING

“An important factor is about knowledge-based changes among providers of women’s health regarding gender-based thinking. For example, Marianne Legato at Columbia University is doing excellent work in gender-based research. It is very clear now that women are medically very different from men, not better than men, just very different at the cellular level. When the GAO Office did an audit of NIH in 1990, it found alarming inequities in how women’s health was funded versus men’s health. That led to multiple regulation changes, so that now gender-based research findings are on the front page of the women’s health and clinical program agendas. But there is still a long way to go.

“It is such a fabulous time to be doing this work. We are on the cusp of understanding so many new things about how hormones react in the body. New research agendas will help us understand if/how a lifetime of exposure to estrogen – whether from her own body, synthetic estrogen intake or environmental factors such a xenoestrogens – are connected to breast cancer, fibrous breast disease, endometriosis, etc. This new level of knowing will revolutionize health choices for women and we are excited to have it happen.”

Soholt refers to herself and her team as sense-makers. By that she means that the clinic has become a clearinghouse for information on gender-based medicine and hormone therapy. “If we don’t understand something, we try to find a knowledge expert who can help us make sense of the research.” Soholt and her colleagues aggregate their findings, make sense of it, and disseminate it to those who are interested or who can benefit from what they have learned.

“There are so many messages coming out regarding whether this or that is good or bad for your heart, or that HRT is safe or unsafe; we need to stay on top of the information. We know it is confusing to our patients and too many family physicians working in rural areas trying to make ends meet. So we make it our job to be the system’s sense-makers. We love it.”

Another factor involves changing medical practice so women are evaluated differently based on the new knowledge, including different testing modalities and different choices in prescription therapy. “Increasingly, physicians have been calling the clinic more and more as we have gone out to meet with our family practice clinics in rural South Dakota, Minnesota and Iowa. We don’t want to tell them how to practice, we just explain what we have to offer, how we can help

them be successful, and what their patients have said about our clinic's services. They can use our consultation or referral services at their own level of comfort. We are constantly trying to extend our hand. It enhances the standard of care and keeps the woman in local primary care – we believe it's the right thing to do.

"Of course there have been many learned lessons along the way. A few years ago, before we had thought about a logical process of approach, we invited Dr. Vliet to talk about her new book *Screaming to be Heard* and more than 350 women attended. Post-program they all wanted to be treated the way Dr. Vliet was advocating. Physicians were swamped with requests and we got put on the hot seat for unleashing this unexpected, and unwelcomed demand. As a result, I spent a year working with physicians to help them understand what we mean by bio-identicals. You cannot embarrass doctors by having their patients demand new approaches when they aren't ready. It took us back to the drawing board on approach, which was a good thing."

"We have started to gain some ground in overall exposure for Midlife Care for Women. We are seeing a higher volume of calls from women with wellness questions as well as calls from physicians. Our business has grown, so that now we are adding in a physician to the clinic with plans for one more in the very near future."

REIMBURSEMENT AND RETURN ON INVESTMENT

Profitability for the clinic remains elusive but Soholt feels that she is getting close. It's a fact that there is just not big money in primary care unless you are doing a lot of high intervention. On the women's wellness side, there is not high intervention so she's had to be able to show the potential of the compounding pharmacy, what that can do in scripts, the potential of shifting market...what does that do to capture new women that you've never enjoyed before on your campus. Additionally there are the solid downstream revenues in mammogram, dexascan, and the specialist referrals out of the clinic for hysterectomies, breast cancers, and colon issues. She tracks all the downstream sub specialist revenue.

"I have been able to demonstrate the return on investments. More than 65% of the compounded pharmacy revenue comes from the midlife clinic. Obviously it is very important to link revenue to our efforts. The toughest programmatic time was when we weren't making money and I worked to avoid getting picked up on our financial return on investment radar! As with any new program, it takes time to build solid return, and we were appropriately challenged to work hard." Reimbursement depends on the insurance companies, some reimbursing very well for wellness, but most compounding pharmacy services are primarily self-pay. Soholt relates that they have chosen to submit compounding prescriptions to insurance companies, but are consistently rethinking the reimbursement strategy. The problem, she notes, is that the co-payments are becoming so large that by the time a woman pays the co-pay, she's nearly out what she would pay the compounding pharmacy for the entire script. An average prescription co-pay runs $35.00 per month; a normal HRT regiment runs about the same. "Actually we've been reimbursed very well. Our contractual and bad debt is very low. It is really a dream payor mix, as midlife women have the most disposable income of anyone coming in."

Soholt has set up her own database to track utilization. A secretarial support person compares inquiries and other contact sources with actual appointments. Everyone we talk with in women's health emphasizes the importance of tracking. Without it, there is very little that can be used to prove that a particular program is generating revenue, thus pulling its weight.

The MidlifeCare for Women clinic is a work in progress and definitely making progress! Soholt notes that it has all been worthwhile and satisfying to develop a service that women really want. "We have worked very hard but it is joyous work...when you start to see women's lives being transformed ('I've never felt this good') and husbands calling to say 'thank you for giving me my wife back'. We tell midlife women that they can never lose their sense of humor about all of this but we have to get it beyond water cooler laughter and start to take it seriously. Women are sick and tired of not being taken seriously when experiencing hormonal transitions, and are ready to take charge of their own health choices if armed with enough understanding. Once you put together something different for them that really works, they will come. They absolutely will."