VASECTOMY: AUA GUIDELINE

Ira D. Sharlip, Arnold M. Belker, Stanton Honig, Michel Labrecque, Joel L. Marmar, Lawrence S. Ross, Jay I. Sandlow, David C. Sokal

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Authors' disclosure of potential conflicts of interest and author/staff contributions appear at the end of the article.

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Purpose: The purpose of this Guideline is to provide guidance to clinicians who offer vasectomy services. This guidance covers pre-operative evaluation and consultation of prospective vasectomy patients; techniques for local anesthesia, isolation of the vas deferens and occlusion of the vas deferens during vasectomy; post-operative follow-up; post-vasectomy semen analysis and potential complications and consequences of vasectomy.

Methods: A systematic review of the literature using the MEDLINE and POPLINE databases (search dates January 1949 to August 2011) was conducted to identify peer-reviewed publications relevant to vasectomy. The review yielded an evidence base of 275 articles after application of inclusion and exclusion criteria. These publications were used to create the evidence-based portion of the Guideline. When sufficient evidence existed, the body of evidence for a particular treatment was assigned a strength rating of A (high), B (moderate) or C (low). Additional information is provided as Clinical Principles and Expert Opinion when insufficient evidence existed.

Guideline Statements

1. A preoperative interactive consultation should be conducted, preferably in person. If an in-person consultation is not possible, then preoperative consultation by telephone or electronic communication is an acceptable alternative. *Expert Opinion*

2. The minimum and necessary concepts that should be discussed in a preoperative vasectomy consultation include the following: *Expert Opinion*
   - Vasectomy is intended to be a permanent form of contraception.
   - Vasectomy does not produce immediate sterility.
   - Following vasectomy, another form of contraception is required until vas occlusion is confirmed by post- vasectomy semen analysis (PVSA).
   - Even after vas occlusion is confirmed, vasectomy is not 100% reliable in preventing pregnancy.
   - The risk of pregnancy after vasectomy is approximately 1 in 2,000 for men who have post-vasectomy azoospermia.
   - Repeat vasectomy is necessary in ≤1% of vasectomies, provided that a technique for vas occlusion known to have a low occlusive failure rate has been used.
   - Patients should refrain from ejaculation for approximately one week after vasectomy.
   - Options for fertility after vasectomy include vasectomy reversal and sperm retrieval with *in vitro* fertilization. These options are not always successful, and they may be expensive.
   - The rates of surgical complications such as symptomatic hematoma and infection are 1-2%. These rates vary with the surgeon's experience and the criteria used to diagnose these conditions.
   - Chronic scrotal pain associated with negative impact on quality of life occurs after vasectomy in about 1-2% of men. Few of these men require additional surgery.

- Other permanent and non-permanent alternatives to vasectomy should be discussed.

3. Clinicians do not need to routinely discuss coronary heart disease, stroke, hypertension, dementia, prostate cancer or testicular cancer in pre-vasectomy counseling of patients because vasectomy is not a risk factor for these conditions. *Standard (Evidence Strength Grade B)*

4. The administration of prophylactic antimicrobials is not indicated for routine vasectomy unless the patient presents a high risk of infection. *Recommendation (Evidence Strength Grade C)*

5. Vasectomy should be performed with local anesthesia with or without oral sedation. If the patient declines local anesthesia or if the surgeon believes that local anesthesia with or without oral sedation will not be adequate for a particular patient, then vasectomy may be performed with intravenous sedation or general anesthesia. *Expert Opinion*

6. Isolation of the vas should be performed using a Minimally Invasive Vasectomy (MIV) technique such as the no-scalpel vasectomy technique or other MIV technique. *Standard (Evidence Strength Grade B)*

7. The ends of the vas should be occluded by one of three divisional methods:
   (1) mucosal cautery (MC) with fascial interposition (FI) and without ligatures or clips applied on the vas;
   (2) MC without FI and without ligatures or clips applied on the vas;
   (3) open ended vasectomy leaving the testicular end of the vas unoccluded, using MC on the abdominal end and interposing fascia between the ends;
   OR by the non-divisional method of extended electrocautery (Marie Stopes International technique). *Recommendation (Evidence Strength Grade C)*

8. The divided vas may be occluded by ligatures or clips applied to the ends of the vas, with or without fascial interposition and with or without excision of a short segment of the vas, by surgeons whose personal training and/or experience indicate that consistently satisfactory results are achieved by these techniques. *Option (Evidence Strength Grade C)*

9. Routine histologic examination of the excised vas segments is not required. *Expert Opinion*

10. Men or their partners should use other contraceptive methods until vasectomy success is confirmed by post-vasectomy semen analysis (PVSA). *Clinical Principle*

11. Eight to sixteen weeks after vasectomy is a reasonable time range for the first post-vasectomy semen analysis (PVSA). The choice of time to do the first PVSA should be left to the judgment of the surgeon. *Option (Evidence Strength Grade C)*

12. To evaluate sperm motility, a fresh uncentrifuged semen sample should be examined within two hours after ejaculation. *Expert Opinion*

13. Patients may stop using other methods of contraception when examination of one uncentrifuged fresh post-vasectomy semen analysis (PVSA) shows azoospermia or only rare non-motile sperm (≤ 100,000 non-motile sperm/mL). *Recommendation (Evidence Strength Grade C)*

14. Vasectomy should be considered a failure if any motile sperm are seen on post-vasectomy semen analysis (PVSA) at six months after vasectomy, in which case repeat vasectomy should be considered. *Expert Opinion*

15. If > 100,000 non-motile sperm/mL persist beyond six months after vasectomy, then trends of serial post-vasectomy semen analyses (PVSAs) and clinical judgment should be used to decide whether the vasectomy is a failure and whether repeat vasectomy should be considered. *Expert Opinion*

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INTRODUCTION

SECTION 1: GUIDELINE PURPOSE

The purpose of this Guideline is to provide guidance to clinicians who offer vasectomy services. The Guideline covers pre-vasectomy evaluation and consultation of prospective vasectomy patients; techniques for local anesthesia, isolation of the vas deferens and occlusion of the vas deferens during vasectomy; post-operative follow-up; post-vasectomy semen analysis to verify sterility and potential complications and consequences of vasectomy. Currently, the practice of vasectomy is characterized by wide variation in pre-operative counseling, surgical technique and post-operative follow-up. The intent of this Guideline is to provide a set of approaches and procedures that maximizes successful vasectomy outcomes and minimizes failure and other adverse events.

The strategies and approaches recommended in this document were derived from evidence-based and consensus-based processes. There is a continually expanding literature on vasectomy. The Panel* notes that this document constitutes a clinical approach to the practice of vasectomy. This Guideline is not intended to replace the judgment of an individual clinician faced with a particular patient. As the science relevant to vasectomy evolves and improves, the strategies presented here will require updating to remain consistent with the highest standards of clinical care.

SECTION 2: GUIDELINE METHODOLOGY

Process for Literature Selection. A systematic review was conducted to identify published articles relevant to key questions specified by the Panel (See Appendix C). The key questions focused on identifying necessary elements of pre-operative evaluation and consultation, optimal procedures for anesthetic administration, the least traumatic and most effective procedures for isolation of the vas deferens during vasectomy, the most effective procedures for occluding the vas deferens during vasectomy, the complications and consequences of vasectomy and the necessary components of post-operative follow-up, including semen analysis to verify sterility.

Literature searches were performed using the MEDLINE® and POPLINE® databases from January 1949 to August 2011 with the goal of identifying literature broadly relevant to the practice of vasectomy (see footnote for search strategy).[±] This literature included studies that focused on the prevalence of vasectomy; the demographics of patients and couples who chose vasectomy; vasectomy operative techniques, including techniques for vas isolation and vas occlusion and associated failure rates; short-term and long-term complications of vasectomy, other outcomes potentially associated with vasectomy (e.g., coronary heart disease, stroke, prostate and testicular cancer, sexual outcomes, psychosocial outcomes) and post-vasectomy semen analysis (PVSA) procedures and timing. Inclusion criteria for operative procedures were conventional vasectomy (CV) and minimally-invasive vasectomy (MIV), including the no-scalpel vasectomy (NSV) technique. Any method for occluding the vas was included. The following topics were excluded from the scope of the review: laparoscopic vasectomy, vasectomy reversal, post-vasectomy options for pregnancy, treatment of post-vasectomy pain syndrome, examination of antibodies to antigens other than sperm post-vasectomy and techniques for teaching vasectomy. Articles on antibiotic prophylaxis also were excluded as the topic of antibiotic prophylaxis in surgical procedures without entering the urinary tract is covered in an AUA Best Practice Policy (http://www.auanet.org/content/media/antimicroprop08.pdf). All settings and all ages of vasectomy patients were included. All study designs were included except for single-group cohort studies on immediate post-operative complications with fewer than 500 participants. Review article references were checked to ensure inclusion of all possibly relevant studies. Multiple reports on the same patient group were carefully examined to ensure inclusion of only non-redundant information.

On topics for which the review revealed insufficient publications to constitute an evidence base, clinical guidance is provided as *Clinical Principles* or as *Expert Opinion* with consensus achieved using a modified Delphi technique if differences of opinion among Panel members emerged.[1] A *Clinical Principle* is a statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature. *Expert Opinion* refers to a statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge and judgment and for which there is no evidence.

Nearly two thousand citations were reviewed by title and/or abstract. After application of inclusion and exclusion criteria, 275 articles were chosen to form the evidence base of this Guideline. Data were extracted on study design (e.g., randomized controlled trial, comparative observational study, case-series); pre-operative, operative and post-operative parameters; complications and other consequences of vasectomy (e.g., patient satisfaction, patient regret) and vasectomy effectiveness and failure rates.

Quality of Individual Studies and Determination of Evidence Strength. Quality of individual studies that were randomized controlled trials (RCTs) or comparative observational studies was assessed using the Cochrane Risk of Bias tool.[2] Since there is no widely-accepted quality assessment tool for single-

*"The Panel" refers to the members of the Vasectomy Guideline Committee of the American Urological Association 2008-2012 as identified on p. 56.

±MEDLINE (PubMed): ("vasectomy"[Text Word]) OR (vasectomy[MeSH Terms]) AND ("1949"[Publication Date]: "2011/08/31"[Publication Date]) Limits: only items with links to full text, Humans, Male POPLINE: (vasectomy/male sterilization); limited to peer reviewed journals

cohort observational studies, the quality of these studies was not assessed.

The categorization of evidence strength is conceptually distinct from the quality of individual studies. Evidence strength refers to the body of evidence available for a particular question and includes consideration of study design; individual study quality; the consistency of findings across studies; the adequacy of sample sizes and the generalizability of samples, settings and treatments for the purposes of the Guideline. The AUA categorizes body of evidence strength (ES) as Grade A (well-conducted RCTs or exceptionally strong observational studies), Grade B (RCTs with some weaknesses of procedure or generalizability or generally strong observational studies) or Grade C (observational studies that are inconsistent, have small sample sizes, or have other problems that potentially confound interpretation of data).

AUA Nomenclature: Linking Statement Type to Evidence Strength. The AUA nomenclature system explicitly links statement type to body of evidence strength and the Panel's judgment regarding the balance between benefits and risks/burdens (see Table 1).[3] ***Standards*** are directive statements that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be undertaken based on Grade A or Grade B evidence. ***Recommendations*** are directive statements that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be undertaken based on Grade C evidence. ***Options*** are non-directive statements that leave the decision to take an action up to the individual clinician and patient because the balance between benefits and risks/burdens appears relatively equal or appears unclear; ***Options*** may be supported by Grade A, B or C evidence. For some clinical issues, there was little or no evidence from which to construct evidence-based statements. Where gaps in the evidence existed, the Panel provides guidance in the form of *Clinical Principles* or *Expert Opinion* with consensus achieved using a modified Delphi technique if differences of opinion existed among Panel members.[1] A *Clinical Principle* is a statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature. *Expert Opinion* refers to a statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge and judgment and for which there is no evidence. The completed evidence report may be requested through AUA.

Panel Selection and Peer Review Process. The Vasectomy Panel was created in 2008 by the American Urological Association Education and Research, Inc. (AUA). The Practice Guidelines Committee (PGC) of the AUA selected the Panel Chair and Vice Chair who in turn appointed the additional panel members, all of whom have specific expertise with regard to vasectomy.

The AUA conducted an extensive peer review process. The initial draft of this Guideline was distributed to 72 peer reviewers; 55 responded with comments. The panel reviewed and discussed all submitted comments and revised the draft as needed. Since the changes were substantial, a second draft was circulated to 64 peer reviewers. The panel reviewed and discussed all submitted comments in response to this second round of peer review and again revised the document. Once finalized, the Guideline was submitted for approval to the PGC. It was then submitted to the AUA Board of Directors for final approval. Funding of the panel was provided by the AUA. Panel members received no remuneration for their work.

Table 1: AUA Nomenclature Linking Statement Type to Evidence Strength

Standard: Directive statement that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be taken based on Grade A or B evidence
Recommendation: Directive statement that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be taken based on Grade C evidence
Option: Non-directive statement that leaves the decision regarding an action up to the individual clinician and patient because the balance between benefits and risks/burdens appears equal or appears uncertain based on Grade A, B, or C evidence
Clinical Principle: a statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature
Expert Opinion: a statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge, and judgment for which there is no evidence

THE PRACTICE OF VASECTOMY

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SECTION 1: THE IMPORTANCE OF VASECTOMY

Vasectomy is the most common non-diagnostic operation performed by urologists in the United States (US). Estimates of the number of vasectomies performed annually in the US vary depending on survey type. Data from the National Study of Family Growth in which only married couples were polled indicate a range from 175,000 to 354,000.[4] In a physician survey, an estimated 526,501 vasectomies were performed in the US in 2002. This number seems to have been approximately stable for the previous decade.[5] More than 75% of vasectomies in the US are done by urologists, and about 90% of urology practices in the US perform vasectomy.[5,6]

In 2002, data collected in the US show that vasectomy was used by 5.7% of men ages 15-44 and that this represents the fourth most commonly-used contraceptive method. The first three were condoms, used by 29.5% of men, oral contraceptives for women used by 25.6% of couples and tubal sterilization used by 8.1% of couples.[7] Compared to tubal sterilization, which is the other method of permanent contraception, vasectomy is equally effective in preventing pregnancy; however, vasectomy is simpler, faster, safer and less expensive. Vasectomy is one of the most cost-effective of all methods of contraception; its cost is about one-fourth of the cost of tubal sterilization.[8] Vasectomy requires less time off work, requires only local rather than general anesthesia and is usually performed in a doctor's office or clinic. The potential complications of vasectomy are less serious than those of tubal sterilization.

Despite the clear advantages of vasectomy, prevalence data for 1998-2002 show that tubal sterilization was performed about two to three times more often than vasectomy.[4] Among all women in 2002, married and unmarried, ages 15 to 44 years in the United States, only 5.7% relied on vasectomy for contraception compared to 16.7% who relied on tubal ligation.[9] Even among married women and married men who desire permanent contraception, in the US the prevalence of tubal occlusion has exceeded the prevalence of vasectomy.[10]

Worldwide, the discrepancy between vasectomy and tubal sterilization is even more marked than in the US. Data compiled in 2008 by the Population Division of the Department of Economic and Social Affairs of the United Nations show that 33 million married women ages 15-49 relied on vasectomy for contraception compared to 225 million who relied on tubal ligation.[11] There are only eight nations in which vasectomy use is equal to or more frequent than tubal sterilization for contraception – Korea, Canada, the United Kingdom, New Zealand, Bhutan, the Netherlands, Denmark and Austria (World Contraceptive Use 2011).

Given the equivalent contraceptive effectiveness of vasectomy and tubal sterilization and seeing as vasectomy enjoys advantages compared to tubal sterilization of lower cost, less pain, greater safety and faster recovery, vasectomy should be considered for permanent contraception much more frequently than is the current practice in the United States and most nations of the world.

SECTION 2: PREOPERATIVE PRACTICE

Background Information About Who Chooses Vasectomy and Why

Reasons for Choosing Vasectomy. Several studies have addressed the reasons that men or their partners chose vasectomy.[10, 12-16] The decision for a partner to undergo a sterilization procedure usually is initiated by the female partner. The decision about which partner undergoes a sterilization procedure often is based on information obtained by one of the partners from medical professionals or from friends. Dissatisfaction with or failure of other contraceptive methods may prompt one or both partners to consider surgical sterilization for one of them. In the US, couples with higher numbers of children, higher educational levels and Caucasian ethnicity are more likely to choose vasectomy.

Miller et al. (1991) surveyed 400 couples regarding their choice of sterilization. Vasectomy was chosen when it was believed to be "easier" than tubal ligation, the physician recommended a vasectomy, there was effective couple communication and the previous method of contraception involved the use of condoms. The use of an intrauterine device (IUD) and the use of coitus interruptus were associated with the selection of tubal ligation. More people known by the wife to be satisfied with either vasectomy or tubal ligation predicted the choice of either vasectomy or tubal occlusion.[12]

Thompson et al. (1991) studied 84 couples in Scotland who selected vasectomy for contraception. In 46% of couples, both spouses were willing to be sterilized, whereas 23% of men requested vasectomy because their wives were unwilling to be sterilized and 24% of men insisted on vasectomy as their contribution to the partnership. The remaining couples gave medical reasons contraindicating a tubal ligation. The main influences for making the choice of vasectomy were favorable reports from other men (40%) and recommendations by general practitioners (21%).[13]

Sandlow and colleagues (2001) examined the psychological correlates of vasectomy in 74 men seeking vasectomy at a urology clinic in a tertiary care

teaching hospital in the mid-western US. Half of the men had contemplated vasectomy for one year or less and 85% had a high level of certainty regarding their decision. Ninety-one percent of men indicated that their wives or partners were involved in the decision and 90% indicated that their wives or partners were very certain about the decision (data were not collected from the partners). Mean anxiety level was 3.5 out of 10 (10 was the highest possible anxiety level). The most common reasons for anxiety were anticipated pain (27%) and fear of the unknown (23%). Finality of the procedure was a source of anxiety in only 5%. Fifteen percent of men indicated they understood that vasectomy was not reversible, while 30% believed that it was reversible.[14]

Barone et al. (2004) reported on 719 men undergoing vasectomy compared to similar men identified from a national practice-based survey. The most common reason for choosing vasectomy over other dependably reversible methods of contraception was that vasectomy was perceived as the most secure way of avoiding pregnancy (50% of respondents). Twenty-two percent of respondents stated that the main reason was that they or their partners disliked other contraceptive measures, and 7% reported the reason was a recent unplanned pregnancy or pregnancy scare. Sixty-two percent of men responded that they chose male sterilization over tubal ligation because it was safer and simpler; an additional 14% stated it was their turn to take responsibility for contraception. Health care providers (31%) were the most commonly reported source of information that helped in the decision-making process, followed by wives/partners (25%) and friends (23%).[15]

Characteristics of Patients and Couples Who Chose Vasectomy. Several studies examined the characteristics of men or their partners who chose vasectomy.[14, 15, 17-19] Forste et al (1995) examined data from the 1991 National Survey of Men and focused on a subset of 1,671 married men aged 20 to 39 years. Eleven and a half percent of men previously had a vasectomy and 12.6% of women had undergone a tubal ligation. Characteristics that were significantly ($p<0.05$) associated with choosing a vasectomy were older husband's age, white race of either spouse, living in the western US, smaller number of pregnancies in the current marriage, longer duration of marriage, prior failure with a male method of contraception and wife without religious affiliation. The husband's religion had no effect on the choice of vasectomy.[17]

In a large case control study on the relationship of vasectomy and prostate cancer from New Zealand (Sneyd, 2001), the demographic characteristics of 1,261 men or their partners who chose a vasectomy were examined.[18] Significant predictors for vasectomy included advanced vocational qualifications, non-Catholic men and men who had fathered one to five children compared with men who had no children. Men with greater numbers of marriages and with more highly-educated wives were significantly more likely to have had a vasectomy ($p<0.05$). After adjusting for age, the following characteristics were not significant predictors ($p>0.05$) for vasectomy: socioeconomic status, geographic region of residence and age at first marriage.[18]

Barone et al (2004) also reported characteristics of men undergoing vasectomy compared to a comparison group. Men undergoing vasectomy differed from the comparison group as follows: a higher percentage were married or cohabitating (91% vs 62% in the general US population), a higher proportion of non-Hispanic whites (87% vs 75%) and a greater percentage of vasectomized men had a bachelor's degree (48% vs 25%). The response rate for this survey was low: only 21% of eligible practices provided data.[15]

Eisenberg et al (2009) examined the use of vasectomy in the 2002 National Survey of Family Growth, a nationally representative survey of US residents ages 15-44 years. They evaluated differences between groups of patients in which the man did and did not have a vasectomy. For men between 30-45 years of age, white race, ever being married, older age, and increasing number of offspring were associated with increased utilization of vasectomy.[16]

Anderson et al (2010) also examined data from male participants in the 2002 National Survey of Family Growth. They found that 13.3% of married men reported having had a vasectomy and 13.8% reported tubal sterilization in their partners. It is notable that tubal sterilization was reported by 21.3% of married women participants of the same ages in the 2002 National Survey of Family Growth. The likelihood of vasectomy increased with older age and greater number of biological children, non-Hispanic white ethnicity and having ever gone to a family planning clinic. Tubal ligation as the contraceptive method was more likely among partners of men who had not attended college, those of older age and those with live births.[10]

Guideline Statement 1.

