

EXPERT CONSULTATION ON VASECTOMY

Meeting Report

Washington, D.C.
December 3-5, 2003

**AN INTERAGENCY WORKSHOP organized by
Family Health International, EngenderHealth, and the ACQUIRE Project**

CONFERENCE OVERVIEW

Over 50 representatives from 24 reproductive health research, service delivery, training, advocacy, and donor organizations and institutions, as well as universities, met in Washington, DC, December 3 to 5, 2003 to prioritize future research related to *vas* occlusion techniques and to develop guidelines for vasectomy techniques in diverse health care settings. The first day of the meeting, led by Family Health International (FHI), featured discussion of recent clinical research findings on vasectomy techniques. Several points of consensus on the strength of the evidence favoring certain occlusion methods were developed (see Appendix I) and news briefs reflecting that level of agreement were disseminated in English and Spanish (see Appendix II). Based on the points of consensus, FHI plans to prepare a manuscript for publication in a peer-reviewed journal.

The second and third days of the meeting, led by the ACQUIRE Project¹, focused on the programmatic implications of the research and key steps needed to improve vasectomy services both regionally (in Africa, Latin America, and Asia) and globally. This strategic meeting built on previous FHI/EngenderHealth collaborative efforts largely supported by the U.S. Agency for International Development.

¹ The ACQUIRE Project, a five-year project of the U.S. Agency for International Development (USAID), is aimed at advancing and supporting the use of quality reproductive health and family planning services. The ACQUIRE Project is a partnership comprised of EngenderHealth, the Adventist Development and Relief Agency International (ADRA), CARE, IntraHealth International, Meridian Group International, Inc., and the Society for Women and AIDS in Africa (SWAA).

Vasectomy Research Experts' Meeting

Wednesday, December 3, 2003

Review of the 2001 Expert Consultation

[Presenter: Dr. Laneta Dorflinger, vice president, clinical research, FHI]

Dr. Dorflinger briefly reviewed the FHI/EngenderHealth-sponsored 2001 Expert Consultation on Vasectomy Effectiveness, which aimed to improve understanding of vasectomy techniques and effectiveness, present new research results, plan for the dissemination of new research, and define future research needs. As background for the current conference, she also summarized findings about the efficacy of ligation and excision, as follows:

- Simple ligation and excision is not as effective as previously thought, according to research conducted in Mexico, as well as a seven-country study conducted subsequent to the Mexico trial (see next bullet). The study in Mexico among 217 men showed that, after ligation and excision, some men needed as long as 24 weeks or more to reach azoospermia. Almost 13 percent of the men were considered to have a failed vasectomy because substantial sperm (more than 3 million per milliliter) remained at 24 weeks. The study, conducted by FHI, EngenderHealth, and the Instituto Mexicano del Seguro Social in Mexico, remains somewhat controversial because the impact of practitioner inexperience is unclear. However, Dr. David Sokal of FHI noted that “failure of simple ligation and excision was probably due to the technique itself, not practitioner inexperience.”

Source: Barone MA, Nazerali H, Cortez M, et al. A prospective study of time and number of ejaculations to azoospermia after vasectomy by ligation and excision. *J Urology* 2003;170(3):892-96.

- A seven-country randomized controlled trial (RCT) among 841 men that compared simple ligation and excision with and without fascial interposition confirmed some previous expert opinions that fascial interposition improves the effectiveness of ligation and excision. Recruitment of new participants into this FHI/EngenderHealth study was halted in May of 2001 when an interim analysis showed a striking difference in sperm counts between men who underwent simple ligation and excision and those who underwent ligation and excision plus fascial interposition.

Source: Chen-Mok M, Bangdiwala SI, Dominik R, et al. Termination of a randomized controlled trial of two vasectomy techniques. *Controlled Clinical Trials* 2003;24(1):78-84.

- Cautery and fascial interposition with an open testicular end are much more effective than ligation using a clip and excision, based on a retrospective analysis of data from 3,761 Canadian men. The failure rate (based on semen analysis) for the former technique was 0.3 percent versus 8.7 percent for ligation using a clip and excision.

Source: Labrecque M, Nazerali H, Mondor, M, et al. Effectiveness and complications associated with 2 vasectomy occlusion techniques. *J Urology* 2002;168(6):2495-98.

- A cross-sectional study of 1,052 Nepalese men found a cumulative percent pregnancy rate of 4 percent at three years after vasectomy. Ligation and excision technique is the most commonly used technique in Nepal. Analysis of semen samples from 924 of the men confirmed that 23 men, or 2.3 percent, still had sperm in their semen. Thus, simple ligation and excision appears to have a higher failure rate – as determined either by pregnancy or semen analysis -- than once thought.
Source: Nazerali H, Thapa S, Hays M, et al. Vasectomy effectiveness in Nepal: a retrospective study. *Contraception* 2003;67(6):397-401.

Recent Research Results

Presented by:

- **Dr. David Sokal, associate medical director, FHI**
 - **Dr. Mark Barone, senior research manager, EngenderHealth**
 - **Dr. Michel Labrecque, Professeur titulaire, University of Laval**
 - **Yancy Seamans, product development technical coordinator, Program for Appropriate Technology in Health (PATH)**
 - **Dr. John Herr, professor, department of cell biology, University of Virginia**
- [Presenter: Dr. David Sokal] Final analysis of the FHI/EngenderHealth RCT conducted among 841 men has shown that ligation and excision with fascial interposition reduced vasectomy failures by about a half compared to ligation and excision alone. It also decreased time to azoospermia and severe oligospermia (<100,000 sperm/mL). Based on semen analyses conducted up to 34 weeks, failure rates for vasectomies with versus without fascial interposition – all of which were performed by experienced practitioners – were 5.9 percent and 12.7 percent, respectively. The number of vasectomy failures in all age groups was similar. No significant differences in terms of safety (adverse events, or mild or moderate scrotal pain at 12 months post-vasectomy) were noted for the two techniques. Fascial interposition added approximately two minutes to the procedure. Physicians reported that 13.8 percent of procedures involving fascial interposition were difficult to perform, but in only nine cases – 2 percent of 419 men – were the practitioners unable to perform fascial interposition on one or both *vas*. This trial, the first large RCT of a *vas* occlusion technique, resolves some of the conflicting results from studies of fascial interposition that have been conducted since 1978, said Dr. Sokal.
Source: Sokal D, Irsula B, Hays M, et al. Vasectomy by ligation and excision, with or without fascial interposition: a randomized controlled trial. *BMC Medicine* 2004;2:6.
 - [Presenter: Dr. Mark Barone] Evidence supporting the superior efficacy of cautery is limited. But an observational study of the efficacy (based on semen analysis) of vasectomy using cautery has shown that most of nearly 400 men undergoing this procedure at four centers were severely oligospermic or azoospermic by 12 weeks. The study also found that, in the absence of semen analysis, 12 weeks is a better endpoint than 20 ejaculations. Notably, cautery methods used by the four sites in this observational study were all intraluminal

but otherwise varied somewhat: two sites used thermal cautery and two electrocautery; one practitioner used an open-ended technique, while others used closed-ended techniques; some excised a portion of the *vas*; and some used fascial interposition. There is no RCT data on cautery occlusion; however, it appears that cautery is more effective than other occlusion methods, Dr. Barone concluded. **Source: Barone MA, Irsula B, Chen-Mok, et al. Observational study of vasectomy using cautery. Unpublished manuscript.**