A preoperative interactive consultation should be conducted preferably in person. If an in-person consultation is not possible, then preoperative consultation by telephone or electronic communication is an acceptable alternative. ***Expert Opinion***

Discussion. There should be a consultation with the

patient prior to vasectomy. Similar to any surgical procedure, vasectomy requires an interactive discussion regarding risks, benefits and alternatives. Patients selecting vasectomy are choosing to make a permanent change in their fertility status. Some patients later regret this decision. Therefore, a thoughtful preoperative discussion is important. The goal of this discussion is to ensure that the patient has appropriate expectations regarding the preoperative, operative and post-operative consequences of the vasectomy choice. A face-to-face discussion is not necessary if the distance between the patient and surgeon or other factors preclude an in-person meeting, but the consultation setting should allow the surgeon to take the patient's reproductive and medical history; the patient to ask questions of the surgeon and receive answers and the surgeon to provide pre-operative, operative and post-operative information relevant to the patient's decision.

Some men need help making the decision to have a vasectomy. The needs for support in making this decision were examined by Balde et al (2006).[20] Forty-eight percent of men reported that the decision to undergo vasectomy was easy; 45% felt that the decision was difficult. Decisional difficulty was associated with the permanence of the procedure, risk of death of a child, fear of the unknown, fear of pain during the procedure and uncertainty about the effectiveness of the procedure. Physicians perceived that the factors that made the decision difficult for patients were fear of pain during the procedure, permanence of the procedure and fear of complications. The consultation procedure should be sufficient to allow the patient to address these kinds of concerns with the surgeon.

The surgeon performing vasectomy should obtain a general medical history, with particular emphasis on bleeding diatheses and other possible contraindications to surgery. For example, if a patient requires chronic anticoagulation and the risks of stopping anticoagulation are significant, then the surgeon and patient should consider alternative methods of family planning.

A physical exam of the genitalia should be performed prior to vasectomy. This exam may be performed immediately before the operative procedure if the preoperative consultation was not conducted in person. Physical examination at the time of in-person preoperative consultation is highly desirable because it will identify genital pathology, such as a testis tumor or undescended testis, which would contraindicate routine bilateral vasectomy. In addition, physical examination may identify patients who are not good candidates for local anesthesia because of unusual scrotal sensitivity, patients who are too uncomfortable or too anxious to tolerate vasectomy under local anesthesia or patients whose vasa are especially difficult to palpate. It is preferable to do this examination far enough in advance of the vasectomy to allow the surgeon to plan for oral or other sedation if necessary. If preoperative counseling cannot be done in person, the preoperative physical examination may be delayed to a later date or to the day of surgery if necessary.

Guideline Statement 2.
The minimum and necessary concepts that should be discussed in a preoperative vasectomy consultation include the following: ***Expert Opinion***

- Vasectomy is intended to be a permanent form of contraception.
- Vasectomy does not produce immediate sterility.
- Following vasectomy, another form of contraception is required until vas occlusion is confirmed by post-vasectomy semen analysis (PVSA).
- Even after vas occlusion is confirmed, vasectomy is not 100% reliable in preventing pregnancy.
- The risk of pregnancy after vasectomy is approximately 1 in 2,000 for men who have post-vasectomy azoospermia.
- Repeat vasectomy is needed in ≤1% of vasectomies, provided that a technique for vas occlusion known to have a low occlusive failure rate has been used.
- Patients should refrain from ejaculation for approximately one week after vasectomy.
- Options for fertility after vasectomy include vasectomy reversal and sperm retrieval with *in vitro* fertilization. These options are not always successful, and they may be costly.
- The rates of surgical complications such as symptomatic hematoma and infection are 1-2%. Rates vary with the surgeon's experience and the criteria used to diagnose these conditions.
- Chronic scrotal pain associated with negative impact on quality of life occurs after vasectomy in about 1-2% of men. Few of these men require additional surgery.
- Other permanent and non-permanent alternatives to vasectomy should be discussed.

Discussion. *Vasectomy as a permanent form of contraception*. It is important for patients to understand that vasectomy is intended to be a permanent form of contraception. For this reason, the surgeon should be sure that the patient's request for vasectomy is soundly reasoned and not made

precipitously. Some states require a delay or cool-down period between signing a consent form for vasectomy and the surgical date. The experience of the Panel members is that almost all men who request vasectomy have given the procedure serious thought for months or years, making a cool-down period superfluous in most cases. Nevertheless, state requirements must be observed.

Vasectomy does not produce immediate sterility. All patients have motile sperm in the ejaculate after vasectomy for some period of time. Other methods of contraception should be utilized until azoospermia or rare non-motile sperm (RNMS, ≤100,000 non-motile sperm/mL) is achieved. The time from vasectomy to azoospermia or RNMS can vary from weeks to months based on multiple factors including frequency of ejaculation, patient age, surgical technique and variations in the anatomy of the vasal ampullae and/or seminal vesicles (for detailed discussion, see Section 6: Postoperative Practice). PVSA showing azoospermia or RNMS is necessary for the surgeon to be able to tell the patient if he can rely on his vasectomy for contraception.

A patient can be considered to be sterile if the PVSA shows azoospermia or RNMS. Patients whose post-operative semen analyses do not meet these criteria may eventually require a repeat vasectomy to assure occlusive effectiveness. This possibility should be mentioned in the preoperative visit.

Another form of contraception is required until vas occlusion is confirmed after vasectomy. Sperm that are left in the male reproductive system distal to the vasectomy site may retain the ability to fertilize an ovum.[21-24] Another form of contraception should be used routinely until PVSA shows azoospermia or RNMS.

Risk of pregnancy after vasectomy. Vasectomy is not 100% reliable in preventing pregnancy even after vas occlusion is confirmed by PVSA. There is a very small but finite risk of pregnancy after vasectomy even if the PVSA demonstrates azoospermia. The pregnancy rate in partners of men who have documented azoospermia after a vasectomy is about 1 in 2000.[25-29] The Elliot Smith Clinic in the UK, in which about three-fourths of 16,796 vasectomies were performed with mucosal cautery (MC) and the remainder were performed with ligation, excision and folding back, reported a risk of about 1 in 2800 after documented azoospermia on two consecutive semen analyses.[25-27] The Marie Stopes International, which used nondivisional extended electrocautery, reported that approximately 1 in 2500 vasectomies resulted in pregnancy after confirmation of azoospermia on two consecutive samples.[29] Alderman et al. (1988), who used ligation and excision for vas occlusion, reported four pregnancies among 5,331 men who completed the recommended PVSA regimen, giving a rate of about 1 in 1,300.[28] However, in other studies using ligation and excision without fascial interposition (FI), the risk of pregnancy has been reported to range from 1 in 300[30] to 1 in 66.[31]

Need for repeat vasectomy/risk of failure. The possible need for repeat vasectomy, although rare, should be discussed with the patient in the preoperative visit. Vasectomy failure is defined as failure to achieve azoopsermia or RNMS or the occurrence of pregnancy. The patient may be told that the risk of vasectomy failure requiring repeat vasectomy is less than 1% if a technique of vas occlusion known to have a low occlusive failure rate was used during vasectomy (see Discussion under Guideline Statements 7 and 8 regarding occlusive failure rates).[15, 26, 29, 32-47]

Patients should refrain from ejaculation for approximately one week after vasectomy. There is considerable variability among vasectomy surgeons regarding the suggested period of sexual abstinence following vasectomy. The opinion of the Panel is that patients should be told to refrain from ejaculation for approximately one week after vasectomy to allow the surgical sites to heal and to allow for development of luminal occlusion of the vas after methods that use MC for vasal occlusion.

Patients who notice hematospermia during the first month or two after vasectomy may be reassured that this will resolve spontaneously and has no clinical significance.

Options for fertility after vasectomy. Vasectomy reversal, sperm retrieval combined with *in vitro* fertilization (IVF) and/or intracytoplasmic sperm injection (ICSI) or previously cryopreserved sperm, if available, may be used to achieve fertility after vasectomy.[4, 48] With these techniques, the chance for pregnancy varies with individual patient conditions and circumstances such as the age of the female partner, the number of years between a vasectomy and its reversal and the number of actively motile sperm after thawing of a cryopreserved specimen. In general, pregnancy with live birth occurs in approximately one of two couples who attempt these techniques. This pregnancy rate is less than the pregnancy rate in couples in whom the male partner has not had a vasectomy. In addition, these reproductive techniques may be expensive. These points should be discussed with patients during the preoperative consultation.

Symptomatic hematoma and infection rates. Many studies with sample sizes >500 patients reported rates of immediate post-operative local complications;[37, 49-59] rates of hematoma and infection were 1 to 2% in most series. There is some evidence that rates are lowest

among urologists compared to family physicians and general surgeons.[50] It is important to note that in this group of studies the method of vas isolation and occlusion often was not reported, making it unclear if surgical technique was related to local complication rate. Although these studies were consistent in their findings, they were observational and largely retrospective, and, therefore, present an unknown risk of under-reporting. In addition to these reports of post -operative hematoma and infection in studies with sample sizes > 500 patients, there are very rare case reports of Fournier's gangrene after vasectomy[60-64] including one patient in Europe who died.[62] The opinion of the Panel is that patients should be counseled that the risk of hematoma and wound infection after vasectomy is approximately 1-2%.

Chronic scrotal pain. Rarely, some men complain of persistent unilateral or bilateral scrotal pain after vasectomy. The medical literature on post-vasectomy pain is comprised of poor-quality studies characterized by small sample sizes, failure to report inclusion criteria, failure to use validated pain measures, high non-response rates, poorly-specified definitions of outcomes, highly variable rates and lack of clarity regarding whether active or passive surveillance was used to determine chronic pain rates. The opinion of the Panel is that the most important information for patient counseling is the risk of chronic scrotal pain which is severe enough to cause the patient to seek medical attention and/or to interfere with quality of life. The most robust study of this (Leslie 2007) indicates a 0.9% rate of such a pain 7 months after the surgery.[65] Only three studies reported follow-up of three years or more regarding severe chronic scrotal pain after vasectomy. Choe and Kikemo (1996) reported in a single-group retrospective study that at 4.8 years of follow-up, 2.2% of vasectomized men reported chronic scrotal pain sufficient to exert an adverse impact on quality of life.[66] McMahon et al. (1992) reported in a prospective single-cohort design with four years of follow-up that 5% of vasectomized men sought medical attention because of testicular pain.[67] In the sole comparative study, at 3.9 years of follow-up 6.0% of vasectomized men reported pain severe enough to motivate the seeking of medical care compared to 2.0% of non-vasectomized men.[68] The opinion of the Panel is that patients should be told that chronic scrotal pain severe enough to interfere with quality of life occurs in 1-2% of men after vasectomy. Medical or surgical therapy is usually, but not always, effective in improving this chronic pain. Few men require surgical treatment for chronic scrotal pain that may occur after vasectomy.

Permanent and non-permanent vasectomy alternatives. As with any surgical procedure, alternatives to vasectomy should be discussed. Benefits and risks of other permanent methods of contraception, (e.g., tubal sterilization) and/or non-permanent options for the patient (e.g., barrier methods) and partner (e.g., oral or injectable contraceptives and barrier methods) should be reviewed.

Additional relevant information. During the preoperative consultation, it is important to discuss the reproductive status of the patient's female partner. If the chance for pregnancy in the female partner is poor, the need for vasectomy may be less than the couple initially expected. In addition, if the female partner is pregnant at the time of the preoperative consultation, the couple may be advised to consider delaying the vasectomy until after delivery to avoid regret about vasectomy, which might occur if the pregnancy is lost unexpectedly.

Clinicians also should provide verbal and/or written instructions regarding post-operative care. The patient should wear supportive undergarments immediately after the procedure to reduce tension on the spermatic cord. This support should be continued until the patient is comfortable without it. Mild swelling and pain are common for a few days. The patient should take oral pain medication as recommended by his physician.

Application of cold temperatures to the scrotum post-operatively is optional. In general, the patient should keep the surgical site clean and dry, but showers may be permitted the day after the surgery including gentle washing of the surgical site(s) with soap and water. Swimming or bathing in a tub of water should be avoided for three to five days.

In the absence of bothersome discomfort, patients may return to non-physical work on the day of or the day after vasectomy. The patient should be provided access to the doctor or his or her staff and should be instructed to call in the event of unusually severe pain, excessive bleeding or drainage, excessive swelling, redness, fever or any other problem that concerns the patient.

Guideline Statement 3.

Clinicians do not need to routinely discuss coronary heart disease, stroke, hypertension, prostate cancer or testicular cancer in prevasectomy counseling of patients because vasectomy is not a risk factor for these conditions. ***Standard***

Discussion. ***(Evidence strength – Grade B; Risk/ burdens outweigh benefits).*** The studies reviewed below under each disease state constitute Grade B evidence strength. Findings for each subgroup of studies were statistically and/or conceptually

consistent, and any sources of bias were likely to result in increased reports of the disease state among vasectomized men compared to non-vasectomized men. Overall, there was no evidence that vasectomy constituted a risk factor for any of the listed conditions. The opinion of the Panel is that discussion of these disease states is not necessary as part of prevasectomy counseling.

Coronary heart disease (CHD). Three case-control studies[69-71] and ten comparative observational studies[72-81] examined a possible association between history of vasectomy and coronary heart disease (CHD). A variety of CHD measures were reported (e.g., new diagnosis of CHD, CHD-related hospitalizations, angina, ischemic heart disease, myocardial infarctions), limiting the feasibility of pooling outcomes across studies. Twelve of 14 studies reported no significant differences between vasectomized and non-vasectomized men in diagnosis of CHD, CHD symptoms, non-fatal myocardial infarction or fatal myocardial infarction. One study reported lower rates of ischemic heart disease among vasectomized men compared to non-vasectomized men (OR 0.7, 95% confidence interval 0.6-1.0).[80] Only one study reported that vasectomized men were at higher risk of angina and CHD-related hospitalization than were non-vasectomized men;[76] however, the findings from this study lack certainty because of the very small number of reported events in both groups. No study reported a significant relationship between years since vasectomy and CHD events, new diagnosis or prevalence when these studies controlled for key confounders such as age. The single study that reported on men with CHD risk factors (e.g., advanced age, cigarette smoking, elevated cholesterol, hypertension, family history) also found no significant relationship with vasectomy status.[71] Overall, the body of evidence indicates that there is no association between CHD and vasectomy.

Stroke. Five comparative cohort studies evaluated the relationship between vasectomy and stroke.[72-75, 80] There were no significant differences in incidence or fatality rates between vasectomized and non-vasectomized men. There also was no relationship between time since vasectomy and risk of stroke.[72-74]

Primary progressive aphasia (PPA) and other forms of dementia. Only one small study has reported a potential link between vasectomy and dementia.[82] This study reported that vasectomy may be a risk factor for PPA, a rare type of dementia. This small case control study has uncertain significance. Anti-sperm antibodies, the putative link between vasectomy and PPA, were not found to be associated with dementia or language ability in a more recent study.[83] Further, a large epidemiologic study found no association between a history of vasectomy and several immune-related diseases.[84] Other large epidemiologic studies of vasectomy have not looked specifically for evidence that vasectomy is a risk factor for dementia; nonetheless, there is no evidence other than the study of Weintraub (2006) that identifies an association between vasectomy and dementia. The opinion of the Panel is that clinicians do not need to routinely discuss PPA or other forms of dementia in pre-vasectomy counseling of patients because there is no convincing evidence that such a relationship exists.

Hypertension. Four comparative cohort studies examined the relationship between vasectomy and hypertension.[76,79,80,85] Three studies reported no significant difference in frequency of hypertension in vasectomized men compared to non-vasectomized men.[79, 80, 85] Mullooly (1993) reported that vasectomized men were at lower risk for the development of hypertension and for the utilization of diuretics and betablockers than were non-vasectomized men.[76]

Prostate cancer. A meta-analysis of 10 comparative cohort studies reported in 11 publications was performed as part of the literature review.[73, 77, 86-93] This analysis indicated that the relative risk of prostate cancer in vasectomized versus nonvasectomized men was not statistically significantly different (Relative risk (RR) 1.08; 95% confidence interval (CI) 0.88 to 1.32). Among studies that reported outcomes by years since vasectomy, meta-analysis revealed no relationship between time since vasectomy and prostate cancer (RR 1.00; 95% CI 0.58-1.73).[73, 86, 87, 92, 93] There also was no relationship between age at time of vasectomy and prostate cancer.[86, 87, 91-93] An additional group of case-control studies also was identified. The findings from these studies were too heterogeneous to allow pooling, but the majority of studies did not detect a relationship between prior vasectomy and prostate cancer.

Two older meta-analyses evaluated essentially the same set of studies retrieved by the panel's literature review. Dennis, et al. (2002) reported an RR of 1.22 (95% CI of 0.90-1.64) for pooled cohort studies, an RR of 1.14 (CI 0.93-1.39) for pooled population-based case control studies and an RR of 1.92 (CI 1.37-2.67) for hospital-based case-control studies.[94] These estimates were characterized, however, by significant unexplained heterogeneity. Bernal-Delgado et al. (1998) pooled findings across study designs and reported an RR of 1.23 (95% CI 1.01-1.49).[95] As with Dennis (2002), these authors also reported the presence of significant unexplained heterogeneity. The authors of these two meta-analyses concluded that the statistical differences could be explained by high risk of selection bias.

Testicular Cancer. Four case-control studies[96-99] and seven comparative observational studies[73, 89, 90, 77,100-102]

investigated whether there is an association between vasectomy and testicular cancer. A meta-analysis conducted as part of the Panel's literature review for the case-control studies indicated no significant difference between groups in terms of the odds of being diagnosed with testicular cancer for vasectomized men compared with non-vasectomized men (Odds ratio (OR) 1.18; 95% CI 0.93-1.49). Outcomes reporting differences across comparative observational studies did not permit a pooled analysis, but all seven studies reported non-significant differences between vasectomized and non-vasectomized men, and in the three studies that reported incidence by group,[73, 90, 101] incidence rates ranged from 0.02% to 0.11% across both groups. There was no association between history of vasectomy and testicular cancer stratified by years since vasectomy.[90, 98]

Guideline Statement 4.
The administration of prophylactic antimicrobials is not indicated for routine vasectomy unless the patient presents a high risk of infection. ***Recommendation***

Discussion ***(Evidence strength – Grade C; Risks/ burdens outweigh benefits).*** The AUA Best Practice Policy on Urologic Surgery Antimicrobial Prophylaxis (http://www.auanet.org/content/media/antimicroprop08.pdf) recommends that prophylactic antibiotics for open and laparoscopic surgery (including genital surgery) performed without entering the urinary tract are indicated only if risk factors are present. Risk factors include advanced age, anatomic anomalies of the urinary tract, poor nutritional status, smoking, chronic corticosteroid use, immunodeficiency, distant co-existent infection and prolonged hospitalization. The Panel affirms this recommendation and believes that diabetes is also a risk factor for post-operative infection. The opinion of the Panel is that the presence of one or more of these infection risk factors does not necessarily require the use of antimicrobial prophylaxis. When operating on certain patients who present with comorbidities associated with a particularly high risk of infection, the surgeon should consider the use of prophylactic antimicrobials.