- [Presenter: Dr. David Sokal] While no RCT of cautery versus ligation and excision (with or without interfascial interposition) has been done, a statistical comparison of two vasectomy techniques – cautery versus ligation and excision with fascial interposition – indicates that cautery was associated with significantly more rapid progression to severe oligospermia and significantly fewer early failures than was ligation and excision with fascial interposition (1 percent versus 5 percent, respectively). Data for the comparison came from two prospective multicenter studies: the fascial interposition arm of the FHI/EngenderHealth RCT and the observational study of cautery described by Dr. Barone. In both cases, practitioners were experienced and vasectomy failure data came from semen analyses. **Source: Sokal D, Irsula B, Chen-Mok M, et al. A comparison of *vas* occlusion techniques: cautery vs. ligation and excision with fascial interposition. *Contraception* 2003;68:143 [abstract #14].**
- [Presenter: Dr. Michel Labrecque] Data from a recanalization analysis of the FHI/EngenderHealth RCT indicates that the rate of probable/definite recanalizations, as measured by consecutive semen analyses, was 25 percent for ligation and excision without fascial interposition in contrast to a recanalization rate of 9 percent for ligation and excision with fascial interposition, Dr. Labrecque reported. The risk of recanalization was highest with ligation and excision alone. It was lowest when cautery was combined with fascial interposition, he concluded. Of note, recanalization rates are higher than the actual risk of vasectomy failure because early recanalization is often a transient process. Early recanalization is a spontaneous reconnection of the two ends of the *vas*, most often occurring within a month or two of a vasectomy.
- [Presenter: Yancy Seamans] A preliminary evaluation of a battery-powered, hand-held cautery device suggests that thermal cautery devices can be effectively reprocessed and reused, thus providing a potentially cost-effective method. Seamans reported that the tip of a hand-held, thermal cautery device – previously found to be of suitable durability for multiple uses – can be effectively steam sterilized and, in combination with an appropriate cleaning method, may be able to be effectively disinfected with a variety of common methods. Disinfection or sterilization using glutaraldehyde seems to cause the least amount of damage to the tip and, depending on local resources, may be the preferred disinfection technique, Seamans said. Other methods of sterilization or disinfection can cause alterations to the tip that could affect its function. For example, disinfection by boiling or steam sterilization can cause dimensional changes in the plastic parts of

the tip, rendering it difficult to insert in the hand piece. Disinfection with bleach can cause surface corrosion, which may be of concern to medical practitioners.

- [Presenter: Dr. John Herr] A review of two rapid tests for detecting sperm – VasMarq and SpermCheck – (a colorimetric and an immunochromatographic assay, respectively) indicates that VasMarq may have limited usefulness in determining vasectomy effectiveness, given its high rates of false positives and false negatives. (In an FHI study in Nepal, VasMarq was used to test 930 semen samples. At the labeled cut-off of 500,000 (0.5 million/mL sperm), the test had a sensitivity of 39 percent, a specificity of 96.4 percent, and positive predictive value of 21 percent. In the 23 men where the hemocytometer count showed more than 0.5 million/mL sperm, the Vasmarq test detected the condition in only nine (i.e., produced a false negative result when, in fact, sperm were present). However, SpermCheck shows more promise, reported Dr. Herr. Currently in clinical testing, SpermCheck features an immunological assay that identifies a marker protein in the head of sperm. With a cut-off setpoint of 250,000 (0.25 million/mL sperm), SpermCheck’s sensitivity is 100 percent and its positive predictive value is 77.8 percent. However, Dr. Herr said the cut-off for the test is currently being determined. He noted that, at a cut-off of 100,000 (0.1 million/mL sperm), the data indicates sensitivity of 90.9 percent and specificity approaching 100 percent. The cut-off for SpermCheck will likely be set somewhere in the 100,000 to 250,000 range. At this stage, the SpermCheck device appears to yield greater sensitivity at a lower threshold. Dr. Herr noted that experts disagree about what sperm count can be equated with infertility after vasectomy.

Discussion

Comparison of occlusion techniques

Tim Black, CEO of Marie Stopes International (MSI), reported that MSI – which has performed some 18,000 vasectomies – routinely uses with excellent success extraluminal cautery without fascial interposition or excision of a part of the *vas*. Sperm granulomas were often seen when the *vas* was ligated with cat gut, he said, but are rare after cautery vasectomy. Dr. Ronald Reynolds of New Richmond Family Practice, New Richmond, Ohio, reported that tying the end of the *vas* with silk ligatures (as used in many developing country settings) can be problematic, and that cotton ligatures may be a better option.

Dr. Labrecque suggested that cautery may reduce time to severe oligospermia or azoospermia by reducing the occurrence of early recanalization. John Pile, senior technical advisor, ACQUIRE (EngenderHealth), noted that time to extreme oligospermia or azoospermia after cautery vasectomy has not been evaluated in low-resource settings, but could indeed be less than 12 weeks.

With or without fascial interposition, cautery apparently will yield low vasectomy failure rates. But Dr. Carlos Huezo, medical director, IPPF, London, pointed out the need for further research about the efficacy of cautery alone – without fascial interposition.

Finally, participants also discussed and cautioned against the danger of tying the *vas* too tightly or overburning it with cautery, in which case the end will necrose and fall off, leaving two open ends.

Potential reuse of a cautery device

Dr. Dorflinger of FHI noted that, based on experience with IUDs, “even if a cautery device is clean, if it ‘looks’ dirty or corroded, the providers may not want to use it.” On the other hand, some tip damage following multiple chemical or heat sterilization procedures might not be a problem for vasectomy providers since they can easily demonstrate whether a device works properly by observing the wire turning red hot.

Semen analysis

Some participants were concerned with the appropriate timing and frequency of semen analysis. Tim Black of MSI noted that “one test is not adequate. We may see larger sperm counts farther out in time, possibly due to recanalization.” (Of note, many men do not come back for a second test even when semen analysis is readily available.)

It was observed that the number of times a man ejaculates post-vasectomy can vary markedly – from once every three or four weeks to up to 10 to 15 times a week. Can ejaculation frequency effect sperm counts or risk of recanalization? Dr. Mario Chen-Mok, senior biostatistician, FHI, noted that data from the cautery study suggested that the greater the number of ejaculations, the greater the chance of more rapidly achieving vasectomy success, measured as either azoospermia or severe oligospermia.

Age also appears to be a factor, with Tim Black noting that older men take much longer to clear sperm. This was also seen in the FHI/EngenderHealth RCT. “If you look at severe oligospermia, rather than azoospermia, however, the differences are fewer,” Dr. Sokal said.