Additional Points for Preoperative Practice
The minimum age requirement for vasectomy is the legal age of consent in the state in which the procedure is performed. The prospective vasectomy patient must, at a minimum, be the legal age of consent according to relevant legal statutes. In addition, each surgeon should exercise clinical judgment to determine the appropriateness of performing a vasectomy on a particular patient. The patient's age, the number of children that the patient has and other factors that the surgeon's experience indicate may be associated with successful outcomes (e.g., patient satisfaction, absence of regret) should be taken into account in making this decision.

In the US, there is no requirement for spousal or partner involvement in preoperative consultation, but patients should be advised that partner or spousal involvement is desirable. Any consenting adult male may proceed with a vasectomy without consultation with his partner unless local laws stipulate otherwise. However, because the prospective vasectomy patient's decision affects the fertility options for both him and his partner or spouse, it is optimal that his partner should be included in the preoperative consultation and decision-making process.

Preoperative laboratory tests are not required for vasectomy patients unless the patient's medical history suggests that laboratory work may be necessary to assess the patient's suitability for the vasectomy procedure. In particular, preoperative coagulation tests should be considered if the patient has a history of liver disease, bleeding diatheses or is taking anticoagulants.

Absence from work. A low-quality, limited amount of literature was available to address how much time men typically take off from work after vasectomy.[25, 26, 52, 53, 103-115] Time off from work appears to be based on several factors, including type of job, day of the week of the procedure and patient preference. Many men took no time off work after vasectomy; others were absent from one to three days and sometimes more. For men who reported no time out of work, it was generally unclear if these men had scheduled time off following the procedure. Time lost from work varied considerably, and there may be cultural and financial reasons that explain the disparities. Insufficient information was provided to explore this hypothesis, however.

Additional Long-term Postoperative Complications and Outcomes:
Epididymitis. Rates of epididymitis varied across studies. Some variability is likely the result of different definitions used for epididymitis. For example, most studies did not differentiate between infectious epididymitis and non-infectious "congestive" epididymitis. Bacterial epididymitis is often confused with pain caused by distention of the epididymal tubule due to back pressure below the vasectomy site or by epididymal sperm granuloma. Nevertheless, across the 36 available studies, rates of epididymitis were generally low. Fifteen studies reported rates ≤ 1 percent.[33, 40, 55, 57, 108, 116-124] Most of the remaining studies reported rates ≤ 3 percent.[30, 32, 35, 36, 46, 125-131] True bacterial epididymitis post-vasectomy was rare and ranged up to 1.5% in the available studies.[117, 118, 128] The majority of studies compared vasectomy techniques, rather than using unvasectomized men for

controls. The lack of an unvasectomized control group does not allow for a true estimate of the rate of these complications among vasectomized men; the rates presented here may be over-estimations.

Sperm granuloma. The rate of formation of a symptomatic nodule (presumed to be a sperm granuloma or a suture granuloma if a ligature was used to occlude the transected testicular end of the vas) varies based on technique, but in the overwhelming majority of available studies it was diagnosed at rates < 5% and was rarely symptomatic.[33, 35-37, 39, 40, 44, 50, 55, 106, 112, 116-119, 122, 123, 125, 130, 132-141] The occurrence of an asymptomatic inflammatory nodule at the vasectomy site is probably common, but this is not considered a complication of vasectomy. The true rate of nodule formation at the vasectomy site has not been identified. Some of these nodules, whether they are histological sperm granulomata or not, are initially painful but the acute pain spontaneously resolves in two to three months or less in most cases. Treatment for a painful nodule at the vasectomy site is symptomatic therapy with anti-inflammatory agents and analgesics if needed. Persistent pain at the vasectomy site is rare and may respond to excision and repeat vasectomy.

Psychosocial outcomes. Relatively few studies examined psychological outcomes among vasectomized men. There is a paucity of high-quality, comparative observational studies reporting outcomes measured with validated instruments. In particular, data with applicability to men in the US or in other developed countries are sparse. Outcomes may vary by year of the study, geographic location, measurement tools used, selection of the study population, length of follow-up and other variables. It is thus impossible to draw firm conclusions on the effect of vasectomy on psychological function.[105, 142-144]

Sexual outcomes. Although there is a large number of studies examining sexual outcomes after vasectomy,[45, 51, 53, 55, 59, 60, 103-106, 111, 114-116, 118, 121, 129, 132, 145-161] there are few studies with a comparison group and few studies that report data before and after the procedure. Thus, it is difficult to attribute changes in sexual satisfaction or function to the vasectomy itself. Outcomes relating to sexual function were heterogeneous, often poorly defined, and were usually assessed with instruments that were not validated.

Despite the relatively weak study designs, the available data with regard to sexual outcomes of vasectomy were consistent. Men generally resumed intercourse within two weeks of vasectomy. There was an increase in frequency or improvement in sexual satisfaction in half or more of patients and a decrease in frequency of intercourse and in sexual habits in only 5% of men across studies. A recent large population-based study confirmed the lack of sexual problems in men following vasectomy.[162] Overall, it appears that for the vast majority of men who undergo vasectomy, there are no negative effects on sexual function. Many patients are concerned that vasectomy may cause changes in sexual function such as erectile dysfunction, reduced or absent orgasmic sensation, decreased ejaculate volume, reduced sexual interest, decreased genital sensation and/or diminished sexual pleasure. Patients may be reassured that there is no evidence that any of these problems are caused by vasectomy.

Dissatisfaction and regret. Rates of dissatisfaction with vasectomy and/or regret at having undergone the procedure were in the range of 1-2% across a large number of studies, settings, and techniques.[51, 59, 66, 104, 105, 107, 114, 115, 117, 125, 127, 137, 147-149, 153, 155-158, 160, 161, 163-166] Eighty to 100% of vasectomized men would recommend the procedure to others. In the few studies that assessed reasons for dissatisfaction or regret, the most commonly reported reason was the desire for more children.[107, 165] These data highlight the importance of thoughtful pre-vasectomy counseling.

Endocrine outcomes. The literature review revealed no evidence of significant effects of vasectomy on testosterone, follicle-stimulating hormone (FSH), luteinizing hormone (LH), lipids (e.g., serum total cholesterol, low-density lipoproteins, high-density lipoproteins, triglycerides) or bone mineral density[167-174] at follow-up durations ranging from one to 21 years.

Urolithiasis. One low-quality study reported on urolithiasis rates of vasectomized compared to non-vasectomized men.[175] The odds ratio of urolithiasis in vasectomized versus nonvasectomized men < 45 years of age was 1.9 (95% CI, 1.2-3.1); the OR was not statistically significant for men > 45 years of age. The OR was highest in men zero to four years post-vasectomy, compared to men without vasectomy.[175] In the absence of more definitive data, it remains unclear whether there is a relation between vasectomy and urolithiasis.

Immunologic outcomes. A limited literature was available on the incidence and relevance of anti-sperm antibodies (ASAs) post-vasectomy.[176-188] Most studies are based on measurement techniques which are no longer used. ASAs were rarely present prior to vasectomy and a number of studies demonstrated the appearance of sperm agglutinins and/or immobilizing antibodies in serum after vasectomy.[181-184, 187, 189] Few of these studies correlated the presence or titer of such antibodies with pregnancy outcome after vasectomy reversal. Linnet (1977) showed the presence of such antibodies in the seminal plasma of only 4% of men

after vasectomy and the appearance of sperm agglutinins in the seminal plasma of 10 of 29 men after vasectomy reversal. Linnet (1982) also showed that pregnancy occurred in the wives of 11 of 13 men without seminal plasma sperm agglutinins after vasovasostomy compared to only 1 of 7 men with seminal plasma sperm agglutinins. To the contrary, Thomas (1981) showed no statistically significant difference in the level of serum sperm agglutinating or immobilizing antibodies one year after vasectomy reversal between 17 men whose partners had become pregnant and 18 men whose partners had not yet become pregnant. These investigators found low to moderate titers of immobilizing or agglutinating antisperm antibodies in the seminal plasma of 5 of 25 men one year after vasectomy reversal; one of these five men had established a pregnancy. Studies pertaining to the influence of antisperm antibodies on pregnancy rates after vasectomy reversal are rare. The precise prevalence of impaired fertility due to anti-sperm antibodies is unknown.

In a review of this topic, Kutteh (1999) concluded that the most rigorous studies have not proven a cause and effect between abnormal immune parameters, such as the presence of antisperm antibodies, and impaired fertility and noted that there is wide variation and inconsistency regarding this association, depending upon which test(s) are employed, the study methodology used and the patient population under study.[190] Kutteh (1999) also concluded that there is no universal agreement regarding which method of anti-sperm antibody test should be used or the proper treatment if anti-sperm antibodies (ASA) are detected. The opinion of the Panel is that, after vasectomy, impaired fertility due to anti-sperm antibodies is infrequent and that the presence of serum antisperm antibodies should not be considered a deterrent to vasectomy reversal.

Testicular changes after vasectomy. Data are sparse on the effect of vasectomy on testicular histology and on pathologic changes following vasectomy. The available studies suggest that there may be significant post-vasectomy pathological changes in testes.[191, 192] Electron microscopy revealed that interstitial fibrosis was present in the testis of 23% ($p<0.01$) of men following vasectomy and that there was a significant correlation ($p<0.01$) between these changes and fertility in men who underwent a successful vasectomy reversal as defined by sperm in the ejaculate.[191] These testicular changes were not associated with antisperm antibody status as measured by the indirect immunobead assay.[192]

Death as a result of vasectomy. The literature review found no reports of death as a result of vasectomy in contemporary American urological practice. There is one report of death after vasectomy due to Fournier's gangrene. This case occurred in Europe and was reported in 1992.[62] In addition, a large cohort study did not show any association between overall mortality and vasectomy.[193]

SECTION 3: TECHNIQUES FOR LOCAL ANESTHESIA

Guideline Statement 5.
Vasectomy should be performed with local anesthesia with or without oral sedation. If the patient declines local anesthesia or if the surgeon believes that local anesthesia with or without sedation will not be adequate for a particular patient, then vasectomy may be performed with intravenous sedation or general anesthesia. ***Expert Opinion***

Discussion. Vasectomy can be safely performed in almost all patients using local anesthesia alone. Occasionally adjunctive oral or intravenous sedation may be optimal or necessary for the few patients who are unable to tolerate vasectomy under local anesthesia alone. For the rare patient in whom preoperative examination suggests that vas isolation will be particularly difficult and in whom oral or intravenous sedation is unlikely to be sufficient for patient comfort, general anesthesia may be necessary. Direct topical application of anesthetic cream at the vasectomy site in addition to standard injection of local anesthesia also may be used. Several small studies have shown that topical application of anesthetic cream before local injection of anesthetic may reduce pain associated with injection of local anesthetic agents.[194-196] One additional study showed no decrease in intraoperative pain when topical anesthetic cream was used.[197] The opinion of the Panel is that there is uncertainty regarding whether the topical application of anesthetic cream reliably reduces pain; the decision regarding the use of anesthetic cream should be left to the judgment of the individual practitioner. The topical cream should be applied by a health care professional rather than by the patient to prevent excessive application and risk of toxicity.

Practitioners are cautioned that topical anesthetic cream should not be the sole source of local anesthesia for the performance of vasectomy. Infiltration of local anesthetic agent into the skin and perivasal tissue is always necessary prior to performance of a vasectomy, regardless of whether topical anesthetic cream is used.

Other Important Points of Technique for Local Anesthesia.
Needle size. In the opinion of the Panel, the smallest available needle should be used for the injection of local anesthesia because small gauge needles typically

produce less pain than larger gauge needles. In the Panel's experience, the optimal range of needle sizes is 25 to 32 gauge. One study evaluated patient visual analog scale (VAS) scores in response to blinded forearm intradermal injection with 25 gauge vs. 30 gauge needles.[198] Mean VAS score was 32mm for the 25 gauge needle compared to 25mm for the 30 gauge needle. Although this difference was statistically significant ($p<0.05$), it is not clear that the difference represents a clinically-meaningful difference in patient pain experience. However, these data do indicate that the pain associated with needle diameters in this range is minor. These data are in agreement with the Panel's opinion that needles between 25 and 32 gauge should be utilized for local infiltration and spermatic cord block to minimize patient pain. Patients may be told that the anesthetic often takes effect within one to three seconds. The majority of members of the panel feel that the use of 30 or 32 gauge needles for injection of the local anesthetic is associated with less pain than occurs with the use of larger needles for this purpose.

Pneumatic injector. A pneumatic injector, also known as a jet or no needle device, has been used to deliver anesthetic agent transcutaneously. However, it is not clear that intra-operative pain is reduced by this technique compared to standard injection technique. In one study, the mean VAS score for initial pain after pneumatic injections was 15.6 mm compared to 21.2 mm with needle injection (on a 0 to 100 mm scale). This difference was statistically significant ($p=0.029$) but may not be clinically meaningful given that VAS scores were low for both techniques.[199] Furthermore, the pain during the remainder of the procedure was 16.8 mm versus 18.6 mm respectively.[199] These differences were not statistically significant.

In a separate cohort study, the mean VAS scores were reported for three separate procedures: 33 mm for local infiltration, 22 mm for no-needle pneumatic injector and 17 mm for local infiltration and cord block. The VAS score differences for the initial injection were significantly different between local infiltration and local infiltration with cord block and between local infiltration and pneumatic injection, but there were no differences for the VAS scores during the remainder of the procedure.[200] Overall, the opinion of the Panel is that it is unclear whether use of a pneumatic injector reliably reduces pain to a clinically significant extent; this decision is left to the judgment of the individual practitioner. Pneumatic injection may be especially suitable for needle-phobic men.

Addition of buffer, epinephrine or corticosteroids to the local anesthetic agent or a topical cutaneous spray. There are insufficient data to know whether addition of buffer, epinephrine or corticosteroids to the local anesthetic agent or topical cutaneous spray reduces pain during vasectomy or reduces postoperative inflammation. Therefore, the addition of these agents is not endorsed by the Panel. Buffers have been added to local anesthetic agents to reduce pain during intradermal injections of various types but not specifically for vasectomy. For example, commercially available xylocaine 1% is buffered to a pH of 6.7 (range 5.5-7.2).[201] In a blinded study, VAS scores for buffered solutions were 18.3 mm and for fresh solutions were 23.5 mm ($p=0.05$).[202] Although VAS scores were lower for buffered solutions, the difference may not be clinically significant. In the absence of data obtained specifically for vasectomy, the Panel does not endorse the addition of these substances to anesthetic agents.

SECTION 4: VAS ISOLATION
Background Information About Vas Isolation

Table 3: Definitions for Vas Isolation Techniques

Conventional Vasectomy (CV): One midline or bilateral scrotal incisions are made with a scalpel. Incisions are usually 1.5-3.0 cm long. No special instruments are used. The vas usually is grasped with a towel clip or an Allis forceps. The area of dissection around the vas usually is larger than occurs with MIV techniques.
No-Scalpel Vaectomy (NSV): A minimally invasive method that uses specific instruments and sequential specific steps. Alteration of any of the specific steps does not allow the surgical technique to be called NSV. The NSV incision is usually less than 10 mm and no skin sutures are needed. Two special instruments (vas ring clamp and vas dissector) are essential to NSV. The area of dissection around the vas is kept to a minimum.
Minimally Invasive Vasectomy (MIV): Methods with minor variations of the NSV technique are defined as MIV methods. Skin openings of ≤10 mm are typical and special instruments such as the vas ring clamp and vas dissector that are used for the NSV technique or similar special instruments are commonly used. The area of dissection around the vas is kept to a minimum.

Vas Isolation Techniques. There are two key surgical steps in performing vasectomy: 1) **isolation** of the vas and 2) **occlusion** of the vas. The risks of intraoperative and early postoperative pain, bleeding and infection are related mainly to the method of vas isolation. The success and failure rates of vasectomy are related to the method of vas occlusion (see next section titled Vas Occlusion Techniques). Methods of vas isolation include Conventional Vasectomy (CV) and Minimally-Invasive Vasectomy (MIV), which includes no -scalpel vasectomy (NSV). For definitions, see Table 3.

Conventional Vasectomy (CV). CV technique was the most common technique before the introduction of MIV techniques and special vasectomy instruments. CV is performed by making either one midline incision or bilateral scrotal incisions using a scalpel. Incisions are usually from 1.5 - 3 cm. No special instruments are used during CV, and the vas usually is grasped with a towel clip or an Allis forceps. During CV, the area of scrotal dissection usually is much larger than occurs with MIV techniques.

No-Scalpel Vasectomy (NSV). The no-scalpel vasectomy technique was developed in 1974 in China by Dr. Li Shunqiang to make vasectomy a more acceptable method of contraception. The NSV isolation technique was the first minimally-invasive technique for vasectomy and is described in detail in text and with diagrams by Li et al. (1991).[203] An excellent description of NSV technique also can be found in training materials prepared by EngenderHealth[204] (www.engenderhealth.org/files/pubs/family-planning/no-scalpel.pdf). Note that the NSV technique is a method of vas isolation and does not specify a method of vas occlusion. For a detailed description of the NSV technique, see Appendix A.

Strictly speaking, to be called a Li no-scalpel vas isolation technique, the surgeon must use the following surgical steps:

1. Use vas ring clamp and vas dissector, both of which have been specially designed for no scalpel vasectomy
2. Apply the vas ring clamp around the vas, perivasal tissue and overlying skin before making the skin opening
3. Create a skin opening of <10 mm by piercing the skin with the vas dissector followed by spreading the tissue overlying the vas with the vas dissector to expose the bare anterior wall of the vas
4. Pierce the bare vas with one tip of the vas dissector
5. Then use a supination maneuver to elevate the vas above the skin opening
6. Re-grasp a partial thickness of the vas with the vas ring clamp rather than encircling the vas with the ring clamp
7. Complete the posterior dissection with the vas dissector to isolate the vas from surrounding perivasal tissue and vessels
8. Divide the vas, with or without excision of a vas segment, and then occlude the vas with the surgeon's preferred technique for vas occlusion
9. Leave the skin opening unsutured except in rare cases that may require a skin suture

If all of these specific steps are not used, then the vasectomy should be called a minimally-invasive vasectomy (MIV) rather than a no-scalpel vas isolation technique.

When difficulty in isolating the vas is encountered or anticipated, as may be expected with a history of surgery for testicular maldescent or perivasal scarring from a previous operative procedure, a larger incision similar to the incision typically used for CV may be needed. Even in these more difficult vasectomies, the vas ring clamp and vas dissector facilitate the procedure and minimize tissue dissection.

Minimally-Invasive Vasectomy (MIV). The term "minimally invasive vasectomy" includes any vas isolation procedure, including the NSV technique, which incorporates two key surgical principles.[39, 205]

1. Small (≤10 mm) openings in the scrotal skin, either as a single midline opening or as bilateral openings
2. Minimal dissection of the vas and perivasal tissues, which is facilitated by using a vas ring clamp and vas dissector or similar special instruments

The three finger technique described in Appendix A for immobilizing the vas or for making the skin opening has been modified slightly by various surgeons using MIV techniques other than the strict NSV technique. These variations include the use of the thumb rather than the middle finger behind the scrotum and other modifications of finger placement, bilateral skin openings or scrotal skin opening(s) made before grasping the vas with the vas ring clamp.

MIV isolation techniques utilize either an open access approach or a closed access approach. In the open access approach, the skin opening(s) are made before the vas ring clamp or similar instrument is applied to the vas. In the closed access approach, the vas ring clamp or similar instrument is applied around the vas, perivasal tissue and overlying skin before the skin opening(s) is (are) made. The vas ring clamp and vas dissector are not required to perform MIV but are always very helpful.[106] Other small or specially designed instruments may be used successfully to isolate the vas.[39, 106, 205] Open access is sometimes necessary for men with thick scrotal skin or other anatomy that makes closed access difficult or impossible.