Can nonmotile sperm cause a vasectomy failure? “Probably not, but we should probably look at this a little more carefully,” said Dr. Labrecque.

In terms of the cutoff setpoint for a test such as Dr. Herr’s SpermCheck method, Dr. Labrecque emphasized that “we want 100 percent sensitivity to provide an absolute guarantee of sterility.”

Review of Other Evidence

[Presenter: Dr. Michel Labrecque] The strongest data to date, those comparing vasectomy approaches – incisional versus no-scalpel vasectomy (NSV) – show that pain, hematoma and infection are significantly reduced with NSV. “We can give a blue ribbon to NSV as the ‘best available method,’ ” Dr. Labrecque said.

However, Dr. Labrecque emphasized the difficulty, based on existing data, of comparing *vas* occlusion techniques. Definitions (i.e., of failure) vary from one study to another and most studies are retrospective reviews of individual physicians’ experience. Follow-up has been relatively short-term and not conducted systematically. Study details are often lacking.

A number of *vas* occlusion techniques exist, and they can be combined in different ways. Theoretically, there are more than 30 different combinations. Ligature and tying of the *vas* is probably the most common technique used worldwide. But, the *vas* can also be ligated with clips. Is there a difference between suture material and clips? The two studies that have addressed this found failure rates to be similar, although “we don’t have enough data to support one over the other,” Dr. Labrecque said. Five studies have examined the technique of folding the *vas* back on itself, but they have shown no real trend in terms of failure rates or complications.

The five studies that have looked at fascial interposition versus no fascial interposition showed similar trends (with fascial interposition being superior), and the “best evidence” from the FHI/EngenderHealth RCT is consistent with these smaller studies. No consistent data exist to determine whether cautery without fascial interposition is superior to ligature. Data about the effectiveness of cautery with fascial interposition versus ligature shows that cautery has much lower rates of failure, although the data are limited to retrospective case series with historical controls. Almost no studies have compared thermal cautery and electrocautery. Finally, while reducing pain is the goal of the open-end technique, the closed-end technique appears to be comparable. More research comparing the two is needed, Dr. Labrecque said.

In conclusion, “keeping in mind that published data are limited, there is good evidence in favor of ligation and excision with fascial interposition over ligation and excision alone,” Dr. Labrecque said. “There is fair evidence in favor of cautery combined with fascial interposition over any other technique. Good data are unavailable to fully support use of any other occlusion method.”

Discussion

Tim Black of MSI argued that while the fascial interposition data are stronger than the cautery data, “our experience with all procedures is that the more we simplify the better the procedure is. Fascial interposition, which reintroduces a sharp needle and sutures and adds time to the procedure, is complicating things.” And Dr. Labrecque agreed that “cautery, with or without fascial interposition, will produce better results.”

Following the presentation and review of research findings, the experts formed three small groups to review a draft consensus statement. Upon reuniting, the experts felt it premature to issue a detailed consensus statement. Instead, general “points of consensus” were established, with a commitment to produce a refined consensus statement at a later date.

Unresolved concerns included:

Persisting lack of data for making informed decisions. Dr. Steven Kaufman, medical officer, National Institute of Child Health and Human Development, National Institutes of Health, agreed that the FHI/EngenderHealth RCT “provides the best available information about fascial interposition. But it is just one study and we cannot make decisions based on just one study.” Three of the North American conference participants raised a theoretical question about Dr. Apichart Nirapathpongporn’s method of fascial interposition, which was used in the RCT. They suggested that a method of fascial interposition that did not include tying a suture around an end of the *vas* itself – but only included the fascia – might produce better results. Dr. Carmela Cordero, provider performance team leader, ACQUIRE (EngenderHealth) agreed that “if we believe that fascial interposition could be improved, we need more information about that.”

Impact on the field (service delivery) of any new recommendations. Considering that ligation is the most commonly practiced vasectomy technique worldwide, declaring cautery to be superior to ligation could be problematic since it might encourage some practitioners to abandon the ligation technique that – while not perfect – is highly effective. Dr. Dorflinger of FHI also noted that cautery “is going to be more expensive and there are tremendous unknowns about our ability to deliver it to the field. We need to think about what we still need to know from the point of view of low-resource settings.” Dr. Job Obwaka, senior medical associate, AMKENI, Kenya, agreed that “we may not be able to sell the idea of cautery in low-resource settings” because it is relatively costly and may be hard for programs to sustain. Also, “we’ve accepted ligation and excision as the standard procedure, and now have just taught vasectomists how to do fascial interposition.” Expecting practitioners to change to cautery now might be confusing and difficult to accomplish, he said.

Nevertheless, Jeff Spieler, chief of the research division of USAID’s Office of Population and Reproductive Health, proposed the following guidance, involving a hierarchical message: Ligation and excision works, but we can improve upon it. Research done to date indicates cautery with fascial interposition is the best option. The next best option is ligation and excision with fascial interposition. Ligation and excision alone is OK, with proper training. But if you have access to training on these other techniques, get trained.

The day’s events concluded with discussion of possible future research, as follows:

- **Use of cautery and fascial interposition in low-resource settings.** Observational comparative studies suggest that cautery with fascial

interposition may reduce vasectomy failures, compared to cautery alone. However, more research on this issue is needed. Meeting participants agreed that research is also needed to: 1) determine the optimal cautery technique for use in low-resource settings, 2) develop and document simple, acceptable, and low-cost methods for cautery tip re-use, and 3) identify the best ways to train physicians to perform fascial interposition.

- **Comparison of efficacy of different occlusion techniques.** Several study designs were discussed. One suggested study design was an RCT with three arms: cautery with fascial interposition of the abdominal end of the *vas*, ligation and excision with fascial interposition of the abdominal end of the *vas*, and cautery alone. In any study, the research should focus on vasectomy failures (as defined by sperm count) and monitor post-vasectomy pain. Also, any study with a fascial interposition arm should carefully define the surgical technique used for fascial interposition.
- **Incorporation of a systematic assessment of complications into future vasectomy studies.** The need for more research about post-vasectomy testicular or scrotal pain was discussed. (Of note, guidelines released in January 2004 by the Royal College of Obstetricians and Gynaecologists (RCOG) included the recommendation that men be informed about the possibility of chronic testicular pain after vasectomy. Such pain may develop months or years after the procedure, and may be occasional or frequent. Although post-vasectomy pain is usually mild, more research is needed to better understand this complication.
- Additional research could include **prospective programmatic evaluations** of different *vas* occlusion techniques; feasibility of training in cautery and fascial interposition; replication of the training; feasibility of implementing techniques; and assessment of results. Programmatic research into practical differences and best recommended techniques for cautery in high-volume versus low-volume settings is needed.
- **Feasibility of using rapid semen analysis tests in low-resource settings.** Currently in clinical testing, the SpermCheck device may be a practical way to increase post-vasectomy semen analyses for men the United States. Unless its cost can be reduced, it is probably too expensive for routine use in low-resource settings, but it may be useful for research there.