Other Important Points of Surgical Technique.

Single midline or bilateral incisions**.** The use of one midline or bilateral scrotal skin openings should be based on the surgeon's preference. One large observational study (N=1,800) compared single incision to double incision procedures. Fewer adverse events were reported with a single incision and the procedure time was reduced, but no statistical testing was performed.[206] The Panel opinion is that there is no clear advantage to making one or two skin openings. The choice between midline and bilateral incisions

should be left to the clinical judgment of the surgeon performing vasectomy.

Site of incision(s). For a midline approach, the scrotal skin opening should be made just below the penoscrotal junction or midway between the penoscrotal junction and the top of the testes. For a lateral approach, some experts recommend that the scrotal skin opening should be made at the level of the penoscrotal junction or higher. Scrotal skin openings for vasectomy should be positioned to provide access to the straight portion of the vas. Higher openings allow better access to the straight portion of the vas, make it easier to perform MC and create longer vas remnants on the testicular side of the vasectomy. The opinion of the Panel is that occlusion of the vas is more easily performed in the straight portion than in the convoluted portion of the vas. In addition, occlusion of the vas in its straight portion may facilitate the performance of the anastomosis during vasovasostomy if reversal of the vasectomy is requested later.

Insuring that one vas is not occluded twice. For a single-incision vasectomy, the surgeon should ensure that the same vas is not isolated and occluded in two locations, leaving the other vas unoccluded. A gentle tug on each vas during isolation will cause the ipsilateral testis to move. In one study, this technique was used in 2,150 vasectomies. There were no pregnancies reported, and all 2,150 patients had a negative PVSA at three months.[207]

Guideline Statement 6.

Isolation of the vas should be performed using a Minimally-Invasive Vasectomy (MIV) technique such as the no-scalpel vasectomy technique or other MIV technique. ***Standard***

Discussion. **No-Scalpel Vas Isolation Technique.** ***(Evidence strength – Grade B; Benefits outweigh risks/burdens).*** The available evidence indicates that use of a minimally-invasive vas isolation procedure such as the no-scalpel vasectomy technique results in less discomfort during the procedure and in fewer postoperative complications. One large randomized controlled trial,[59] one comparative study,[208] one observational study,[201] and three systematic reviews[209-211] concluded that the NSV technique of vas isolation has fewer early postoperative complications than CV. The randomized trial was a multi-center study at eight sites and included 1,429 men.[59] Sokal et al (1999) found significantly fewer hematomas and infections, significantly less pain and a more rapid resumption of sexual activity among men who had an NSV procedure. The comparative study included 1,203 vasectomies.[208] While not a randomized trial, the 28 surgeons in the study were all experienced and had participated in previous vasectomy "festivals" in Thailand. Nirapathpongporn et al (1990) found that the men who had the NSV technique had significantly fewer hematomas and infections, with an overall complication rate of 0.4/100 procedures for the NSV technique compared with 3.1/100 for conventional vasectomy ($p<0.001$).[31] Both studies found that NSV took less time than CV.

Other MIV Techniques. ***(Evidence strength – Grade B; Benefits outweigh risks/burdens).*** Reports on other MIV techniques have proposed special instruments other than the vas ring clamp and vas dissector[39, 103, 106, 205] or alternative ways to use the vas ring clamp and vas dissector.[212] The rate of intraoperative and early postoperative complications appear similar to those of the NSV technique.[39, 103, 106, 205, 212]

When any MIV incision including the NSV incision is used, the skin opening may be closed with a suture or left open at the end of the procedure. With a skin opening of ≤ 10 mm, sutures are usually not needed for wound closure. The choice of suturing the skin or leaving it open should be based on individual operative conditions and the surgeon's experience.

The body of evidence showing the superiority of MIV techniques (reduced intraoperative discomfort and reduced postoperative complications) compared to conventional vasectomy techniques is given Grade B for strength of evidence because it is comprised of a good quality RCT and several systematic reviews in addition to a body of observational studies. Overall, the findings across reports were consistent. It is the strong opinion of the Panel members that isolation of the vas with an MIV technique is superior to CV isolation procedures.

SECTION 5: VAS OCCLUSION
Background Information About Vas Occlusion

In the US, virtually all techniques of vasectomy use complete division of the vas with or without excision of a segment of the vas. Following division of the vas, the divided vasal ends may be separated by one of several techniques and/or the flow of fluid and sperm within the vas lumen may be blocked by one of several methods. There is only one technique of vas occlusion, non-divisional extended electrocautery or the Marie Stopes International technique (see below), which does not use division of the vas. This technique is rarely, if ever, used in the United States. **Therefore, in this guideline, vas occlusion means that the vas has been completely divided with or without excision of a vas segment, unless otherwise noted. Further, in this document, division/excision (D/E) means that the vas is divided and that a segment may or may not be excised. The panel found no**

consistent evidence indicating that division with excision of a short vas segment (< 4 cm) is preferable to division without excision of a vas segment.

Table 4: Definitions for Vas Occlusion Methods

Contraceptive effectiveness: The absence of pregnancy.
Division/excision: Division with or without excision of a vas segment.
Fascial interposition: Placing a layer of the vasal sheath (internal spermatic fascia) between the two severed ends of the vas in order to cover one end, but not the other end, with the vasal sheath.
Folding back: A method of folding and suturing each divided vas end on itself to prevent the two cut ends from facing each other.
Marie Stopes International (MSI) (non-divisional extended electrocautery technique of vas occlusion) The method used by Marie Stopes International (MSI) in the United Kingdom and its international clinics. This method utilizes electrocautery to destroy approximately 2.5 to 3.0 cm of the anterior wall of the vas, the mucosa and a part of the posterior wall of the vas without dividing the vas. This method is rarely, if ever, used in the US.
Mucosal cautery: Application of thermal or electrical cautery to the vasal mucosa via intraluminal positioning of the cautery device to create a luminal plug of scar tissue without creating full-thickness thermal damage to the vas after division/excision of the vas
Occlusive effectiveness: Azoospermia or RNMS without any motile sperm at any time after vasectomy.
Open ended vasectomy: Division/excision with the use of fascial interposition to cover one end of the divided vas combined with occlusion of the abdominal end of the divided vas without occlusion of the testicular end.
Vasectomy effectiveness: Contraceptive or occlusive effectiveness.

Vasectomy effectiveness can be defined as either **contraceptive effectiveness**, which is the absence of pregnancy, or **occlusive effectiveness**, which is demonstrated by the finding on PVSA of azoospermia or of RNMS, as defined in a subsequent section of this Guideline. For definitions, see Table 4.

The most commonly utilized vasectomy occlusion techniques are the following:

Fascial interposition is the technique of placing a layer of the internal spermatic fascia between the two divided ends of the vas. The fascial layer may be placed over the testicular or the abdominal end. Typically it is combined with other techniques such as ligation and excision or MC.

Ligation means occlusion of the vas with ligatures with division/excision of the vas between the occluded points and with or without FI. The number of ligatures on each end of the divided vas varies between one (most common) and three. The length of the vas segment excised is most commonly approximately 1 cm but varies between 0 and 5 cm.

Clips means occlusion of the vas with clips with division/excision of the vas between the occluded points and with or without FI. The number of clips placed on each end of the divided vas is usually one or two but may be more. The length of the vas segment excised is most commonly approximately 1 cm.

Folding back is the technique of folding and suturing each divided vas end on itself to prevent the two cut ends from facing each other.

Mucosal cautery is the technique of applying thermal or electrical cautery to the mucosa of the cut ends of the vas to destroy the vasal mucosa while avoiding or minimizing damage to muscle layers. The goal of MC is to create a plug of scar tissue which occludes the vas lumen. The length of the cauterized segment varies from a few mm to 1.5 cm. MC may be combined with excision of a vas segment, folding back or FI. Cauterizing the mucosa while simultaneously limiting cautery damage to the muscular layer of the vas prevents sloughing of the cauterized portion of the vas, which could occur if its full thickness is destroyed by cautery.[44]

Non-divisional extended electrocautery technique of vas occlusion (Marie Stopes International technique) consists of electrocoagulation of the full thickness of the anterior wall and a partial thickness of the posterior wall of the vas for a length of approximately 2.5 to 3 cm without dividing the vas.[29, 133] It is the only technique which does not completely divide the vas. It uses monopolar electrocautery delivered by a Hyfrecator through a re-usable needle. The technique was developed by Marie Stopes International in London (United Kingdom) as a vasectomy technique that could be easily disseminated, particularly in Third World conditions.[133]

Open-ended vasectomy is the technique of leaving the testicular end of the divided vas unoccluded while

occluding the abdominal end. The hypothetical aims of this technique are 1) to prevent or reduce post-vasectomy pain by decreasing back pressure in the epididymis[46] and 2) to allow the formation of a sperm granuloma at the transected testicular end of the vas, which some experts speculate might increase the chance of success of vasectomy reversal.[46, 130] When open-ended vasectomy is performed, FI is used to prevent recanalization.

Challenges in Interpreting the Evidence. The Panel undertook review of the vas occlusion literature with the goal of identifying with a high level of certainty specific techniques that consistently produce occlusive effectiveness. However, the vas occlusion literature suffers from serious methodological flaws that reduce certainty regarding conclusions about the relative efficacy of various occlusion techniques. These flaws include failure to identify whether enrollment is comprised of consecutive or selected patients; failure to obtain at least one PVSA in large percentages of vasectomized men, resulting in incomplete information regarding vasectomy outcomes; lack of information about follow-up protocols; unclear criteria for vasectomy failure; wide variations in follow-up duration; very short periods of follow-up duration and, possibly, failure to report series which had high failure rates. Examples of reports which have uncertain significance are Philp (1984a) and Schmidt (1995).[25, 45] Philp (1984a) reported on a series of 14,047 vasectomies among which six men reported late recanalization with pregnancy. It is not clear from this report exactly how many couples were followed for pregnancy occurrence. In the absence of this information, it is not possible to conclude with certainty that the pregnancy failure rate is 6 in 14,047; the pregnancy failure rate may be higher if pregnancy data was not available for all patients. Schmidt (1995) reported no cases of sperm persistence and no pregnancies in 6,248 vasectomy patients. Because the number of patients who were followed and the timing of follow-up are not detailed in this paper, it is not possible to know whether successful vasectomy occurred in 6,248 men or in some number less than 6,248. Methodologically strong studies of occlusion technique effectiveness that would result in a high level of certainty regarding findings are characterized by the following:

- Randomized controlled trial procedures
- Enrollment of consecutive patients
- Clearly described technique of vas occlusion
- Standardized PVSA protocol
- Clearly described criteria for PVSA failure
- PVSA data on all patients for a minimum of six months post-vasectomy
- Follow-up regarding pregnancy for a minimum of one year after vasectomy
- Studies with sufficient sample size to allow precise estimation of effects

None of the studies reviewed by the Panel met all of these criteria, and only three studies met a majority of these criteria. This resulted in assigning Grade C as the strength of evidence for the body of literature on the efficacy of vas occlusion. Given the limited certainty associated with the use of Grade C evidence, the Panel focused on identifying methods of vas occlusion that produced consistent findings, including acceptably low failure rates, across multiple studies with large numbers of patients. Four methods of vas occlusion that appear to be consistently reliable with regard to contraceptive and occlusive effectiveness were identified: (1) MC with FI and without the use of ligatures or clips on the vas; (2) MC without FI and without the use of ligatures or clips on the vas; (3) open ended vasectomy leaving the testicular end unoccluded while using MC of the abdominal end of the vas and with FI; and (4) the Marie Stopes International method of vasectomy with extended non-divisional electrocautery of the vas. Based on this analysis of the literature, the Recommendations below were created. The Panel acknowledges that, in creating an evidence-based guideline, these Recommendations are necessarily based on the data that are available in the medical literature. The panel recognizes that there may be other techniques of vas occlusion that are reliable in producing occlusive effectiveness, even though detailed reports of the results of such occlusive methods have not been published.

Guideline Statement 7.

The ends of the vas should be occluded by one of three divisional methods:

1. **Mucosal cautery (MC) with fascial interposition (FI) and without ligatures or clips applied on the vas;**
2. **MC without FI and without ligatures or clips applied on the vas;**
3. **Open ended vasectomy leaving the testicular end of the vas unoccluded, using MC on the abdominal end and interposing fascia between the ends;**

OR by the non-divisional method of extended electrocautery. ***Recommendation***

Discussion (Body of Evidence Strength – Grade C; Benefits outweigh risks/burdens). *Reliable Techniques of Vas Occlusion.* The Panel chose to define the acceptable rate of vas occlusion failure as ≤ 1%. In researching the results of vas occlusion techniques, 89 study arms reporting on 126,821 patients were found (see Table 5 below; see text under Discussion sections for citations). Failure of vas occlusion was reported in most of these studies as failure to achieve azoospermia

or in a few studies as failure to achieve azoospermia or RNMS.

The opinion of the Panel is that, for a method of vas occlusion to be recommended, it should have occlusive failure rates which are consistently ≤1% in large numbers of patients across studies conducted by different surgeons. Three divisional techniques that fit these criteria were identified and are recommended by the Panel: (1) MC with FI and without ligatures or clips applied on the vas; (2) MC without FI and without ligatures or clips applied on the vas; and (3) open ended vasectomy leaving the testicular end of the vas unoccluded, using MC on the abdominal end and interposing fascia between the ends. One non-divisional technique also is recommended: non-divisional extended electrocautery. The evidence for these recommendations is described below.

Table 5: Characteristics of Vas Occlusion Studies

Occlusion Technique* *Assumes division/excision as a technique component unless otherwise indicated	**# of Study Arms**	**# of Patients**	**Range of Occlusive Failure Rates**
Recommended Techniques			
Mucosal cautery (MC) of both ends and fascial interposition (FI)	13	18456	0.0% - 0.55%
MC of both ends	6	13851	0.0% - 1.0%
MC of one end; other end open; FI	4	4600	0.0% - 0.50%
*Non divisional extended electrocautery (Marie Stopes technique)	1	41814	0.64%
Optional Techniques for Surgeons with Training and/or Experience That May Produce Acceptable Failure Rates			
Ligation of both ends	31	24797	0.0% - 13.79%
Ligation of both ends and FI	9	2782	0.0% - 5.85%
Clips on both ends	7	4337	0.0% - 8.67%
Other Techniques with Insufficient Evidence			
MC of one end; other end left open	2	171	4.35% - 4.73%
Ligation of one end; other end left open; FI	1	2150	0.00%
MC and ligation of both ends, and FI	1	1379	0.36%
MC and ligation of one end; other end left open; FI	1	61	3.28%
Clips on both ends; FI	1	1073	0.0%
MC and ligation of both ends	3	1220	2.0% - 4.75%
MC and clips on both ends	1	324	0.62%
Ligation of one end; other end left open	1	718	1.11%
Ligation and cautery (non-mucosal) of both ends	1	500	0.40%
Ligation and cautery (non-mucosal) of both ends and FI	1	3867	0.08%
Ligation and cautery (non-mucosal) of one end; other end left open; FI	1	4330	0.02%
One end clipped; other end open	1	262	0.38%
One end ligated; one end open	1	40	2.5%
*Clips only; no excision/division	2	89	0.0% - 2.56%
	Total Study Arms = 89	**Total # Patients = 126,821**	

Definitions and Diagrams:

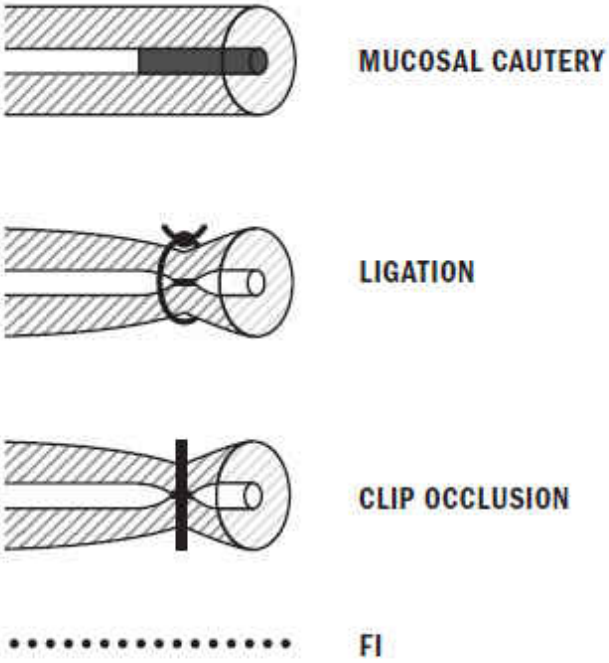
FI fascial interposition

MC mucosal cautery

T testicular end of divided vas

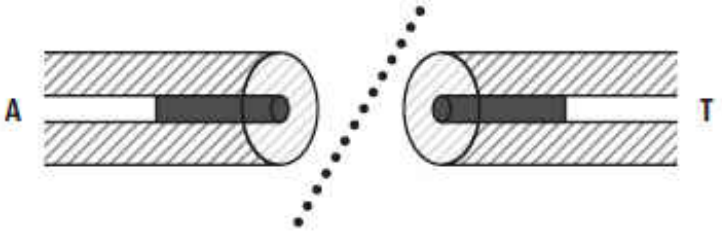
A abdominal end of divided vas

MSI non-divisional extended electrocautery (Marie Stopes International Technique)



Mucosal cautery with fascial interposition. Thirteen study arms evaluated MC of both vas ends and FI to occlude the vas in approximately 18,456 patients.[33, 35-37, 39-41, 43-45, 47, 213, 214] In nine study arms FI was performed over the abdominal end, in two study arms FI was performed over the testicular end and in two study arms the end was not specified. Failure rates for this technique ranged from 0.0% to 0.55%, with most study arms reporting rates of 0.0% failure. Although the majority of these data were from non-randomized observational designs, one study arm was from a high-quality observational study[213] that reported an occlusive failure rate of 0.0% and one technical failure associated with a missed vas. Additional support for the efficacy of MC of both vas ends and FI is provided by Labrecque (2006), which is a secondary analysis of PVSA data from Barone (2004).[215] This paper reported 0% recanalizations with use of this technique. Given the large number of patients evaluated, the overall consistently low failure rates, and the low failure rate from the single high-quality study, the panel judged that this vas occlusion technique is likely to be consistently effective.

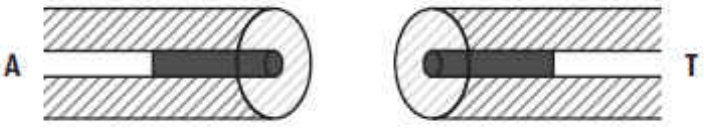
1 MC with FI



Occlusive Failure Range = 0.0–0.55%

Mucosal cautery without fascial interposition. Six study arms (Barone 2004 – 2 arms; Coffman 1974; O'Brien 1995; Philp 1984; Shapiro 1979) evaluated MC of both vas ends but without FI to occlude the vas in approximately 13,851 patients.[26, 32, 42, 46, 213] Failure rates for this technique ranged from 0.0% to approximately 1.0%. Four of the six study arms were from non-randomized observational designs, but two arms were from Barone (2004), the high-quality observational study; these two arms reported an overall failure rate of 1.0% It should be noted that the failures in Barone (2004) all occurred in the Brazil arm which is the only arm of the six discussed here that used division without excision. All of the other study arms both divided the vas and excised a segment. Given the relatively large number of patients evaluated, the consistently low failure rates, and the low failure rate from the single high-quality study, the panel judged that MC without FI also is likely to be consistently effective.