Vasectomy Research Utilization Meeting

Thursday, December 4, 2003

At a breakfast presentation, Dr. David Sokal, associate medical director, FHI, recapped highlights of the previous day's discussions about recent vasectomy research. The programmatic implications of these research findings were then explored.

Dr. Carmela Cordero, ACQUIRE Project (EngenderHealth), noted that vasectomy is safe, highly effective, and inexpensive, but underutilized. Reasons for this underutilization include both men and women's lack of awareness about the method, frequent misconceptions about it, and relative lack of access to it. Program and provider bias against the method also exists, with family planning still largely perceived as a woman's responsibility.

Dr. Cordero emphasized that acting upon new evidence about post-vasectomy pregnancy rates, effectiveness of different *vas* occlusion techniques, and when men can rely on their vasectomy for contraception necessitates substantial changes in service delivery. Vasectomy techniques, equipment, procedures, training, logistics systems, service guidance and/or protocols all will require change.

For example, "if cautery is going to be introduced," she said, "we need to ensure the availability of appropriate equipment, including battery replacement for cautery devices. Having to change batteries every 10 days can be a hardship for developing world budgets." Also, counseling clients about what new vasectomy research findings mean for them (i.e., the possibility of post-vasectomy pregnancy or scrotal pain) is crucial, so research developments will need to be included in the training of new providers. When introducing new clinical findings into programs, it will be important to recognize that "one size does not fit all," Dr. Cordero noted. "Translating these findings into practice is a layered process that needs to build on the gains of actual practices."

The difficulty of just what to tell men about vasectomy, based on new evidence, became clear in a discussion following this presentation, Dr. Sokal noted that the nature and incidence of post-vasectomy scrotal pain is poorly defined. While anecdotal reports suggest a prevalence of 7 percent, only 3 percent of men in the FHI/EngenderHealth RCT said they had had scrotal pain in the last three months and is was usually mild or moderate. In a retrospective 1996 study conducted in Detroit among 182 vasectomized men, most men said they did not regret having had a vasectomy, and – while discomfort could last one or two years – it was more annoying than painful. "It is not clear then how much scrotal pain is due to the vasectomy," Dr. Sokal said, "although we know that the NSV approach results in fewer acute problems and probably is less likely to cause chronic pain."

It was also noted that vasectomy success or failure depends not only upon the technique used, but provider experience and the behavior of men after the procedure.

Furthermore, vasectomy failures may be either overreported (as in China where the one-child policy allows for the birth of an additional child if a vasectomy fails) or underreported (by women in the developing world, for example, who become pregnant after their husbands have been vasectomized and fear being stigmatized).

In a subsequent overview and review of experience/lessons learned, presenter Lynn Bakamjian, project director, ACQUIRE (EngenderHealth), returned to the issue of why vasectomy is underutilized and why this underutilization needs to be addressed. “Why give attention to vasectomy?” she asked. “Much unmet need to limit childbirth exists. Sterilization [of women and men] is the most widely used method of contraception worldwide, with 253 million couples using it. Sterilization is projected to remain the most widely used contraceptive method over the next decade. It is projected to account for 29 percent to 42 percent of the contraceptive method mix in the developing world in 2015.” While female sterilization is far more common than male sterilization, vasectomy is safer, simpler, and about half the cost of female sterilization.

Yet, vasectomy is the least known method of modern family planning. In Africa, fewer than one of every four women know about it. Even when men and women are aware of vasectomy, their understanding is often incomplete or incorrect. Many men believe that vasectomy is akin to castration. They fear that if they are vasectomized, they will not be able to ejaculate; will become fat, weak, and less productive; and will need to rest for several days. They also believe that female sterilization is easier and has fewer complications. Vasectomy services are also less accessible than other family planning services. Even robust vasectomy services may have declined due to shifts in program emphasis. “In Bangladesh, there was a big spike [in vasectomies] when NSV was introduced in the mid-1980s, but due to quality issues and other problems, this could not be sustained,” Bakamjian said. One of biggest factors contributing to vasectomy underutilization is program and provider bias. A 1996 Ghana situation analysis found that fewer than 5 percent of physicians had recommended vasectomy in the previous few months, largely due to provider assumptions that men did not want vasectomies. “Even when one asks staff about vasectomy, they giggle and are uncomfortable,” she said. “So a lot of work needs to be done to make vasectomy palatable to service providers. Finally, because family planning is still considered a woman’s responsibility, we need to work on informing women about vasectomy.”

Despite these obstacles, the next presenter, John Pile, senior technical advisor, EngenderHealth, summarized five key characteristics of successful vasectomy programs as ascertained from literature reviews and experience. Those programs have:

1. Addressed both demand and supply. Successful programs have to advertise their vasectomy services and then have those services available.
2. Paid attention to provider skills. Few family planning providers have experience working with men and many may be uncomfortable doing so. Clinic staff may

- hold prejudices against men and may even discourage them from seeking family planning information and services. Thus, training needs to focus on changing attitudes, not just on imparting information or developing skills. On-site training about provision of male-friendly services is important not only for providers but for everyone at a facility. Providers also need to learn to improve their interpersonal communication skills and to recognize that they must talk to men differently than to women.
3. Paid attention to client needs and interests. Men want privacy, confidentiality, an array of services, discretion, often male providers, flexible hours, short waiting time, and affordable services.
 4. Had strong leadership. Heading almost every energetic vasectomy program is a director who is personally interested in involving men.
 5. Effectively promoted the method. Community outreach and multimedia campaigns to promote vasectomy have proven successful. Programs in Brazil, Colombia, and Guatemala were able to double their vasectomy caseload through multimedia campaigns. Men are frequently easier to reach with multiple, reinforcing messages because they have better access and more exposure to mass media and community-level communication than do women. Men, however, have less contact with health workers than do women. Personal contacts – friends, relatives, and co-workers – are key to introducing new ideas and providing support for behavior change. Testimonials from satisfied clients/couples have been especially successful. Because partners can be a barrier to men’s acceptance of vasectomy and often have more misconceptions and concerns about vasectomy, messages should be targeted to women, as well. Notably, multimedia campaigns targeting men should employ factual messages that are relevant to men’s perceived concerns.

Discussion

The discussion following these presentations further explored the challenges and opportunities of reaching men with vasectomy messages. Dr. Karen Foreit, senior fellow of the corporation, The Futures Group International, pointed out that the post-partum period often gives women a chance to consider sterilization, but men don’t have that opportunity. She also noted that a ProPater vasectomy campaign 18 years ago revealed that vasectomy messages must reach men and women before they arrive at a family planning clinic, since most people already have a method in mind at that point.

What should those messages emphasize in order to be most effective? It is important, Dr. Foreit said, that messages convey that the method “is for limiting births once you have all the children you want.” Also, care should be taken not to target inappropriate clients. “You need to convey an image of an older couple, not a young, glamorous couple,” she said. Other promotion techniques need to be further researched since vasectomy is, at best, a “niche product.”

Bakamjian agreed that the family planning clinic visit is not the time to offer vasectomy, “but men often accompany their wives to the clinic and feel excluded

from the process. Often men are hungry for information, so we need to make it a more open environment.” She added that EngenderHealth had had some success with postpartum male initiatives.

Pile concurred that messages must be targeted to the appropriate male audience. A campaign to reach men with vasectomy information failed in Turkey, he said, because it focused on male factory workers, most of whom were young, unmarried, or recently married. Failure of promotional strategies is more often a consequence of poor media selection/targeting rather than a lack of response by men.

Several participants emphasized that men seldom quickly accept the idea of vasectomy, which is a new and often frightening concept. In fact, they may consider it for years. Notably, in India in the early 1970s when vasectomy was more popular than tubal ligation and vasectomized men were recruiters, men still had to be approached two or three times before they decided to be vasectomized. It would be helpful, said Jeff Spieler, chief of the research division of USAID’s Office of Population and Reproductive Health, to conduct qualitative research to find out why some men chose vasectomy and to ask them what they would do to encourage more men in their communities to be vasectomized.

Pile agreed that the dynamics of vasectomy decision-making are poorly understood: “Little attention has been paid to this, but cost-efficiency is more important than it used to be and vasectomy is one of the most cost-efficient methods.”

Dr. Neil Pollock of Pollock Clinics, Vancouver, Canada, said he performs 40 to 45 no-scalpel vasectomies each week, with demand quickly increasing, and he shared “what has worked to increase vasectomy utilization in my practice. The biggest fears that men have overcome when they walk through my door are fear of pain and fear of the scalpel. In my ads, placed in family or baby magazines, I say ‘no scalpel, no needle’ vasectomy. Also, I offer comedy videos and short waits of 20 minutes to reduce anxiety. I try to make the experience super positive. Satisfied clients are hugely effective.”

Tim Black, CEO of Marie Stopes International (MSI), emphasized the importance of persistent advertising, such as regularly running small classified ads. “Men think about vasectomy for a year or two,” he said. “They don’t ‘come out’ and get a vasectomy until there is a critical mass” of other men getting vasectomies who spread the word through informal social networks.

In some settings, promoting vasectomy may be particularly difficult, requiring rigorous, long-term efforts to change social norms, said Dr. Alfred Yassa, senior health and communication advisor, Center for Communication Programs, Johns Hopkins University. Dr. Yassa said he feared that in Africa, “vasectomy is a non-starter. The problem goes beyond awareness, quality, or access. Society there is male-dominated and virility is very important. Procreation is the only manifestation of virility and that matters for family and society.”

Pile of EngenderHealth said that similar arguments were once made about the acceptability of vasectomy in Latin America. But “while it’s true that vasectomy is not for everyone, everywhere, it would be a missed opportunity if we didn’t do vasectomy in Africa,” he said. The procedure, in fact, is being done now in such countries as Kenya, Tanzania, Ethiopia, and South Africa.

Margarita Diaz, president of REPROLATINA, Brazil, added that “in our Latin American experience, men think about sex and they worry that vasectomy could affect their sexual performance, so any campaign that talks about this is important.”

Dr. Michel Labrecque of Laval University concluded the discussion by noting that, in some settings, cultural attitudes can be very supportive of vasectomy. “In Quebec, we had 16,000 vasectomies and only 8,000 tubal ligations last year,” he said. “Once a couple has two kids, it’s totally normal to start considering vasectomy.”

Presentations that followed addressed strategies and opportunities for NSV programming and perspectives from the field. These included experiences from Brazil, India, Ghana, the Philippines, and Mexico.

Describing the Brazilian experience with vasectomy, Diaz said the procedure was once available almost exclusively in the private sector. The 1996 Demographic and Health Survey showed that vasectomy prevalence was only 2.2 percent, while oral contraceptives and tubal ligation were the main family planning methods.

Subsequently, a non-private-sector pilot project that included implementation of vasectomy services and involved 180,000 people was conducted in the municipality of Santa Barbara. After an initial assessment showed that men wanted access to vasectomy, the project trained personnel to improve the quality of reproductive health services in general and to incorporate services addressing men’s needs. Implementation of a vasectomy program included: educating all clients about all family planning methods; providing information/education on vasectomy; teaching providers how to interview clients and obtain informed consent; reviewing and approving requests for vasectomy; surgery; follow-up seven days after surgery; and sperm count analyses 90 days or later. Some 535 men had a vasectomy in the first three years of the program and reported being satisfied with the services. Following this effort, the program was expanded to three more municipalities. Ituiutaba, Sumare, and Campo Largo. In Campo Largo, the program was implemented in a rural area by family doctors. Obstacles included the difficulty of sustaining and scaling up the services; lack of strong political commitment; and interference by physicians (related to public versus private sector issues and tensions between urologists and other specialists). Also, reproductive health providers often were unprepared to attend men. However, Diaz said, the project showed that it is possible in resource-constrained settings to incorporate vasectomy services into those originally planned only for women in a way that contributes to a general improvement in quality of care.

Next, Dr. S.S. Bodh, senior clinical training advocate, EngenderHealth/New Delhi, discussed NSV in India. Although a vasectomy campaign was introduced in Kerala, India, in 1970 and more than 60,000 procedures were performed, a forced sterilization program in 1975 and 1976 resulted in a decline in vasectomies that has persisted. Now, vasectomy accounts for only 2.5 percent of all sterilizations in India. "Vasectomy has been forgotten by both clients and service providers," Dr. Bodh said. "Men do not come forward due to attitude/gender issues, misconceptions, and fears of complications and pain. Other obstacles include: the absence of male-oriented information, education, and communication (IEC), absence of an effort to approach men; provider and spousal resistance, and poor services." Nevertheless, "we have tried to revive vasectomy," he said. In 1992, Dr. Ram Chander Murti Kaza, professor of surgery at Maulana Azad Medical College in New Delhi, was trained to perform vasectomies and, in 1998, the Indian government started the NSV training project in Delhi. Some 4,000 doctors have since been trained and there are 100 trainers in several states. Furthermore, there have been multi-media activities and advocacy from political leaders, religious leaders, academicians, administrators, sports personalities, and the public sector. At the state level, Madhya Pradesh had focused coordinated IEC about vasectomy that resulted in better acceptance of the method. In Karnataka, committed IEC efforts showed promising preliminary results, in spite of apathetic district administrations and disinterested health care workers. In Maharashtra, cooperative district administration, lobbying with local panchayats, small incentives for clients, and frequent vasectomy camps have produced encouraging results. In Sikim, efforts were relatively successful due to focused IEC and committed providers. In contrast, in Uttar Pradesh, training was often unsuccessful and administrators were apathetic. Among lessons learned are that "vasectomy is, first and foremost, an IEC operation and NSV, although easily taught, it is not always easily mastered," Dr. Bodh said. "But surgeons who have traditionally ignored vasectomy are looking at NSV with renewed interest. And while it is easy to blame men for not accepting vasectomy, they are often not responsible if vasectomy IEC or services are inadequate."