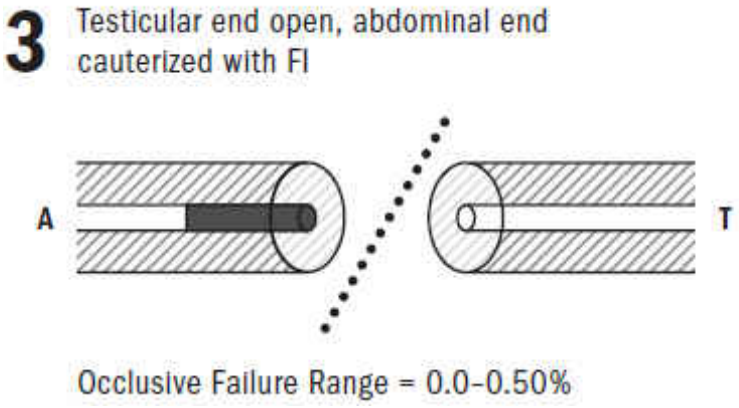
2 MC without FI



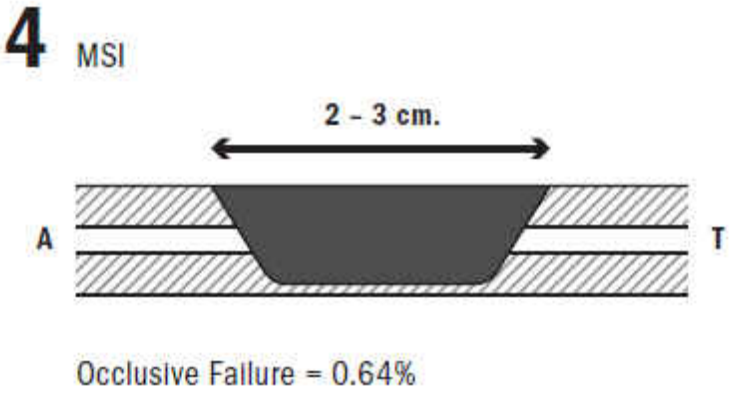
Occlusive Failure Range = 0.0–0.60%

Open ended method leaving the testicular end unoccluded with mucosal cautery of the abdominal end and FI. Four study arms[38, 41, 138, 213] evaluated approximately 4600 men with an open ended method in which the testicular end was left unoccluded, the abdominal end was occluded with MC and FI was performed. Failure rates ranged from 0.0% to 0.50%. One of the three study arms was from Barone (2004), the high-quality observational study, and reported a failure rate of 0.0%.[213] Additional support for leaving the testicular end open, applying MC to the abdominal end and performing FI is provided by Labrecque et al. (2006), which is a secondary analysis of PVSA data from Barone (2004).[215] Labrecque (2006) reported 0% recanalizations with use of this technique. Because of the low failure rates, including the low failure rate from the high-quality study arm, the panel judged that this technique also is consistently effective.

With regard to the same technique of open ended vasectomy with MC but without FI, only two study arms were found. Both study arms were from the same study (Shapiro, 1979), evaluated a total of 171 patients, and reported failure rates of 4.73% and 4.35% in the two arms of the study.[46] The panel judged that, given the available evidence, uncertainty remains regarding the efficacy of open ended vasectomy with MC to occlude the abdominal end without FI. Therefore, the panel does not advocate the omission of FI in performing open ended vasectomy with MC.



Non-divisional vasectomy with extended electrocautery (Marie Stopes technique). One paper reports the findings from a 10-year period at the Marie-Stopes Clinic during which 45,123 vasectomies were performed at more than 20 centers by up to 30 clinicians. PVSAs were obtained on 41,814 patients and revealed 267 early failures (a failure rate of 0.64%) defined as patients whose PVSAs continued to show the presence of sperm and required reoperation.[29] Failure rates ranged from 0.28% to 1.3% across centers that used this method. Given the consistency of low failure rates across many centers and many clinicians as well as the very large number of patients (n=41,814), the panel interpreted these data to indicate that non-divisional vasectomy with extended electrocautery of the vas also is consistently effective.



Guideline Statement 8.
The divided vas may be occluded by ligatures or clips applied to the ends of the vas, with or without fascial interposition (FI), and with or without excision of a short segment of the vas by surgeons whose personal training and/or experience indicate that consistently satisfactory results are achieved with such methods. *Option*

Discussion (Body of Evidence Strength – Grade C; Balance between benefits and risks/burdens uncertain). The Panel has defined consistently satisfactory results as an occlusive failure rate of 1% or less and has focused occlusive technique recommendations on techniques that produced consistently satisfactory results across multiple surgeons and large numbers of patients. The Panel is aware, however, that large numbers of surgeons in the US and elsewhere occlude the vas using ligatures or clips. The available literature reporting on these techniques is characterized by great variability in failure rates, with single surgeons from single institutions reporting satisfactory results (i.e., ≤1.0% failure) and others reporting unacceptably high failure rates. In addition, many studies, including more than half of those that reported on the use of ligation, were published more than 30 years ago and may not reflect the skill level of current surgeons.

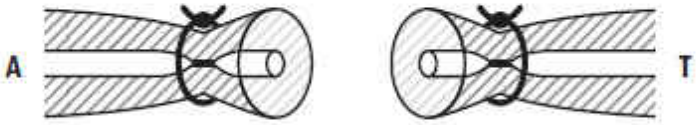
This highly-variable literature is reviewed in the paragraphs below. The Panel interpreted these data to mean, overall, that the balance between benefits and risks/burdens for these techniques is uncertain. However, individual surgeons who have the training and/or experience that produce consistently satisfactory failure rates of 1% or less are justified in using these techniques.

Occlusion of both vasal ends with ligatures without FI. Thirty-one study arms evaluated occlusion by ligatures of both ends of the vas without FI.[23, 26, 28, 31, 35, 36, 43, 47, 111, 117, 118, 120, 122, 124, 125, 127, 129, 135, 140, 164, 204, 216-223]

Failure rates ranged from 0.0% to 13.79%. Specifically, twelve studies reported failure rates of 1.0% or less (including four studies from the US, one from Canada, three from the UK, two from India, one from Australia and one from Brazil). Six studies reported failure rates between 1.0 and 2.0% (including two studies from the US, one from Canada, one from Thailand, one from El Salvador and one from China). Thirteen studies reported rates higher than 2.0%, including five studies that reported rates higher than 5.0% (comprised of one study from the US, two from Mexico, one from the UK and one from Finland). Two of the three highest failure rates were reported in high-quality studies. The only randomized trial (Sokal 2004) reported a failure rate of 12.74%.[223] A single-group design (Barone 2003) with more methodological rigor than most studies (e.g., a clear and complete follow-up protocol and all patients accounted for) reported a failure rate of 11.5%.[204] Labrecque (2006) reported that in the only randomized controlled trial (Sokal 2004) the early recanalization rate for this technique was 25.0% with approximately half of these patients eventually achieving a successful vasectomy after delayed occlusion was detected.[215]

The panel interpreted this wide range of failure rates to mean, overall, that the balance between benefits and risks/burdens of this technique is uncertain. Nevertheless, the Panel recognizes that some surgeons achieve consistently satisfactory results with this technique.

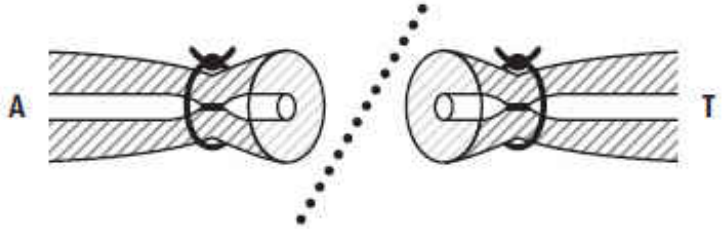
5 Ligation both ends without FI



Occlusive Failure Range = 0.0–13.79%

Occlusion of both vasal ends with ligatures and FI. Nine study arms evaluated the use of ligatures on both ends of the vas in combination with FI. Six study arms reported failure rates of less than 1.0% (including one UK study, one study from Denmark, one study from Africa, one study from the US and one study from New Zealand); five of these six studies reported 0.0% failure rates. The remaining studies reported failure rates of 1.11%, 1.98%, and 5.85%. The high rate of 5.85% was reported in Sokal (2004), the only RCT among the included studies.[223] Because the highest qua lity study also reported the highest failure rate, the Panel interpreted these data to mean that the balance between benefits and risks/burdens for this technique is uncertain but that some surgeons achieve consistently satisfactory results.

6 Ligation both ends with FI

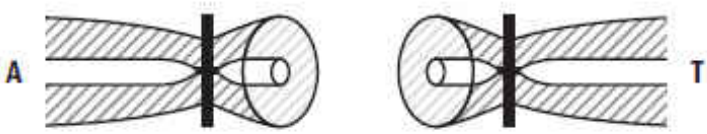


Occlusive Failure Range = 0.0–5.85%

Occlusion of both vasal ends with clips without FI. Seven study arms used clips on both ends of the vas without FI.[38, 40, 112, 122, 136, 224] These studies reported failure rates ranging from 0.0% to 8.67%. Four studies reported failure rates less than 1.0% (including three US studies and one Canadian study), one US study reported a failure rate of 1.18% and the remaining studies (both from Canada) reported failure rates of 5.42% and 8.67%. Again, the Panel interpreted this wide range of failure rates to indicate that, overall, the balance between benefits and risks/burdens of this technique is uncertain but that some surgeons achieve consistently satisfactory results.

The literature review identified only one study that combined clips with FI; 0.0% occlusive failures were reported in 1,073 patients.[225] Given the lack of additional studies using this technique, the reliability of clips combined with FI across surgeons and centers is not known. The opinion of the Panel, however, is that vas occlusion by clips and FI is unlikely to produce higher occlusive failure rates than vas occlusion by clips alone.

7 Clips both ends without FI



Occlusive Failure Range = 0.0–8.67%

Other Occlusive Techniques. Numerous other occlusive techniques or combinations of occlusive techniques with adjunctive methods have been reported (see Table 5), but insufficient evidence was retrieved to address whether these other techniques with or without adjunctive methods produced consistently satisfactory results. In many cases, a particular technique was reported in only a single study by a single surgeon, making it unclear if results would replicate and generalize to other surgeons and settings.

Adjunctive Techniques for Vas Occlusion. The literature was also examined to determine whether adjunctive techniques for vas occlusion are associated with consistently lower failure rates. Insufficient evidence was found to draw conclusions with regard to the techniques of folding back, irrigation of the abdominal end of the divided vas, excision of different lengths of vas segments and FI over the abdominal end compared to FI over the testicular end. With regard to folding back of the vas on itself as a method to separate the ends of the divided vas, the available studies used a variety of occlusive techniques in addition to folding back, making it unclear whether folding back affected failure rates.[23, 47, 124, 127, 129, 130, 140, 216] Due to these inconclusive reports, the Panel cannot make a recommendation for or against folding back as an adjunctive technique for vasectomy. Similarly, it is not clear whether irrigation of the abdominal end of the vas with various solutions enhances sperm clearance rates.[226-231] There also is insufficient evidence to establish the optimal length of vas which should be excised, if any. Although failure is very rare with any occlusive technique when a 5 cm or larger vas segment is excised (e.g., Carlson 1970; Edwards 1973; Labrecque 2003), excising such a long segment requires more extensive dissection of the spermatic cord. The extended dissection may be associated with a higher risk of surgical complications, may make vasectomy reversal more difficult to perform and may make vasectomy reversal less likely to be successful. Most surgeons excise a segment of the vas that ranges from 0.5 to 2.0 cm; the Panel believes that 1.0 cm is an adequate length. In addition, based on the available evidence, there do not appear to be differences in effectiveness when FI is performed over the testicular vs. the abdominal end.

Guideline Statement 9.
Routine histologic examination of the excised vas segments is not required. ***Expert Opinion.***

Discussion. Although there is no evidence for or against routine histologic examination of excised vas segments, the American Urological Association recommended in 1998 and reaffirmed in 2003 and again in 2007 "that physicians in practice and residency training programs no longer require histologic confirmation of the vas deferens as a measurement of vasectomy success" because the PVSA is the determinant of success of the procedure. The panel agrees with the lack of value of histologic examination of resected vas deferens segments as a determinant of success of the vasectomy. At the discretion of the surgeon, it may be helpful to send excised tissues for histological evaluation for confirmation of vasal tissue.

SECTION 6: POSTOPERATIVE PRACTICE
Background Information About Patient Follow-Up and Post-Vasectomy Semen Analysis

PVSA is used to confirm the effectiveness of a vasectomy postoperatively (for definitions, see Table 6). **Vasectomy effectiveness** can be defined as either **contraceptive effectiveness** or **occlusive effectiveness.** The standard definition of contraceptive effectiveness is the absence of pregnancy. The standard definition of occlusive effectiveness is post-vasectomy azoospermia. However, some men fail to achieve azoospermia after vasectomy yet never father a pregnancy. For example, one study (Lemack 1996) found sperm in the semen of 18 of 186 (9.7%) men prior to vasectomy reversal.[232] The average time since vasectomy was 10.7 years and no pregnancies occurred in the partners of these 18 men. Thus the definition of occlusive effectiveness should not be restricted to azoospermia but should include those men whose PVSAs show rare non-motile sperm (RNMS, or ≤100,000 non-motile sperm/mL) and no sperm motility.

Table 6: Definitions for Post-Vasectomy Semen Analysis (PVSA)

Azoospermia: Absence of sperm during microscopic exam of at least 50 hpfs in a single well mixed, un-centrifuged semen specimen.
Rare non-motile sperm (RNMS): Presence of ≤100,000 non-motile sperm/mL based on micro-scopic exam of at least 50 hpfs in a single well mixed, uncentrifuged post-vasectomy semen speci-men assuming no motile sperm are observed
Recanalization: A histologic diagnosis that shows reconnection of the vas ends, either directly or by microcanaliculi, after vasectomy. Recanalization can be suspected clinically based on PVSA results or af-ter an unexpected post-vasectomy pregnancy if a previous PVSA showed azoospermia or RNMS.
Sterility: The inability to cause pregnancy

Vasectomy failure. Vasectomy failure is the occurrence of pregnancy or failure to achieve azoospermia or RNMS after a reasonable period of time following vasectomy. Vasectomy failure may be a *technical*

failure resulting from a surgical error such as occluding one vas twice without occluding the other vas or failure to identify the very rare situation of vas duplication on one side. *Technical* failure is characterized by persistently normal or nearly normal motile sperm counts and sperm motility after vasectomy. Vasectomy failure also may result from *recanalization* at the vasectomy site.

Recanalization following vasectomy should be suspected if motile sperm or rising sperm concentrations are seen after a routine PVSA has shown azoospermia or RNMS. Recanalization can be either transient or persistent based on the results of serial PVSAs. It is impossible to know the true incidence of late recanalization because PVSA is rarely repeated after a PVSA shows azoospermia or RNMS. Pregnancy due to recanalization is estimated to occur after approximately 1 in 2000 vasectomies or less often.[25-28,31] The incidence of recanalization is very likely greater than the reported rate of pregnancy after post-vasectomy azoospermia because not all recanalizations result in pregnancy.

PVSA Principles. Controversies in the timing, technique, reporting and significance of PVSA include the following:

- When the first PVSA should be done
- Number of PVSAs which should be done
- Necessity for the PVSA to be performed on a fresh specimen
- Necessity for centrifugation of the specimen
- Reliability of PVSAs sent for analysis by mail
- Reliability of PVSA home test kits
- Criteria of vasectomy success defined by absolute azoospermia or the presence of RNMS
- Volume of semen which should be examined
- Number of semen aliquots which should be examined
- Number of high power fields which should be examined

The aim of a PVSA is to confirm occlusive effectiveness and to advise a patient that he can safely rely on his vasectomy for contraceptive purposes. Practical principles relevant to PVSA are as follows:

- The PVSA protocol should be as simple as possible to encourage patient compliance
- The PVSA should allow for confirmation of occlusive effectiveness as soon as possible after vasectomy while simultaneously minimizing the number of PVSAs required to document occlusive effectiveness
- The PVSA protocol should confirm occlusive effectiveness with the highest possible level of certainty
- Patients should be informed that post-vasectomy pregnancies are rare but have been documented even after multiple serial PVSAs reveal azoospermia

Considering these principles, a vasectomy should be considered successful as soon as a PVSA confirms that the risk of pregnancy is sufficiently low to allow the patient to rely on the vasectomy alone for contraception. Conversely, a vasectomy should be considered a failure – or not yet a success – when a man needs to use another contraceptive method or needs to repeat the surgical procedure before relying on his vasectomy.

Sperm Clearance After Vasectomy. Sperm clearance after vasectomy is time dependent with both large inter-individual variations as well as variability across published reports, including those that used the same vas occlusion technique. Inter-individual variation may result from differences in reproductive anatomy and possibly patient age. Sperm may persist in the ejaculate for many months after vasectomy. Such persistence may be due to residual sperm in the seminal vesicles or ampullae of the vasa,[233] recanalization, or, very rarely, a failure to have performed the vasectomy on one vas. The main reason for the presence of non-motile sperm is probably that residual sperm in the seminal vesicles or ampullae of the vasa are slowly released from the reproductive tract.[233] There are wide variations in the clearance of residual sperm in the seminal vesicles or ampullae of the vasa among men due to differences in the anatomic structures.[233] However, in most men, either no sperm or only small numbers of non-motile residual sperm in the PVSA are seen at three months or later after vasectomy. Nevertheless, some men continue to have sperm or sperm parts in the semen for as long as 31 years post-vasectomy.[232, 234]

With regard to age, several studies have suggested that sperm clearance may take longer in older men compared to younger men.[10, 15, 218, 235, 236] For example, Marshall and Lyon (1972) reported that younger patients may achieve azoospermia with fewer ejaculations than older patients.[237] Marwood (1979) reported that the frequency of ejaculation affected time to azoospermia more in older than in younger men, with a frequency of three times a week associated with rapid clearance regardless of age.[238]

The published literature also contains mixed results regarding the relationship between sperm clearance and number of ejaculations. After 10 ejaculations, rates of azoospermia ranged from 43% to 50%.[34, 214, 239] After 12 ejaculations, rates of azoospermia have

been reported as 66%[237] and 88%.[240] However, one study with relatively complete follow up showed that only 44% of patients were azoospermic after 20 ejaculations.[204] Many practitioners recommend that the first PVSA should be done after 20 ejaculations. The opinion of the Panel is that rates of azoospermia related to number of post-vasectomy ejaculations are too variable to be useful in determining when to do the first PVSA.

Variability across published reports in sperm clearance rates may result from surgical technique used to occlude the vas; differences in criteria for vasectomy success (e.g., one, two or three azoospermic specimens); variations in PVSA laboratory techniques and reporting; small sample sizes in some studies and varying time points at which PVSA was performed. In addition, in many studies, although patients were instructed to report at specific intervals post-vasectomy, some report at later intervals. This inconsistency between requested PVSA timing and actual PVSA timing creates uncertainty regarding true sperm clearance rates because not all articles clearly indicate when patients actually returned for PVSAs. In addition, in most studies about a third of patients do not return for the requested PVSAs.[241] The lack of complete follow-up data also creates uncertainty regarding true sperm clearance rates.

Another source of variation in the proportion of men achieving azoospermia is variation in the laboratory techniques used for PVSA and for reporting of PVSA results. Rigorous semen examination including centrifugation and examination of hundreds of microscopic fields is likely to find more sperm than less rigorous laboratory techniques. If the physician sends PVSA specimens to a commercial laboratory, the physician should request that the laboratory perform the PVSA without centrifugation because centrifugation may reduce or eliminate sperm motility (see below). The physician should also request the laboratory to report both the presence or absence of sperm and the presence or absence of sperm motility. If only non-motile sperm are present, the physician should request the laboratory to report the number of non-motile sperm per mL. If no sperm are found in the uncentrifuged specimen, then ideally the laboratory should report that the presence of sperm is "below the limit of detection," although most laboratories report "azoospermia" in this situation.

Clearance of motile sperm. Clearance of motile sperm is much more rapid than clearance of non-motile sperm. Older studies suggest all motile sperm disappear within three weeks after vasectomy.[242, 243] More recent studies confirm that when MC and FI are combined to occlude the vas, essentially all motile sperm have disappeared by five to six weeks[215] with only 1% of men continuing to show motile sperm.[239] At 7 to 14 weeks, this proportion drops to 0.4% and by more than 14 weeks post-vasectomy, no motile sperm were observed.[239]

Numerous studies have reported the reappearance of nonmotile sperm[28, 244-246] and even motile sperm[22, 28, 35, 42, 237, 244, 247] after azoospermia was confirmed, with most studies reporting this phenomenon in small numbers of patients (i.e., < 1%). However, it should be noted that many patients in these studies did not return for PVSAs or did not return for a second PVSA when requested, making the true rates of sperm reappearance (both motile and non-motile) unclear.