Vicki Baird, director of the Meridian Group International Inc. (Meridian), next addressed the marketing of vasectomy. Notably, little marketing of vasectomy has been done. However, short campaigns were conducted in the United States, Jamaica, Kenya, and Brazil between 1995 and 2002. And, in 2003, Meridian (on behalf of EngenderHealth) developed a marketing-advertising initiative for Ghana and the Philippines. There, "NSV suffers from almost total lack of awareness and any awareness is negative and consists of false myths and rumors," Baird said. Qualitative research conducted in Ghana and the Philippines in 2002 confirmed earlier research that NSV users are very satisfied but nonusers are very negative; thus, it was determined that a marketing approach needed to both educate and "inspire." Meridian provided technical assistance to selected local ad agencies on developing marketing strategies. The group also conducted research among men to evaluate a proposed campaign strategy. Research findings in both Ghana and the Philippines showed that the key to the marketing/advertising of vasectomy was conveying the message that the procedure was fast and simple, and advertising had to include specific site

names/addresses and/or hotline numbers. Critical to the campaigns was giving vasectomy a positive/upbeat image and using testimonials from satisfied clients to inspire potential users.

Discussing the Mexican experience with vasectomy, Consuelo Juarez, a consultant with EngenderHealth, said that in 1997 vasectomy prevalence was only 1.2 percent in that country, where the public sector provided 73 percent of family planning services. Challenges within the Instituto Mexicano del Seguro Social (IMSS) included: little active participation by men in contraceptive matters and medical barriers.

Contraceptive methods, for example, were only offered in hospitals, and vasectomy – which was performed only by urologists – competed with other surgical procedures for facility resources. The procedure was also performed only by conventional or incisional vasectomy, but Juarez described an intervention to introduce NSV services. The intervention included NSV training, whole-site training about the procedure, counseling/training, internal and external promotion, supervision, and referrals. In 1990-1991, four demonstration sites were selected and received technical assistance to create and administer outpatient vasectomy services. From 1991-93, service sites and training units in selected family medicine facilities were established. Some 98 family physicians were trained at IMSS headquarters and 60 were then certified as trainers. Efforts were also made to provide and/or improve equipment and organization of services, whole-site training, counseling training to nurses and social workers, and referral systems. Subsequently, research was conducted on vasectomy decision-making, vasectomy user profiles, three strategies for vasectomy promotion, NSV and tubal ligation client satisfaction, and post-vasectomy time to azoospermia. A follow-up study of vasectomized clients and a comparative study of two occlusion techniques were also conducted. As a result, from 1986 to 2001, vasectomies have increased from 5,323 to 21,526, respectively. Among lessons learned were that support from central level management was critical at the introduction phase and contributed to the success of the program; introduction of the NSV technique and its implementation via family physicians in outpatient care was helpful; mass media campaigns were effective; and personal communication was important in terms of interpersonal counseling and client referrals.

Following these presentations, small groups were formed to discuss programmatic implications of clinical findings and lessons learned from 30 years of providing vasectomy services.

Synopsis of small group findings:

Several factors facilitating provision and uptake of vasectomy already may exist: in many settings, men are interested in their reproductive health, providers can be enthusiastic implementers, and a global mandate from the International Conference on Population and Development (ICPD) to work with men has produced facilitating national norms and standards. In some settings, reproductive health programs are increasingly integrated, providing more opportunity to introduce services for men.

Still, many factors can constrain provision and uptake of vasectomy. Suggested ways to address these factors – from the viewpoint of clients, providers, and programs include:

From the providers' perspective:

- Improve vasectomy education in medical schools;
- Provide in-service training to dispel myths that providers hold;
- Improve provider competence in male physiology and increase provider knowledge about how to address sexuality and socially constructed ideas about masculinity;
- Explore the possibility that paramedical personnel (as well as physicians) may be able to perform vasectomy;
- Consider the financial costs/benefits for providers;
- Strengthen existing infrastructures, supervision, monitoring, and evaluation.

From the clients' perspective:

- Create demand through sustained IEC to dispel myths and rumors (although it was noted that some countries have advertising restrictions);
- Consider issues of transportation and days and wages lost for men seeking vasectomy services;
- Use women, who are easy to reach and mobilize, as agents of change in attitudes about vasectomy;
- Emphasize that vasectomy is very cost-effective (provides a higher return on investment than most other methods) over time.

From a programmatic/policy perspective:

- Obtain a comprehensive knowledge of the local context. This includes looking at contraceptive prevalence and the history of vasectomy uptake. Where vasectomy is not being used, what is the method mix? What organizations, such as health ministries or nongovernmental organizations are already working to provide vasectomy in an area? What lessons have already been learned in that country or region? What are the cultural/religious attitudes that may either support or undermine vasectomy efforts?
- Identify vasectomy champions. Most successful vasectomy programs have a high-profile champion of the method. It would be helpful to have vasectomy champions at national, regional, and facility levels.
- Start small, then scale up.
- Develop and foster political and managerial commitment to the provision of vasectomy.
- Share and adapt vasectomy materials and lessons learned. (REPROLATINO, for example, has strategies for reintroducing new contraceptive methods.) Transfer capacity and experience within and between countries.
- Improve communication among researchers, program planners, providers, and clients.

- Build support from women's groups so men's health is not seen as being in competition with women's health.
- Consider vasectomy's place in the context of existing priorities and services. For example, in Honduras, vasectomy was included in a strategy to reduce maternal mortality.

Finally, several general observations were made:

- Vasectomy should not be pushed just to increase its prevalence. It should be introduced to the extent that it enhances the method mix, increasing clients' choices.
- Many successful vasectomy programs exist, but lessons learned are limited. It would be useful to do operations research to document successes. But, first, it may be necessary to define what a successful program is.
- Attention should be paid to both supply and demand factors.
- Given limited resources, consideration should be given to whether existing services should be improved or new services introduced.
- Promoting vasectomy in specific areas of a country might be wise in order to achieve a high volume of uptake.

Summarizing the day's discussions, John Townsend, project director, FRONTIERS, Population Council, reiterated that vasectomy should be readily available for reasons other than simply increasing contraceptive prevalence or decreasing fertility rates. Rather, availability of vasectomy is important because it:

- 1.) enhances human rights (by recognizing men's rights to contraceptive services);
- 2.) increases quality of care (by increasing choice for couples), and
- 3.) supports a gender perspective (by acknowledging many men's interest in their own reproductive health and many women's desire that men assume responsibility when a couple wants a permanent contraceptive method).

Townsend emphasized the importance of thinking strategically about ways to increasingly move vasectomy from the private to the public sector; sharing lessons learned about best practices; and considering how costs will be distributed and successful vasectomy efforts sustained. Finally, he said, the social issue of gender equity remains very complex and must be addressed in each cultural context. Vasectomy is more than a technology, he said: "It is a relationship."