PVSA Analytic Techniques: Centrifugation of semen samples for PVSA is unnecessary. Laboratory techniques, especially centrifugation, influence the presence or absence of azoospermia observed in a PVSA. Over the past two decades, data suggest that centrifugation leads to the identification of more men with small numbers of sperm. This means that correspondingly fewer men are reported with azoospermia, leading to increased follow-up testing and more repeat vasectomies, some of which may not be necessary. [248]

The British Andrology Society and the 1992 (3rd edition) and 1999 (4th edition) of the *World Health Organization laboratory manual for the examination of human semen and sperm-cervical mucus interaction* specifically recommended centrifugation of azoospermic semen samples as part of the routine post-vasectomy semen analysis. [249] However, centrifugation is not necessary to confirm that only rare non-motile sperm are present. The 2010 (5th edition) *WHO laboratory manual for the examination and processing of human semen* suggests relying on careful examination of an uncentrifuged specimen, similar to a recent PVSA protocol proposed by Korthorst (2009).[225, 250] The 2010 (5th edition) WHO laboratory manual states in Section 2.10.3, page 46, "When motile spermatozoa are sought (e.g., in a post-vasectomy semen sample), diluting the specimen in fixative or high-speed centrifugation of spermatozoa must be avoided."[250] Steward et al. (2008) examined uncentrifuged azoospermic semen specimens compared with centrifuged specimens (n=2014 samples) and concluded that uncentrifuged semen analysis is a reliable method of identifying samples with > 100,000 sperm/ml.[251] The sensitivity of the uncentrifuged sample was 99.3% and the negative predictive value was 99.8%.

Because centrifugation may interfere with sperm motility[250] and clinically relevant numbers of sperm can be identified without centrifugation, a surgeon should request a clinical laboratory not to perform centrifugation for a PVSA.

Office examination of uncentrifuged post vasectomy semen samples. In the US, CDC regulations implementing the 1988 Clinical Laboratory Improvement Act (CLIA) (42 CFR 493.19) distinguish provider-performed microscopy (PPM) analysis from that in laboratories performing tests of high complexity. These regulations allow for semen analysis in a doctor's office, i.e., "provider performed microscopy," as long as the reported result is qualitative, i.e., "limited to the presence or absence of sperm and detection of motility."* Thus US physicians are permitted to conduct PVSA in their offices, but they are not allowed to determine sperm concentration unless the office laboratory has a high-complexity level of CLIA certification. There is now interest in developing a method of estimating the number of sperm per mL of semen from the number of sperm per Hpf found in a PVSA. Such a method would allow vasectomy surgeons to correlate the number of sperm per Hpf in PVSAs which do not show azoospermia to various concentrations of sperm/mL.

Self-PVSA Testing. A self-PVSA home test has been approved by the FDA and is available for clinical use. This test is sensitive to sperm counts >250,000/ml,[252] but the test does not assess for sperm motility. If two tests are performed and both are negative, then the negative predictive value of a sperm count >250,000 sperm/mL is 99.9%, but the 250,000 sperm/mL cut-off is higher than the most commonly cited cut-off in the literature of 100,000 non-motile sperm/mL to declare a vasectomized man sterile . Furthermore, no other studies have shown that clearing men at this cut-off without evaluating for motility is reliable enough to recommend discontinuation of contraception, and no studies have followed patients who used the test to assess for the risk of unanticipated pregnancy. In addition, it has been suggested that a home PVSA test might increase patient compliance with PVSA instructions, but improved patient compliance has not yet been studied or proven.

Because the test results are read by the patient, the surgeon must instruct the patient on all aspects of the test prior to its use. To avoid potential legal problems, careful instruction is essential to ensure that the patient will use the test in a valid manner. The disclosures must include how to set up the test, how to read the final result and the relative risks of pregnancy. Given this requirement and the lack of long-term follow-up data on patients who have used the test, the opinion of the Panel at this time is that, although this test may have potential value that may be proven in the future, there are insufficient data for the panel to come to a conclusion regarding its use in clinical practice.

Guideline Statement 10.
Men or their partners should use other contraceptive methods until vasectomy success is confirmed by post-vasectomy semen analysis. ***Clinical Principle***

Discussion. During the first few weeks after vasectomy, sperm that are left in the male reproductive system on the abdominal side of the vasectomy site may retain the ability to fertilize an ovum.[239, 242, 243] Semen analysis after vasectomy is very strongly advised because it provides assurance for the patient and his partner that the risk of future pregnancy is very low, and it provides a continuing measure of quality control for the physician.

Guideline Statement 11.
Eight to sixteen weeks after vasectomy is a reasonable time range for the first post-vasectomy semen analysis (PVSA). The choice of time to do the first PVSA should be left to the judgment of the surgeon. ***Option***

Discussion (Evidence strength – Grade C; benefits and risks/burdens balanced).

Discussion. The choice of time to do the first PVSA should be left to the judgment of the surgeon. It is desirable to select a time for the first PVSA that will minimize the number of PVSAs needed to establish that azoospermia or RNMS has been achieved but still allow men to abandon other forms of contraception as soon as possible after vasectomy. The longer the time period before the first PVSA, the better the chance that the PVSA will show azoospermia or RNMS, but the longer the time that the patient must use another method of contraception. Motile sperm disappear within a few weeks after successful vasectomy.[215, 239, 242, 243] Performing the first PVSA earlier than 12 weeks may allow some men to rely on their vasectomy for contraception sooner than if the first PVSA is done at 12 weeks or later. However, if the first PVSA is performed before 12 weeks post-vasectomy, more men will have to submit additional samples for PVSA to confirm the success of the procedure if the initial sample contains motile sperm or >100,000 non-motile sperm/ml.

While rates of sperm clearance vary across studies, including studies that used the same vas occlusion technique, the available literature indicates that, in general, the proportion of men who achieve azoospermia or RNMS after vasectomy increases with time. Eleven study arms from nine studies reported rates of azoospermia at eight weeks post-vasectomy.[23, 35, 37, 118, 150, 223, 253-255] Azoospermia rates ranged from 30.0% to 88.5% with six studies reporting rates above 80%.

Sixteen study arms reported azoospermia rates at 12

*The Code of Federal Regulations: 42CFR493, Section 493.19(c) contains the current list of provider-performed microscopy (PPM) procedures, accessed February 13,2011 at: http://wwwn.cdc.gov/clia/ppm.aspx

weeks post-vasectomy.[23, 35, 37, 118, 204, 213, 219, 223, 227, 244, 245, 253-255] Rates ranged from 48.0% to 99.0% with eight study arms reporting rates of 90.0% or above and ten study arms reporting rates of 80.0% or above. The lowest rate of 48.0% was reported in the randomized controlled trial (RCT)[223] in a group of men who underwent vas occlusion by ligation (value estimated from Kaplan-Meier graph).

Thirteen study arms reported azoospermia rates at six months post-vasectomy.[23, 111, 117, 118, 121, 204, 213, 217, 221, 223, 255, 256] Rates ranged from 61.5% to 99.6% with five study arms reporting rates of 90.0% or above and ten study arms reporting rates of 80.0% or above. The low rate of 61.5% was reported by Barnes (1973) in a group of men who underwent vas occlusion by ligation.[117]

Given the potential confounders to interpretation discussed in the Vas Occlusion section of this Guideline, it is not clear if vas occlusion technique affects the rate of achieving azoospermia. Of the six studies that reported azoospermia rates above 80% at eight weeks, four used ligation, one used MC and FI and one used ligation and FI. It is worth noting, however, that the methodologically strongest study in this group (the Sokal 2004 RCT) reported relatively low rates of 30.0% and 48.0% at eight weeks (estimated from Kaplan-Meier graphs) in patients who underwent vas occlusion by ligation without and with FI, respectively, with the higher rate in the group that had FI.

Similarly, of the eight study arms reporting azoospermia rates of 90.0% or above at 12 weeks, one used MC and clips, one used MC and suturing of the testicular end, three used ligation of both ends, one used MC and FI, one used ligation of both ends and FI and one reported on a mixed group of techniques (Barone 2004; MC with or without FI and MC only).[213] Of the five study arms reporting azoospermia rates of 90.0% or higher at six months, three used ligation, one used ligation of both ends and FI, and the third study reported on mixed techniques (Barone 2004).[213]

Additional useful information regarding the potential influence of vas occlusion technique is provided by Labrecque et al. (2006), which is a secondary analysis of serial PVSA data from Barone (2004) and Sokal (2004).[215] The authors document the presence of motile sperm and note that when thermal MC and FI were used, all motile sperm cleared by six weeks post-vasectomy. When mucosal electrocautery without FI was used, all motile sperm cleared by 10 weeks post-vasectomy. When ligation alone was used, 5 to 10% of tested men continued to exhibit motile sperm at periods up to 26 weeks post-vasectomy. When FI was combined with ligation, 1 to 4% of men continued to exhibit motile sperm at up to 26 weeks post-vasectomy.

Because the majority of studies reporting azoospermia rates at 12 weeks post-vasectomy indicated that 80% or more of men had achieved this goal, the Panel interpreted these data to indicate that at 12 weeks most men will be azoospermic or will meet the RNMS criterion. In addition, Barone et al. (2003) found that a 12-week time period was a more reliable parameter for vasectomy success than a specific number of ejaculations (e.g., 20).[204] WHO incorporated this finding in its 2004 guideline and now recommends a waiting period of three months.[257] With regard to the influence of vas occlusion technique on the time to achieve azoospermia or RNMS, the Panel notes that one study[215] demonstrated that the fastest motile sperm clearance rates occurred when MC was combined with FI, and the slowest rates occurred when ligation was used. This study provides additional information that may be considered by the surgeon in the decision regarding when to request the first PVSA.

Guideline Statement 12.
To evaluate sperm motility, a fresh uncentrifuged semen sample should be examined within 2 hours after ejaculation. ***Expert Opinion***

Discussion. WHO guidelines (2010) recommend that semen analysis to assess motility should be done within 60 minutes of ejaculation when the semen sample is provided in the laboratory facility.[250] If a man is unable to ejaculate at the clinic, then delivery of a semen sample to the laboratory should be within one hour of ejaculation so that the motility assessment can occur during the second hour after ejaculation. Semen samples should be transported at ambient temperatures, i.e. between 20° and 37°C. In most semen samples, sperm motility does not decrease between one and two hours post-ejaculation.[258]

Some clinicians recommend, for convenience and compliance reasons, that PVSA specimens can be sent by mail (following regulations regarding shipping biohazards). This approach is adequate to assess only the presence or absence of sperm. Motility cannot be evaluated reliably in a semen sample produced more than two hours before microscopic examination.

Guideline Statement 13.
Patients may stop using other methods of contraception when examination of one uncentrifuged fresh post-vasectomy semen analysis (PVSA) shows azoospermia or only rare non-motile sperm (≤100,000 non-motile sperm/ mL). ***Recommendation***

Discussion ***(Evidence Strength – Grade C; Benefits outweigh risks/burdens)*****.** Both azoospermia and

RNMS are acceptable criteria for vasectomy success. The definition of RNMS used in the medical literature has varied from more than 0 to less than 1 million/mL, but the most commonly used definition of RNMS is ≤100,000 per mL.[249, 259]

Several studies show that the risk of pregnancy associated with the presence of ≤100,000 non-motile sperm/Hpf is very low and similar to the risk when sperm are absent. Absence of sperm motility appears to be a robust criterion to indicate occlusive effectiveness. Edwards (1993) reported routine testing of men at three to four weeks after vasectomy using MC and FI and provided clearance based on the absence of motile sperm.[239] Among 3,178 vasectomized men, two pregnancies were documented. One man had an apparent late recanalization; the other had not returned for a PVSA. This pregnancy rate is not significantly different from the risk of about 1 in 2,000 after documented azoospermia on two consecutive semen analyses, based on data from the Elliot Smith Clinic,[25-27] from Marie Stopes International,[29] and from large case series reports.[28] Even in men with some motile sperm, risk of pregnancy appears to be low if the concentration of motile and non-motile sperm is ≤100,000/mL. In a WHO study of a hormonal male contraceptive, 8.1 pregnancies/100 person-years were observed in men with 100,000 to 3 million sperm/ml (motile and nonmotile) and 0 pregnancies/100 person-years in men with 0 to 100,000 sperm/ml (motile and nonmotile).[260] Contraceptive failure (pregnancy) after declaration of vasectomy success is a rare event despite the reappearance of nonmotile sperm,[42, 232, 246, 261] and even motile sperm[22, 35, 247] after azoospermia was confirmed.

Philp et al. (1984) proposed a method for defining when a patient who has persistence of small numbers of non-motile sperm in the PVSA can rely on vasectomy alone for contraception.[25] They analyzed data from 16,796 patients at the Elliot Smith Clinic in Oxford (United Kingdom). About 4,500 vasectomies were performed with ligation and excision between 1970 and 1974, and about 12,300 vasectomies were performed with MC but not FI after 1974. Philp et al. (1984) used the term "special clearance" to determine when a man whose PVSA showed RNMS could be informed that he is sterile. They defined three criteria for "special clearance:" (1) a level of 10,000 sperm/mL or less in two consecutive semen exams, (2) no motile sperm and (3) at least seven months post-vasectomy. However, the method of semen analysis at the Elliot Smith Clinic has not been reported, except for the information that patients provided semen samples by mail, which precludes an examination for motility. Nonetheless, subsequent reports from this clinic have confirmed a lack of pregnancies among men with only rare sperm.[27, 42]

Korthorst et al. (2009) reported prospective findings from 1,073 men who underwent vas occlusion by clips and FI.[225] Using the threshold of <100,000 non-motile sperm/mL in accordance with the recommendations of the Dutch Urological Association,[259] men were cleared if they met this criterion in a single sample at 12 weeks or later. No pregnancies were reported among 481 men who had had < 100,000 non-motile sperm, with a median follow-up of 14 months. Based on data from Haldar et al. (2000), most recanalizations occur during the first year post-vasectomy.[262] Therefore, Korthorst's results would seem unlikely to change with longer follow-up.

The opinion of the Panel is that both azoospermia and ≤100,000 non-motile sperm/mL are reliable indicators of vasectomy success.

Guideline Statement 14.
Vasectomy should be considered a failure if any motile sperm are seen on post-vasectomy semen analysis (PVSA) at six months after vasectomy, in which case repeat vasectomy should be considered. ***Expert Opinion***

Discussion. When the vas is successfully occluded, motile sperm disappear by a few weeks after vasectomy.[215, 239, 242, 243] The presence of motile sperm at 6 to 12 weeks after vasectomy indicates that recanalization has occurred or that there was a technical failure in vas occlusion. However, vasectomy should not be repeated immediately if motile sperm are found on PVSA prior to six months after vasectomy. Additional PVSAs should be performed at intervals of four to six weeks for up to six months after vasectomy for further evaluation. Motile sperm may represent a risk of pregnancy and indicate the need for continued use of another contraceptive method, further PVSA testing and, if persistent, repeat vasectomy. However, approximately 30% to 50% of men with recanalization eventually achieve azoospermia or RNMS over a period of six months after vasectomy due to fibrosis of the vas and occlusion of the recanalization.[22, 223] These men continue to have effective occlusion on long term follow-up.[22] Therefore, the decision to repeat the vasectomy should not rely on a single semen analysis showing motile sperm within six months after vasectomy. Repeat vasectomy should be done if the number of motile sperm increases in subsequent semen analyses or if motile sperm persist for >6 months after vasectomy. There are no data to suggest that delayed occlusive success occurs in men who still have any motile sperm in a PVSA at six months after vasectomy.

Guideline Statement 15.
If >100,000 non-motile sperm/mL persist beyond six months after vasectomy, then trends of serial PVSAs and clinical judgment should be used to decide whether the vasectomy is a failure

and whether repeat vasectomy should be considered. ***Expert Opinion***

Discussion ***(Evidence Strength – Grade C; Benefits outweigh risks/burdens)***

If non-motile sperm are present on the first PVSA in the surgeon's office, one or more repeat PVSAs should be performed in the surgeon's office laboratory to determine if azoospermia develops over time. If azoospermia is not achieved by six months after vasectomy, then a PVSA should be performed in a laboratory approved for high complexity semen testing. If the PVSA shows <100,000 non-motile sperm/mL and no motile sperm, then the couple may stop using other methods of contraception.

If the PVSA shows > 100,000 non-motile sperm/mL or any motile sperm, then further PVSA monitoring or repeat vasectomy may be considered. The Panel's opinion is that the decision to consider vasectomy a failure if >100,000 non-motile sperm/mL persist should be based on clinical judgment that includes the trend of sperm counts, the patient's preferences and the patient's tolerance for the risk of pregnancy.

Additional Important Points of Postoperative Practice.

After completion of a vasectomy, physicians should consider giving men a specific appointment for the first PVSA to improve compliance with follow-up. Based on 46 published studies reviewed in 49 papers, a median of 78% (range 33-100%) of men return for a single PVSA and a median of 73% (range 21-100%) are fully compliant with PVSA study protocols.[13, 22-28, 30, 34, 37, 38, 52, 111, 114, 117, 118, 121, 123, 150, 161, 204, 213, 214, 217, 219, 224, 234, 237-246, 253, 256, 263-269] Compliance rates varied greatly across studies and might be lower in clinical practice than in published studies. In the largest cohorts that appear typical of North American vasectomy practice, only about two thirds of men (between 55% and 71%) return for at least one PVSA.[28, 30, 38, 224, 241, 269]

The number of tests requested (one or two) and the time at which samples were requested (one to two months vs. three to four months) do not appear to make a significant difference in compliance rates. When the second test was requested at three to four months post vasectomy, rates of full compliance were decreased somewhat compared to protocols where two tests were ordered within two months.[270]

One randomized controlled trial including 228 men evaluated the effectiveness of scheduling an appointment for the first PVSA versus simply asking men to return at two months post-vasectomy. In the appointment group 84% of men returned for semen analysis versus 65% in the no appointment group.[271]

The Panel suggests that the practice of scheduling a follow-up PVSA appointment should be left to the judgment of the individual clinician.

A postoperative visit with the surgeon specifically for physical examination of the scrotum is not routinely necessary. The results of the PVSA and/or the need for one or more additional PVSAs can be conveyed by telephone or other modes of communication. When giving PVSA results, men should be reminded that no contraceptive method, including vasectomy, is 100% effective. At this time, patients should be informed that there is always a remote risk of pregnancy even if azoospermia has been achieved. Each patient should know that if his partner becomes pregnant, he may have experienced a rare vasectomy failure and should return to his surgeon for a semen analysis. Even if a PVSA at such a time reveals azoospermia, a transient recanalization may have occurred with the subsequent disappearance of sperm from the semen, as shown by DNA studies on parents and the child in such situations.[272]

Most men whose partners become pregnant after vasectomy have motile sperm in the semen, but some are found to be azoospermic on multiple examinations following identification of the pregnancy. If a man reports that his wife has become pregnant and his semen analysis reveals azoospermia, then the physician should inform him that the pregnancy could have been due to a previous transient recanalization, i.e., a vasectomy failure, despite the semen analysis results. A number of case reports have confirmed paternity based on genetic testing even though the men previously had multiple semen analyses showing azoospermia, i.e., sperm counts below the limit of detection.[272-274] Patients may be informed that genetic analysis to document paternity is available.

SECTION 7: FUTURE RESEARCH DIRECTIONS

One purpose of a systematic review is to illuminate deficits in the scientific knowledge base, the amelioration of which would move the field forward and allow for advances in clinical care. The Panel identified the following areas for future research efforts.