Vasectomy Research Utilization Meeting

Friday, December 4, 2003

In a keynote presentation, Manisha P. Mehta, ACQUIRE (EngenderHealth), reviewed the results of efforts since the ICPD to involve men in reproductive and sexual health and cited various causes for optimism. While use of female contraceptive methods accounts for 74 percent of contraception worldwide and vasectomy prevalence is only 4 percent (and declining in some countries), condom use – mostly with occasional partners -- is increasing in some countries. Social marketing of condoms has dramatically increased, as well. A meta-analysis by the Population Council (Hawkes, et al. 2001) found evidence of sexual partner reduction in eight of 14 studies; increased intention to use condoms in five of nine studies; and attitude improvements related to safer sexual behavior in two of six studies. Meanwhile, research suggests that couple counseling is effective: a study conducted in Ethiopia showed twice the rate of contraceptive continuation when husbands were involved.

Innovative programs have produced valuable lessons about ways to better reach men. These lessons indicate that providers need more training to increase their comfort and competency when working with men; special communication and marketing strategies are needed to reach men; men often need a space apart from women when receiving services; involving men need not be an expensive additional service; and recognizing the influence of social and gender norms on men's behavior is crucial.

Some of those lessons have been implemented. However, “efforts to evaluate these programs have not caught up,” Mehta said. “More intensive evaluation is needed.”

Finally, she described several issues and future trends that have been articulated by Instituto Promundo director Dr. Gary Barker):

Fathers: Men's interest in being good fathers is an untapped resource.

Frankness: It is necessary to address what men want to talk about.

Fear: Health professionals have an ethical obligation to discuss such sensitive topics as homophobia, men who have sex with men, and sexual violence.

Faith: One must believe that men are interested in “doing right” by their partners and themselves

Mehta noted that youth represent “an historic opportunity to engender changes for future generations.”

Next, small groups met to identify any gaps in knowledge or research needs. They also sought to outline regional priorities, highlighting specific countries and activities, for implementing vasectomy findings.

Asia:

This group noted that policy issues include if, and when, to introduce cautery as a *vas* occlusion technique. Since fascial interposition is just being introduced in the region, introducing cautery may lead to confusion and/or training fatigue, as well as excessive

costs. In terms of gaps in knowledge, the group emphasized the need for more behavioral research. How are providers performing vasectomy? What is post-procedure compliance? How many clients experience post-vasectomy pain? What are the misconceptions about vasectomy? What would an improvement in vasectomy effectiveness mean to couples/men? Are providers willing to try new occlusion techniques? With vasectomy prevalence so low, is it worth the cost and effort to improve the technique? From a programmatic perspective, shouldn't more emphasis be placed on increasing access and utilization than on improving the technique?

Dr. Tika Man Viadya, Nepal Fertility Care Center, Kathmandu, Nepal, recommended continuing current vasectomy practices in that country, while introducing cautery in some centers. Meanwhile, IEC/BCC/marketing efforts are needed there to address vasectomy misconceptions, he said. Similar efforts are needed in India, where vasectomy was described as being more an IEC operation than a surgical one. Although the country has virtually no experience with cautery, it was noted that introducing this occlusion technique might draw attention to and increase adoption of vasectomy, in general. In Bangladesh, fascial interposition has just been adopted as an occlusion technique, making the introduction of cautery impractical at present, said Dr. Abu Jamil Faisal, Bangladesh Program Manager, EngenderHealth. But "cautery may help down the line," he said.

Latin America:

The Latin America group identified several "next steps" to be taken, including the need to:

- Disseminate among service providers research findings showing that modifying ligation and excision to include fascial interposition increases effectiveness; then, develop guidelines based on the findings, establish training criteria for fascial interposition, and create places for training.
- Conduct research on post-vasectomy pain.
- Standardize the criteria for defining vasectomy success (sperm counts, lack of pregnancy, oligospermia, or azoospermia).
- Address men's fear of vasectomy's effect on sexual function.
- Mention vasectomy in the sex education of youth.
- Review medical training curricula to ensure they contain updated vasectomy information.

Africa

This group acknowledged the difficulty of increasing vasectomy throughout Africa. A strategic approach, recognizing that vasectomy would likely always be a niche method, was suggested, as follows:

- Be conservative in measuring success. Success might be defined as steady growth in acceptance, even if prevalence remains very low.
- Go for the easy targets first. Support for the method varies within the region and there are areas where vasectomy efforts have been more successful (i.e., eastern and southern Africa) than in others. Investigate situations where vasectomy promotion has occurred, determining why it did or did not work.
- Conduct qualitative research to look for trends. For example, might the presence of missionary hospitals that have pioneered acceptance of family planning in the region have a positive impact on vasectomy promotion?
- Whatever is done, keep it low-cost, low-tech.
- Study men's health-seeking behavior, and base communication strategies on that behavior.

Summarizing the conference, John Pile of ACQUIRE/EngenderHealth addressed three different perspectives: that of the client, the provider, and history. From the clients' perspective, he said, men need to be informed of the recent findings about vasectomy effectiveness. From the providers' perspective, places for further training in emerging new *vas* occlusion techniques need to be identified. And, from the historical perspective, advances in occlusion techniques hold the potential to increase interest in vasectomy. Vasectomy increased after the no-scalpel approach "appeared on the scene" in 1980, he noted. "That new technology was a hook to interest providers, and we can view fascial interposition and cautery as another hook to get providers interested in the method."

Pile cautioned against promoting vasectomy "in a vacuum. It's a choice/rights matter. Whether vasectomy is a niche method or not, the point is how to provide better quality services."

For the three key regions discussed – Africa, Asia, and Latin America – Pile noted that the status of vasectomy is quite different. Strategies for moving forward need to reflect this. Knowing when and where it is appropriate to give programmatic attention to vasectomy is critical to success. Family planning programs need to both critically assess opportunities for introducing vasectomy services and integrate services in existing programs and initiatives. For example, in Turkey, vasectomy was successfully integrated with a postabortion family planning initiative. While this approach may be unique to Turkey, the take-home message is to look for opportunities where men can be reached. Programs offering maternal health, antenatal care, and postpartum care provide ample new opportunities for informing men about vasectomy.

There is a continued need for programs to undertake studies of the attitudes of communities, couples, and men toward vasectomy, to determine specific barriers to or concerns about services. Learning more about men's needs or their satisfaction with existing services need not remain in the domain of researchers. Managers and local service providers can do much to better understand their clients' needs, perceptions, and satisfaction. Programs can design and conduct investigations that require little additional cost and effort.

Evidence from the past two decades has demonstrated that when program managers and providers take an active role in addressing men's needs (rather than simply making vasectomy services available), men will respond and more vasectomies will be requested. In every region of the world and in nearly all social and cultural settings, men will use vasectomy services, provided they are appropriately offered. This is still the key.

APPENDIX I.