<u>Preoperative Evaluation and Counseling</u>

- Identification of the information most important to patients and partners during and after the decision-making process and, in particular, the type of information and information presentation that is most effective to gain the patient's attention, maximize understanding and minimize post-procedure regret and dissatisfaction. One recent study addressed the value of a patient decision aid before and after

the procedure and concluded that it was helpful in both a comprehensive and an abridged version.[275]

- The percentages of couples who select vasectomy vs. tubal ligation when fully informed regarding both options. This information is central to understand the extent to which the relative under-utilization of vasectomy in the US is a function of lack of understanding of the procedure.
- The selection of vasectomy or tubal occlusion depending upon whether the patient/couple sees a gynecologist or urologist first.
- Whether rates of dissatisfaction and/or regret are related to the inclusion of the spouse or partner in the preoperative counseling process.
- Do men and partners of men considering vasectomy believe that vasectomy is a family or an individual decision?

Anesthesia

- Pain levels (measured with visual analog scales) associated with the use of smaller gauge vs. larger gauge needles for local anesthesia administration, with the use of a mini-needle technique (30-32 gauge needle with 3 cc xylocaine) compared to the Li anesthetic block technique (25-27 gauge needle with 10 cc xylocaine) and the use of mini-needles compared to jet injection.
- Whether or not topical anesthetic cream application before injection of local anesthetic reduces the amount of pain (measured by a visual analog score). If the pain of local anesthetic injection is reduced, the extent to which topical anesthetic cream before local anesthetic injection reduces the pain of injection as well as the pain of the vasectomy.
- Pain level during local anesthesia administration as opposed to during the vasectomy procedure itself.
- Whether or not application of a topical cutaneous spray such as ethyl chloride, cocaine or other products prior to injection of local anesthetic reduces the pain of injection.

Vas Isolation

- Whether pain is reduced when an NSV or MIV vas isolation technique is used compared to a conventional technique.
- Intraoperative and post-operative pain levels and surgical complications (e.g., at one, two and four weeks) with an MIV technique compared to a conventional vasectomy.
- The incidence of failed vasectomy with use of a single midline incision compared to bilateral incisions.
- Information regarding how the technical skills required to perform NSV are learned and translated into practice and to what extent practitioners reporting that they perform NSV are adhering to each of the requirements of the technique.
- The incidence of early post-vasectomy scrotal hematoma and abscess formation according to the method of vas isolation.

Vas Occlusion

- Methodologically robust (e.g., well-designed prospective observational studies and RCTs) are needed of large cohorts in developed countries that compare occlusive techniques with regard to surgical complication rates, post-vasectomy pain and occlusive and contraceptive effectiveness at short-, medium- and long-term follow up points.
- Evaluation of the effectiveness of thermal cautery vs. electrocautery for vas occlusion.
- RCTs to evaluate the occlusive effectiveness and complication rates associated with cautery and FI vs. cautery alone, open versus closed testicular end with FI and cautery of the abdominal side and complications including anti -sperm antibodies.
- Reliable techniques for applying cautery to the vasal mucosa and avoid damage to the vasal muscularis .
- Information regarding the potential value and possible complications from the addition of folding back to any technique.
- Whether postoperative bleeding complications are more common if FI is performed than if FI is not performed.
- The development of percutaneous occlusion techniques.

Post-Vasectomy Follow-up

- More rigorous study of the prevalence of azoospermia and RNMS related to the method of vas occlusion at various time intervals after vasectomy (e.g., at weeks 6, 9, 12, 16, 20 and 24).
- Study of why some men have RNMS for substantial intervals post-vasectomy (e.g., three, six, nine months) while others do not.
- Information about the prevalence of paternity at various post-vasectomy time intervals as long as 5 to 10 years.
- Contraceptive effectiveness at different PVSA

thresholds (including varying levels of RNMS).

- Whether the PVSA thresholds of commercially available home test kits are sufficient to ensure contraceptive effectiveness.
- How couples who desire to have more children after a vasectomy choose between vasectomy reversal and sperm retrieval with IVF/ICSI and the percentage of couples choosing each technique.
- Comparisons of PVSA results when the analysis is done by physicians in office laboratories certified for provider performed microscopy compared to results of commercial laboratories certified for high complexity testing.
- Comparison of the number of sperm/HPF between standard light microsopy and phase contrast microsopy.
- Patient preferences for the timing of PVSA with regard to achieving earlier clearance vs. the need for more than one PVSA.
- Investigations of post-vasectomy testicular changes (i.e., histologic changes in the seminiferous tubules and in spermatogenesis, electron microscopic changes of interstitial fibrosis) and how they may correlate with both post-vasectomy antisperm antibody status and with vasectomy reversal outcomes.

The incidence of serum antisperm antibodies as determined by immunoglobulin A, G and M testing after vasectomy and how they affect fertility rates after vasectomy reversal and after sperm retrieval with IVF/ICSI (including sperm surface antibody studies in seminal plasma after vasectomy reversal).

Complications

- Methodologically rigorous studies to provide accurate rates of early post-vasectomy hematoma, wound infection and scrotal abscess formation.
- Studies that distinguish between post-vasectomy pain due to epididymal congestion or epididymal sperm granuloma (resulting from rupture of the epididymal tubule caused by back pressure below the level of the vasectomy) vs. pain due to true bacterial epididymitis.
- Studies of various imaging modalities that allow the accurate diagnosis of the cause of post-vasectomy epididymal pain.
- Incidence of chronic post-vasectomy pain according to standardized scales starting at three to six months and continuing until up to three to five years post-vasectomy.
- Incidence of chronic pain of differing severity, the percentage of patients who feel that their quality of life has been impacted by the pain, the percentage of patients who seek medical help for relief of such pain, the percentage who undergo some type of surgical procedure for pain relief and the success rate of the various procedures for relieving the pain.

Table 2: Abbreviations

Table 2: Abbreviations	
ASA(s)	anti-sperm antibodies
AUA	American Urological Association
cc	cubic centimeter
CHD	coronary heart disease
CI	confidence interval
CLIA	Clinical Laboratory Improvement Act
Cm	Centimeter
CV	conventional vasectomy
D/E	division with or without excision of a vas segment
ES	evidence strength
FI	fascial interposition
FSH	follicle-stimulating hormone
Hpf(s)	high power field(s)
ICSI	intracytoplasmic sperm injection
IVF	in vitro fertilization
LE	ligation and excision
LH	luteinizing hormone
MIV	minimally invasive vasectomy
mL	Milliliter
Mm	millimeter
MSI	Marie-Stopes International
NSV	no-scalpel vasectomy
OR	odds ratio
PPA	Primary Progressive Aphasia
PPM	provider-performed microscopy
PVSA	post-vasectomy semen analysis
RCT	randomized controlled trial
RNMS	rare non-motile sperm
RR	relative risk
uL	Microliter
US	United States
VAS Scale	visual analog scale
WHO	World Health Organization

APPENDIX A: THE NO-SCALPEL VAECTOMY (NSV) TECHNIQUE*

For the NSV technique, a single upper scrotal midline skin opening is used. The surgeon uses a three finger approach to immobilize each vas, one at a time, at the site of the intended single upper scrotal midline opening. To perform the three finger method of vas immobilization, the right-handed surgeon stands on the patient's right side. The surgeon places his or her left thumb and index finger on the midline scrotal raphe just below the penoscrotal junction or midway between the penoscrotal junction and the top of the testes. The surgeon then places his or her left middle finger behind the vas on the posterolateral scrotal skin and uses the middle finger to sweep or push the vas towards the thumb and index finger at the midline scrotal raphe. In this way, the vas is placed just underneath the upper midline of the anterior scrotal skin. The surgeon uses his or her thumb and index finger to flatten and stretch the skin tightly over the vas at this position where the skin opening will be made. A similar three finger technique is used to immobilize the left vas at the position of the skin opening in the anterior midline scrotal raphe. For the right-handed surgeon operating from the patient's right side, the surgeon must reach across the genitalia and curl his or her left hand around the scrotum to place the middle finger behind the left side of the scrotum and the thumb and index finger on the midline scrotal raphe.

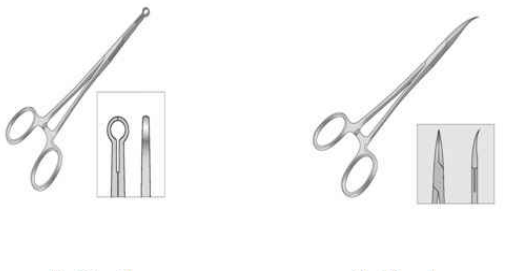
Once the vas has been immobilized in the midline scrotal raphe using the three finger technique, local anesthetic is delivered to raise a skin wheal in the midline scrotal raphe, and additional local anesthetic is delivered in the direction of the inguinal ring, parallel to the vas and under its sheath. Then the skin wheal should be pinched gently for a few seconds to reduce its thickness so that the vas ring clamp can be applied more easily. The vas ring clamp with an internal diameter of 3.0, 3.5 or 4.0 mm is placed around the tightly stretched skin, subcutaneous tissue, peri-vasal tissue and vas. The diameter of the vas ring clamp is chosen according to the thickness of the scrotal skin.

With the vas immobilized in the vas ring clamp, one tip of the vas dissector, which is a modified curved hemostat with very sharp tips, is used to pierce the skin, subcutaneous tissue, vasal sheath and superficial part of the vas muscularis. Then, both tips of the vas dissector are introduced through the skin opening and spread transversely to create an opening about twice the diameter of the vas (4—6 mm). The tips of the vas dissector should penetrate deeply enough to expose the bare vas and enable one tip of the vas dissector to skewer the vas wall. When the vas dissector is rotated by supination of the forearm, the skewered vas will be elevated above the opening in the scrotal skin.

At this point, the vas ring clamp is removed from the skin surface and quickly reapplied to a partial thickness of the vas rather than around it. Dissection behind or posterior to the vas is performed by inserting one tip of the vas dissector between the back wall of the vas and the vasal sheath. The tip of the vas dissector then is removed and both blades of the vas dissector subsequently are inserted through the opening behind the vas that was created when the single blade was inserted. When both tips are inserted behind the vas and spread, a section of vas will be isolated from the adjacent vasal sheath and perivasal tissue. The bare vas is ready for division (with or without excision of a vas segment) and occlusion by the surgeon's method of choice. After the occlusion of the vas is finished and FI, if used by the surgeon, is performed, the ends of the vas are returned to the scrotum and the edges of the skin opening are squeezed together for about one minute. A dressing is applied without the use of sutures. The NSV technique is a technique for vas isolation only. It is not a technique for vas occlusion. After using the no-scalpel vasectomy technique for vas isolation, the surgeon must choose a method for vas occlusion.

The following diagrams of the NSV technique are modified with permission from the EngenderHealth No-Scalpel Vasectomy, An Illustrated Guide for Surgeons, Third Edition, 2003.

Figure 1



Vas Ring Clamp
(internal ring sizes are 3.0, 3.5 and 4.0 mm)

Vas Dissector
(with specially sharpened tips)

With permission: No-Scalpel Vasectomy: An Illustrated Guide for Surgeons, EngenderHealth. Third Edition 2003

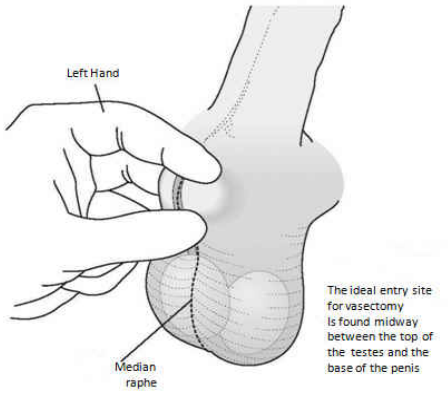
*Diagrams of the NSV technique are available in Li (1991), in Barone (2003), and at the following weblink: www.engenderhealth.org/files/pubs/family-planning/no-scalpel.pdf

American Urological Association

Vasectomy

Appendix A

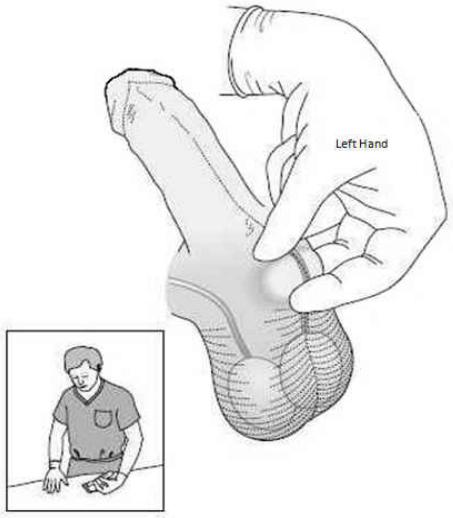
Figure 2



Three finger technique for immobilizing the right vas (right-handed surgeon)

With permission: *No-Scalpel Vasectomy: An Illustrated Guide for Surgeons*, EngenderHealth. Third Edition 2003

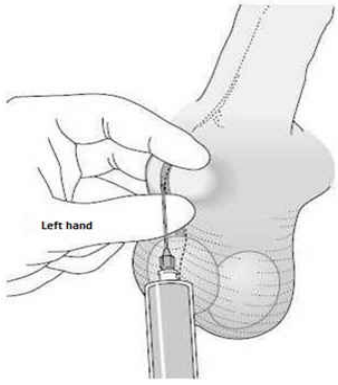
Figure 4



Three finger technique for immobilizing the left vas (right-handed surgeon)

With permission: *No-Scalpel Vasectomy: An Illustrated Guide for Surgeons*, EngenderHealth. Third Edition 2003

Figure 3



Injection of local anesthetic

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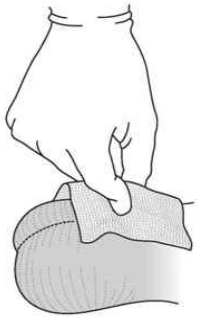
Figure 5



Pinch the site of local anesthetic injection to distribute the fluid in the skin, reduce the size of the skin wheal and facilitate application of the vas ring clamp

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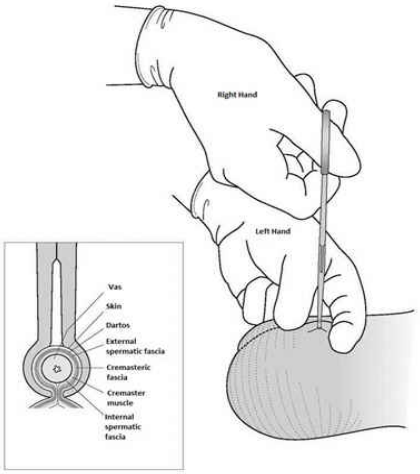
American Urological Association

Vasectomy

Appendix A

Figure 6



Apply the vas ring clamp around the vas, perivasal tissue and overlying skin

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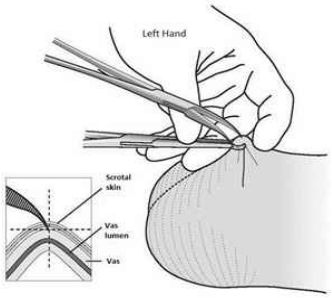
Figure 8



Pierce the skin and underlying tissue down to or into the vas with a single blade of the vas dissector

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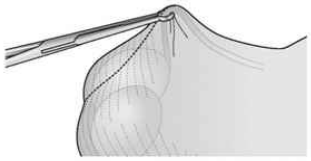
Figure 7



Lower the handle of the vas ring clamp to elevate the vas

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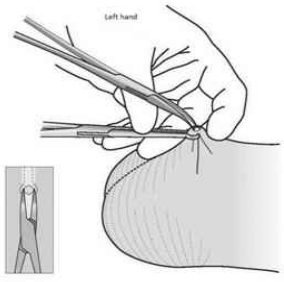
Figure 9



Insert both blades of the vas dissector into the same skin opening and spread the internal spermatic fascia (vas sheath) to expose the anterior wall of the vas

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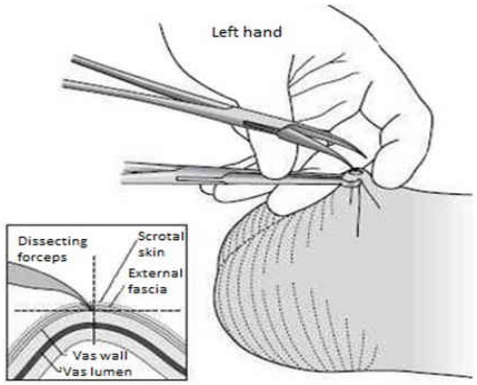
Vasectomy

Appendix A

Figure 10



Skewer the vas muscularis with a single blade of the vas dissector

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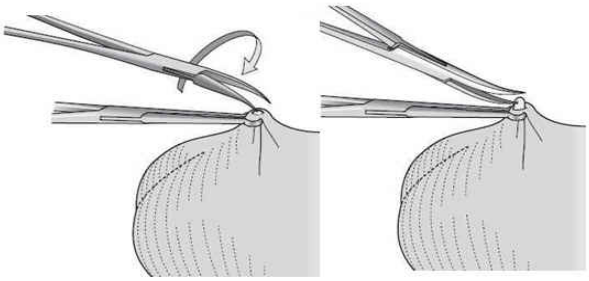
Figure 11



Rotate the vas dissector to extract the vas from the surrounding internal spermatic fascia

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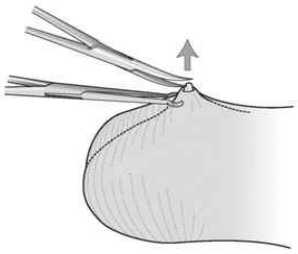
Figure 12



Briefly release the vas ring clamp to allow the vas to be elevated above the internal spermatic fascia and skin

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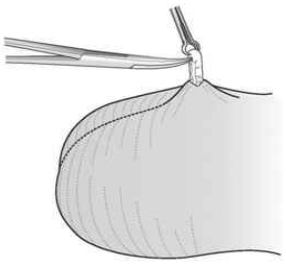
Figure 13



Re-grasp a partial thickness of the vas with the vas ring clamp

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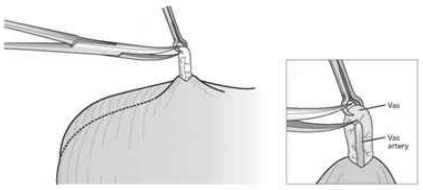
Figure 14



Insert a single blade of vas dissector behind posterior wall of vas to create space for subsequent insertion of both blades

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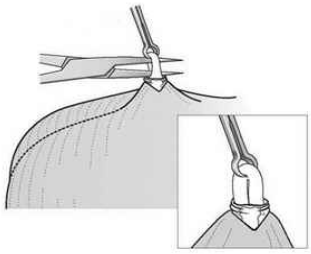
Figure 16



Spread the vas dissector to isolate the vas from all adjacent tissue

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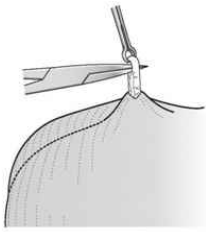
Figure 15



Insert both closed tips of the vas dissector between the posterior vas muscularis and the posterior part of the internal spermatic fascia

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APPENDIX B: SAMPLE FORM FOR PROVIDING VASECTOMY INFORMATION TO PATIENTS

If you are thinking of having a vasectomy, there are some important things you should know before the vasectomy is done.

- Vasectomy is intended to be a permanent form of contraception. There are options for fertility after vasectomy, but they are not always successful and they are expensive. You should not have a vasectomy unless you and your partner are sure that you do not want to have any more children.

- Vasectomy does not produce immediate sterility. It takes about 8-16 weeks before you can be sure that you are sterile.

- Following vasectomy, another form of contraception must be used until sterility is confirmed by the finding of no sperm or at most rare non-moving sperm on a semen analysis. Your doctor will tell you when he or she thinks the post-vasectomy semen analysis (also known as PVSA) should be done.

- Even after sterility is confirmed by a PVSA, you must understand clearly that vasectomy is not 100% reliable in preventing pregnancy. There is no method of contraception that is 100% certain to prevent pregnancy. Pregnancy occurs in 1 of 2,000 couples when a PVSA after a vasectomy shows no sperm in the semen. The rare pregnancies that occur after vasectomy can occur at any time, even years later.

- A second vasectomy is occasionally necessary when the original vasectomy does not produce sterility. The chance that you will need a second vasectomy is less than 1%.

- Your doctor will inform you about how long you should be sexually abstinent after vasectomy.

- Vasectomy does not cause any physical change in sexual performance, function, pleasure, sensation, interest, desire, satisfaction, penile erection, volume of semen or ejaculation.

- The options for fertility after vasectomy include vasectomy reversal and sperm retrieval with *in vitro* fertilization. These options are not always successful. Overall, about 50% of couples are able to have children with these techniques. Also, before the vasectomy, it is possible to freeze your sperm in a sperm bank. Freezing sperm is expensive, but it gives you a little insurance in case you decide after the vasectomy that you want more children.

- The complications of vasectomy which may occur within about one to two weeks after vasectomy are bleeding and infection. Bleeding usually takes the form of blood oozing from the vasectomy incision or a painful collection of blood under the skin at the vasectomy site (called a hematoma.) Active bleeding usually stops by itself; opening the scrotal skin to perform suturing or cauterization at the vasectomy incision site is rarely needed. Hematomas usually get absorbed by the body; occasionally hematomas need to be surgically drained. Infections are usually treated with antibiotics. Rarely an abscess due to infection will require surgical drainage. The risk of these complications is 1-2%.

- Medical journals report that about 1-2% of men develop significant chronic pain in the scrotal sac after vasectomy. This pain can last for months or years and can even be permanent. Chronic pain in the scrotum after vasectomy is usually treated with non-steroidal anti-inflammatory drugs (NSAIDS), antibiotics or injections of cortisone-like drugs or anesthetic agents. Few men have chronic pain after vasectomy that is severe enough to require additional surgery.

- There are many other permanent and non-permanent alternatives to vasectomy. You should discuss other options for contraception with your doctor to decide which method is best for you.

- This information sheet is intended to give you the basic information you should know before you decide to have a vasectomy. Your doctor can provide you with more detailed information if you need it.

APPENDIX C: KEY QUESTIONS

Key Question 1

1. Preoperative assessment and patient education
   a. Why do men and their partners choose (or not choose) vasectomy?
      i. Consider factors relating to the man, his partner, the health care provider, access to the procedure and others.

   Revised inclusion and exclusion criteria
   1. Restrict review to studies of men and women living in developed economies (we have a list).
   2. Exclude studies set in emerging/undeveloped economies.
   3. Restrict review to studies published in or after 1990.

   Rationale: Publications on why men or their partners choose vasectomy that are set in undeveloped countries are of little relevance to the target audience of this report (Western countries urologists and other providers performing vasectomies). In addition, studies published prior 1990 are likely less applicable to the reasons that men currently choose vasectomy, as social and cultural values, patient preferences, socioeconomic status and health care access all change over time in the developed world.

   b. What is the optimal preoperative assessment with respect to the following:
      i. general health, co-morbidities including coagulopathies? [This will be based on the review of the association of various patient factors and outcomes in question (6a).]
      ii. social factors including marital status, number of children, history of fatherhood? [This will be based on the review of the association of various patient factors and outcomes in question (6a and 7a).]
      iii. physical examination of the genitalia?
      iv. screening for bleeding diatheses?
      v. laboratory work-up?
   c. What are patients' expectations and perceived needs with respect to preoperative education?
   d. Does preoperative patient education correlate with the following:
      i. rates of post-vasectomy pain syndrome?
      ii. rates of other complications?
      iii. patient satisfaction?
      iv. rates of requests for vasectomy reversal?
   e. What information should the urologist give the patient and his partner during the preoperative visit in order to obtain informed consent from the patient and their partner?
      i. failure rates (early and late)
      ii. intra-operative and immediate post-operative pain
      iii. post-vasectomy pain syndrome
      iv. other complications
      v. options for reversal
      vi. other options for fertility in future
      vii. time at which sexual activity can be resumed
      viii. timing for resumption of unprotected sexual activity [This will be based on the review of latency of post-operative sterility in (5e).)

      Note: Questions i-vii above are based on EO in part, but we will have data from Key Questions #4 (occlusion methods, including complication outcomes) and #6 (complications not related to a specific technique) to inform these aspects of pre-operative counseling.

   f. What is the prevalence of regret and satisfaction by the patient or his partner after vasectomy?
      i. What are the predictors of regret and satisfaction by the patient or his partner after vasectomy?

      Note: Much of the data on regret are contained in studies for Key Questions 4 and 6, where we examine complications in detail, including psychological and sexual outcomes, we will move (1f) to key Question #6, Complications. This will markedly simply our organization, and decrease the presentation of studies in multiple sections of the report.

   g. What is the prevalence of reversal after vasectomy? (EO, based on Dr. Sharlip's review of the data)
      i. What are the predictors of patient request for reversal? (EO, based on Dr. Sharlip's review of the data)

      Note: We have identified some data for question (1g), but much of the relevant data are likely in studies on reversal (Key Question #7), which we will not be examining. After discussion with Dr. Sharlip 7/29/09, he has agreed to review titles and abstracts from vasectomy #7 (reversal), and choose the relevant data that he wishes to include. Thus this section will not be part of the (systematic) evidence review that the Evidence Center will be analyzing. In addition, Susan will supply Dr. Sharlip with studies from Vasectomy #1 which have potentially relevant data on the prevalence of reversal. As noted above, the relevant data for the audience of this report are likely contained in more recent studies set in developed countries (Appendix D).

   h. Should vasectomy be performed with the anticipation of later reversal?

Key Question 2

2. Anesthesia
   a. Does the use of topical anesthesia delivered by cutaneous spray reduce intra-operative pain compared to direct topical application or to standard injection of local anesthetic?
   b. Does direct topical application of anesthetic reduce intra-operative pain compared to standard injection of local anesthetic?
   c. Does the use of a pneumatic injection system reduce intra-operative pain compared with standard injection of local anesthetic?
   d. Should epinephrine be injected with local anesthetic?
      i. How do the rates of intra-operative and post-operative complications compare with and without the use of epinephrine injection with local anesthetic?
   e. What size needle should be used for injection of local anesthetic?
   f. What are the appropriate pain scales to assess intra-operative pain?
   g. Does intra-operative pain correlate with post-operative pain in the immediate (first 6 weeks) and late (3 to 6 months or years) post-operative periods?
   h. Should sedation (oral, IV, or by mask) be used immediately preoperatively or intra-operatively?
   i. What are the indications for using general anesthesia for vasectomy?

Key Question 3

3. Isolation of the vas
   a. How does one incision compare to two incisions for the following:
      i. Intraoperative outcomes?
      ii. Severity of intraoperative pain?
      iii. Duration of procedure?
      iv. Vasectomy failure rates?
      v. Postoperative outcomes, including post-vasectomy pain syndrome?
   b. For single-incision vasectomy, what is the optimal location of the incision?
   i. What is the optimal site for injection of local anesthetic?
   c. For single-incision vasectomy, how does the surgeon avoid isolating the same vas twice?
   d. For two-incision vasectomy, what is the optimal location for the incisions?
   i. What is the optimal site for injection of local anesthetic?
   e. How does the technique of no-scalpel vasectomy compare to other vasectomy techniques for the following:
      i. intraoperative complications?
      ii. duration of the procedure?
      iii. postoperative complications and symptoms including post-vasectomy pain syndrome?

Key Question 4

4. Intraoperative procedures
   a. How do testicular vas occlusion techniques compare for the following:
      i. Intraoperative complications?
      ii. Postoperative symptoms including post-vasectomy pain syndrome?
      iii. Postoperative sperm granuloma formation at transected testicular end of vas?
      iv. vasectomy failure rates?
      1. early
      2. late
      v. vasectomy reversal success rates?

   Testicular vas occlusion techniques include:
   1. ligature: absorbable, non-absorbable
   2. surgical clips
   3. cautery (thermal or electro-cautery; monopolar or bipolar)
   4. looping back or fold-back technique with suture ligation/clip
   5. fascial interposition
   6. excising a segment of the vas
   7. testicular vas end left open ("open-ended" technique)
   8. chemical occlusion
   9. vas plugs
   10. various combinations of the above

   b. Should length of the testicular remnant be maximized to reduce post-vasectomy pain syndrome?
   c. Should length of the testicular remnant be maximized to increase the chance for successful reversal?
   d. Should the vas be irrigated at vasectomy in order to increase clearance of sperm?
   e. Should a segment of the vas be excised or should the vas be simply divided?
   i. If a segment is excised, how long should it be?
   f. Is it necessary to divide the vas?
      i. Is it sufficient to permanently disrupt the vas wall and sheath without transection of the vas (Marie Stopes procedure)?
      ii. What is the failure rate if the vas sheath is left intact?
      iii. Is it sufficient to permanently disrupt the vas wall and sheath without transaction of the vas (Marie Stopes procedure)?
   g. Should excised vas segments be sent for pathologic exam?

Key Question 5

5. Post-vasectomy follow-up
   a. Sperm clearance post-vasectomy
      i. What factors affect the clearance of sperm? Factors to consider include the following:
         1. Age
         2. Time since vasectomy
         3. Number of ejaculations since vasectomy
         4. What percent of men have sperm counts of 0 at various intervals post-vasectomy?
         5. What percent of men have 0 motile sperm at various intervals post-vasectomy?
   b. Number and timing of post-vasectomy semen analyses (PVSA)
      i. When should PVSA be performed?
      ii. What is the recommended number of post-vasectomy semen analyses?
         1. Is age a factor when determining the recommended number of post-vasectomy semen analyses?
   c. Technique of PVSA
      i. Are centrifuged specimens preferable for assessing success of vasectomy or are un-centrifuged specimens adequate?
      ii. Does the duration or speed of centrifugation affect the finding of sperm in PVSA?
      iii. How many high power fields need to be examined?
      iv. Should PVSA be performed by a laboratory or can the surgeon reliably and accurately perform PVSA?
         1. What is the diagnostic accuracy of PVSA by surgeons in the clinic/office setting and how does that compare to diagnostic accuracy in the laboratory setting?
      v. What is the accuracy of home semen tests?
      vi. How should PVSA results be reported? (e.g., sperm/ml or sperm/ high power field?)
   d. How is vasectomy failure defined?
      i. What sperm count, including assessment of motility, at what time defines vasectomy failure?
      ii. How is post-vasectomy pregnancy defined?
   e. For how long after vasectomy should patients abstain from unprotected sexual activity? [This is based on evidence from (5a and b).]
   f. Is a post-operative visit with the surgeon necessary or is a semen analysis adequate?
   g. Can men who are azoospermic after a vasectomy be responsible for a pregnancy?
      i. How should the azoospermic man whose wife is pregnant after his vasectomy be investigated, managed, and advised?

Key Question 6

6. Complications
   a. What are the incidence rates and predictors for the following:
      i. vasectomy failure?
      ii. post-vasectomy pain syndrome?
      iii. painful sperm granuloma formation at the vasectomy site?

      Patient predictors include the following:
      i. demographic characteristics (e.g., age)
      ii. psychosocial characteristics (e.g., personality)
      iii. co-morbidities

      Surgeon predictors include the following:
      i. surgical techniques, including open vs. closed approach to the testicular vas
      ii. surgeon volume and training
   b. What are the incidence rates and predictors of other long-term complications, including the following:
      i. prostate or testicular cancer?
      ii. other chronic diseases
         1. coronary and other vascular disease
         2. dementia
         3. others

APPENDIX D: VAS OCCLUSION TECHNIQUES

Definitions and Diagrams:

FI fascial interposition
MC mucosal cautery
T testicular end of divided vas
A abdominal end of divided vas
MSI non-divisional extended electrocautery (Marie Stopes International Technique)

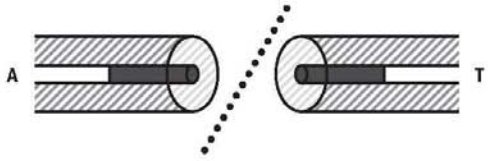
MUCOSAL CAUTERY

LIGATION

CLIP OCCLUSION

FI

1 MC with FI

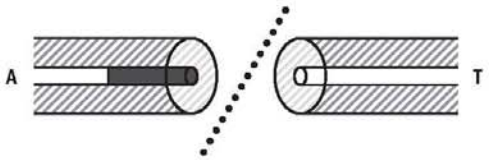


Occlusive Failure Range = 0.0–0.55%

2 MC without FI

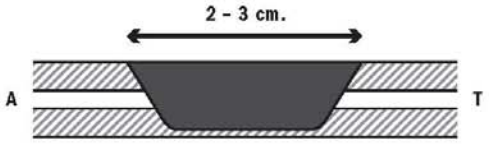
Occlusive Failure Range = 0.0–0.60%

3 Testicular end open, abdominal end cauterized with FI



Occlusive Failure Range = 0.0–0.50%

4 MSI

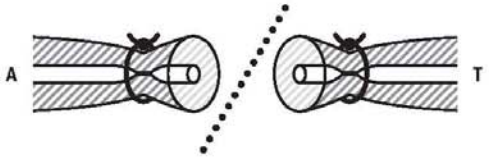


Occlusive Failure = 0.64%

5 Ligation both ends without FI

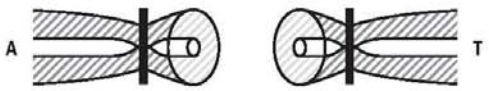
Occlusive Failure Range = 0.0–13.79%

6 Ligation both ends with FI



Occlusive Failure Range = 0.0–5.85%

7 Clips both ends without FI



Occlusive Failure Range = 0.0–8.67%

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VASECTOMY PANEL MEMBERS, CONSULTANTS, AND AUA STAFF

Panel Members

Ira D. Sharlip, M.D.
Clinical Professor
Department of Urology
University of California, San Francisco, CA
San Francisco, CA

Arnold M. Belker, M.D., Facilitator
Emeritus Clinical Professor
Department of Urology
University of Louisville School of Medicine
Louisville, Kentucky

Stanton Honig, M.D.
Associate Clinical Professor of Surgery/Urology
University of Connecticut
Farmington CT
The Urology Center
New Haven, CT

Michel Labrecque, M.D., Ph.D.
Professor
Department of Family and Emergency Medicine
Université Laval
Quebec City, Canada

Joel L. Marmar, M.D.
Professor of Urology
Cooper Medical School of Rowan University
Camden, NJ

Lawrence S. Ross, M.D.
Clarence C. Saelhof Professor Emeritus
Department of Urology
University of Illinois at Chicago
Chicago, IL

Jay I. Sandlow, M.D.
Professor of Urology
Medical College of Wisconsin
Milwaukee, WI

David C. Sokal, MD
Senior Scientist
Clinical Sciences Department
FHI 360
Durham, NC

Consultants

Suzanne Pope, M.B.A.
Susan Norris, M.D., M.P.H., M.S
Brittany Burda
Veronica Ivey
Natalie R. Jacuzzi, M.P.H.
Tarra McNally, M.A., M.P.H.
Martha M. Faraday, Ph.D., Senior Consultant, Four Oaks, Inc.

Staff

Heddy Hubbard, Ph.D., M.P.H., R.N., F.A.A.N.
Michael Folmer
Abid Khan, M.H.S.
Erin Kirkby, M.S
Ashley Keys

CONFLICT OF INTEREST DISCLOSURES

All panel members completed COI disclosures. Relationships that have expired (more than one year old) since the panel's initial meeting, are listed. Those marked with (C) indicate that compensation was received; relationships designated by (U) indicate no compensation was received.

Consultant/Advisor: Ira D. Sharlip, Absorption Pharmaceuticals (C),Pfizer (C), Lilly(C), Bayer (C)) (expired), Plethora Solutions (C)(expired); **Stanton C. Honig**, Endo Pharmaceuticals (C), Serono (C), Lilly/ ICOS (C), Coloplast (C), AMS (C), menMD (C), Slate Pharmaceuticals (C)(expired); **Michel Labrecque**, Shepherd Medical (expired) (C)**; Joel L. Marmar**, Wellspring Urology (C); **Lawrence S. Ross**, Gerson Lehrman Group (C)

Investigator: Stanton C. Honig, Auxilium(C); **Michel Labrecque**, Contravac (C)

Meeting Participant or Lecturer: Stanton C. Honig, Sanofi (C), Novartis (C), Lilly/ICOS(C), Pfizer (C), Coloplast (C), Auxilium (C), American Medical Systems (C), Slate Pharmaceuticals (C); **Ira D. Sharlip**, Lilly (C), Pfizer (C), Bayer, (C)(expired), Johnson & Johnson (C)(expired), Shionogi Pharma (C)(expired)

Scientific Study or Trial: David Sokal, Family Health International (C)

Other-Employee, Owner, Product Development: David Sokal, Family Health International(C)

Peer Reviewers

We are grateful to the persons listed below who contributed to the Vasectomy Guideline by providing comments during the peer review process. Their reviews do not necessarily imply endorsement of the Guideline.

Gopal H. Badlani, MD
Natan C. Bar-Chama, M.D.
Mark Barone, D.V.M. MS
John M. Barry, M.D.
William W. Bohnert, M.D.
Robert Edward Brannigan, M.D.
Peter Chan, M.D.
Daniel J. Culkin, M.D.
Philipp Dahm, M.D., M.H.Sc
Gert R Dohle, M.D.
Erma Z. Drobnis, Ph.D.
Deborah R. Erickson, M.D.
Tony Felbrower , M.D.
Harry Fisch, M.D.
Robert C. Flanigan, M.D.
David F. Green, M.D., FACS
C. D. Anthony Herndon, M.D.
Jeff Holzbeierlein, M.D.
Jonathan P. Jarow, M.D.
Keith Allen Jarvi, M.D.
Jeffrey E. Kaufman, MD, FACS
Ramchandra Kaza, M.D.
Edward D. Kim, M.D.
Peter Nicholas Kolettis, M.D.
Sushil S. Lacy, M.D.
Dolores J. Lamb, Ph.D.
Deborah J. Lightner, M.D.
Larry I. Lipshultz, M.D.
Elaine Lissner
John H. Lynch, M.D.
R. Dale McClure, M.D.
Arturo Mendoza-Valdes, M.D.
Abraham Morgentaler, M.D.
Harris Mark Nagler, M.D.
Ajay K. Nangia, M.D.
Robert D. Oates, M.D.
Margaret Pearle, M.D., Ph.D.
Neil Pollock, M.D.
Kevin Pranikoff, M.D.
Michael A. Pretl
John C. Prince, M.D.
Hassan Razvi, M.D.
Andrew Rynne, M.D.
Mark Sigman, M.D.
Pramod C. Sogani, M.D.
William J. Somers, M.D.
William D. Steers, M.D.
Craig Stuart Niederberger, M.D.
J. Brantley Thrasher, M.D.
Thomas M.T. Turk, M.D.
Luc Valiquette, M.D.
Datta G. Wagel, M.D.
Moshe Wald, M.D.
Ronald Weiss, M.D.
J. Stuart Wolf, Jr., M.D

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This document was written by the Vasectomy Guideline Panel of the American Urological Association Education and Research, Inc., which was created in 2008. The Practice Guidelines Committee (PGC) of the AUA selected the panel chair and co-chair. Panel members were selected by the chair and co-chair. Membership of the panel included urologists, family medicine physicians, and other clinicians with specific expertise on vasectomy techniques. The mission of the committee was to develop recommendations that are analysis-based or consensus-based, depending on Panel processes and available data, for optimal clinical practices in the surgical technique of vasectomy.

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While these guidelines do not necessarily establish the standard of care, AUA seeks to recommend and to encourage compliance by practitioners with current best practices related to the condition being treated. As medical knowledge expands and technology advances, the guidelines will change. Today, these evidence-based guideline statements represent not absolute mandates but provisional proposals for treatment under the specific conditions described in each document. For all these reasons, the guidelines do not pre-empt physician judgment in individual cases.

Treating physicians must take into account variations in resources, and patient tolerances, needs, and preferences. Conformance with any clinical guideline does not guarantee a successful outcome. These guidelines are not intended to provide legal advice about use and misuse of these substances.

Although guidelines are intended to encourage best practices and potentially encompass available technologies with sufficient data as of close of the literature review, they are necessarily time-limited. Guidelines cannot include evaluation of all data on emerging technologies or management, including those that are FDA-approved, which may immediately come to represent accepted clinical practices. For this reason, the AUA does not regard technologies or management which are too new to be addressed by these guidelines as necessarily experimental or investigational.