Points of Consensus on the Effectiveness of Different *Vas* Occlusion Techniques

Emerging from a Vasectomy Experts' Meeting (Draft²)

Washington, DC, December 3, 2003

Co-sponsored by Family Health International and EngenderHealth

Introduction

Vasectomy is a very effective and safe contraceptive method used by millions of men worldwide. Vasectomy can be thought of as consisting of both an approach to the *vas* and a *vas* occlusion technique.

With respect to approach, there is strong, high-quality evidence that no-scalpel vasectomy (NSV) has significantly fewer side effects and complications than the standard incisional approach. Therefore the NSV approach to the *vas* is recommended.

The remainder of this document addresses different techniques of *vas* occlusion, for which high-quality data are limited. However, some recent evidence suggests that certain occlusion techniques can further increase vasectomy effectiveness.

Research Findings

Because post-vasectomy pregnancies are rare and difficult to study, the vasectomy research findings described below are based on semen analysis data.

1. Fascial Interposition

A number of observational studies and a recent randomized controlled trial indicate that fascial interposition, when used with ligation and excision, reduces the likelihood of vasectomy failure (as defined by semen analysis).

2. Cautery

Available data suggest that cautery is more effective than ligation and excision for *vas* occlusion. Furthermore, some data suggest that cautery is more effective than ligation and excision with fascial interposition. Data are insufficient to determine if either of the cautery techniques – thermal or electrocautery – is more effective than the other.

A preliminary evaluation of a battery powered, hand-held cautery device suggests that the thermal cautery tips can be effectively re-sterilized and reused safely, and can be inexpensively manufactured.

² This draft was last revised by David C. Sokal, MD, FHI, January 9, 2004, per comments from Jeff Spieler and Tim Black at the close of the meeting, with only minor editorial changes since then. The listing of a person as a participant does not necessarily indicate their agreement to the points of consensus.

Recommendations

Training of vasectomy providers should emphasize the potential increased effectiveness of adding fascial interposition to the standard technique of ligation and excision.

Providers now using simple ligation and excision should consider adopting fascial interposition, with appropriate training as needed.

Where resources, training, and logistical support are available, cautery is recommended as an effective and safe *vas* occlusion technique.

Further research is needed about simple ways to learn how to perform fascial interposition and about the programmatic feasibility of using cost effective cautery devices in low-resource settings.

APPENDIX II.

A news brief (below) based on these points of consensus was released December 4, 2003, and is available in English at:

<http://www.fhi.org/en/AboutFHI/News+Releases/dec42003ModVasTec.htm> or
<http://www.engenderhealth.org/news/newsreleases/031204.html>.

The news brief in Spanish is available at:

<http://www.fhi.org/en/AboutFHI/News+Releases/dec42003ModVasTecs.htm> or
<http://www.engenderhealth.org/news/newsreleases/031204-sp.html>.



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News

For Immediate Release
December 4, 2003

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Modifying Vasectomy Technique Increases Effectiveness

WASHINGTON, DC — Based on a review of a growing body of both published and unpublished research, global vasectomy experts concluded Wednesday that a simple ligation and excision technique commonly used in developing countries to perform male sterilization should, when possible, be modified to increase its effectiveness.

The recommendation was made at a three-day expert consultation on vasectomy cosponsored December 3 to 5, 2003, by the Research Triangle Park, NC-based Family Health International (FHI) and the New York City-based EngenderHealth. Working together, the organizations have recently completed a series of studies addressing the effectiveness of different vasectomy methods.

Simple ligation and excision vasectomy involves cutting and removing a short piece of the *vas deferens* (each of two tubes that carry sperm from the testicles to the penis), then tying the remaining two ends.

However, participants at the experts' meeting agreed that modifying ligation and excision by adding a technique called fascial interposition significantly improves effectiveness. Fascial interposition involves pulling the sheath that covers the *vas* over one severed end, then sewing it shut to create a natural tissue barrier. Based on analyses of sperm counts, this modification more than halves the chance of vasectomy failure, according to unpublished findings

“Modifying ligation and excision with fascial interposition and/or cautery techniques appears to improve vasectomy effectiveness by reducing the chance that the two ends of the vas will reconnect following the procedure.”

-- Dr. David Sokal, associate medical director, Family Health International

from a recent multicenter randomized controlled trial. Preliminary published results of that trial showed that combining fascial interposition with ligation and excision resulted in 93 percent of men reaching a low sperm count (less than 100,000 sperm per milliliter of semen) by 22 weeks after surgery compared to 81 percent of men without fascial interposition. A man's normal sperm count is above 20 million per

milliliter. This study did not look at pregnancy rates, but it is likely that the risk of pregnancy would be lower among women whose partners reach a low sperm count more quickly.

The vasectomy experts also concluded that use of cautery (burning the inside of the ends of the *vas*) with or without fascial interposition appears to be more effective than ligation and excision with fascial interposition. In a recent comparison of data from two multicenter studies, researchers looked at early failures, defined as high sperm concentrations 12 to 14 weeks after vasectomy, rather than actual pregnancy rates. They found early failure rates of about 1 percent for cautery with and without fascial interposition versus about 5 percent for ligation and excision with fascial interposition.

Some data suggest that combining cautery and fascial interposition is the most effective vasectomy method, but some vasectomy providers have had good success using cautery without fascial interposition, the experts agreed. Both thermal cautery and electrocautery appear to be similarly effective, but no prospective studies have been conducted to look for differences.

However, the experts agreed that clinicians and program managers who provide vasectomy services in low-resource settings should consider using already marketed battery-powered, hand-held thermal cautery devices to close the *vas*. Ideally, this procedure would be combined with fascial interposition. Meanwhile, research on this option in low-resource settings should continue, they said.

Regardless of the combination of techniques used, the vasectomy experts recognized that providers should – at least – know how to perform fascial interposition. Not only can it increase the effectiveness of ligation and excision if cautery is unavailable, but it can decrease bleeding.

“These findings have important implications for vasectomy services in low-resource settings. There is a critical need to identify innovative and feasible strategies for introduction of a more effective vasectomy method such as cautery.”

-- Dr. Amy E. Pollack, president,
EngenderHealth

Data remain insufficient to determine whether post-vasectomy side effects are affected by the technique used to block the *vas*. However, strong evidence indicates that the no-scalpel vasectomy approach to reaching the *vas* results in significantly fewer side effects than the standard incisional approach.

More information about vasectomy is available at: <http://www.fhi.org/en/topics/malesteril.htm> and <http://www.engenderhealth.org/wh/fp/cvas2.html>.

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Family Health International is dedicated to improving lives, knowledge, and understanding worldwide through a highly diversified program of research, education, and services in family health and HIV/AIDS prevention and care. Since its inception in 1971, FHI has formed partnerships with national governments and local communities in countries throughout the developing world to support lasting improvements in the health of individuals and the effectiveness of entire health systems.

Founded in 1943, EngenderHealth is a nonprofit organization that has been working internationally for more than 30 years to support and strengthen reproductive health services for women and men worldwide. Since its inception, its work has improved the health and lives of more than 100 million individuals in 90 countries.

APPENDIX III.

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