Access to Care for Male Factor Infertility

▼ Continued from page 15

as SART-CORS (Society of Assisted Reproductive Technology Clinical Outcome Reporting System) and NASS (National ART Surveillance System), contain limited demographic information about the male partner and lack etiological male subfertility data, making it difficult to quantify the severity of a couple's male factor problem.

Men between 15 and 44 years old are 2 to 2.5 times less likely than women to visit a doctor for a medical condition and, therefore, are less likely to be educated about the male contribution to reproduction and less likely to undergo evaluation for infertility. Specifically, social barriers, such as race, ethnicity, religious beliefs and cultural stigma, can also discourage men from seeking evaluation and treatment for infertility. Public and provider perception of infertility primarily representing a gynecologic problem combined with the misperception that the use of ART can circumvent a male factor problem can further minimize the importance of the male evaluation.

Finally, when consultation for male factor infertility is sought, geographic access to a male reproductive medicine specialist can be difficult and the cost of undergoing treatment prohibitive. There is considerable disparity in the distribution of male reproductive specialists relative to the U.S. population of young men of reproductive age, with large areas of the country being underserved or overserved.[3] Not only do these geographic limitations preclude access to care for men with an established diagnosis of infertility, they also diminish the potential diagnosis of subfertility in men who are not actively seeking ART services.

One of the biggest challenges in access to care for male infertility in the United States remains the perception of infertility related care being an elective option rather than a medical necessity. Although infertility was recognized as a disease by the American Society of Reproductive Medicine (ASRM) in 2008, federal and third-party insurers have failed to follow suit, characterizing reproduction as a lifestyle choice instead. Therefore, health insurance coverage for the diagnosis and treatment of male factor infertility is variable and usually limited, resulting in thousands of dollars in out-of-pocket costs for affected patients.[4] Men with a concomitant diagnosis of cancer are twice as disadvantaged because insurance coverage for fertility preservation is also nonexistent. However, financial barriers to care for male infertility exist at many different levels and include not only the aforementioned out-of-pocket costs faced directly by patients, but also the less visible limitations in research and public health funding faced by scientists and health care providers.

In summary, male infertility is under recognized scientifically, epidemiologically, socially, psychologically, financially and politically. Overall, male infertility is underrepresented as a disease. Fortunately, there appears to be increasing awareness of infertility as a public health problem. The ASRM Strategic Action Plan and the CDC (Centers for Disease Control) National Public Health Action Plan for the Detection, Prevention, and Management of Infertility, both released in 2014, share the common goals of increasing public consciousness of the impact of infertility and promoting health care efforts in the management of infertility. Continued advocacy efforts, ideally unified across specialty societies, community organizations and the media, are necessary to alleviate cost barriers, correct health policy inequities, and improve reproductive health and outcomes for men or couples struggling with male factor infertility. ◆

Appendix. Barriers in access to male reproductive care

Epidemiological barriers	Lack of population level databases that accurately define the burden of disease, and difficulties in access to care
Geographic barriers	Disparity of services available for specialized male infertility and andrology care, and ART centers
Knowledge barriers	Limited patient and public awareness due to gender, societal norms, education level and limited provider awareness due to scientific biases, preset expectations, conflicts of interest and scientific knowledge
Financial barriers	Lack of health insurance coverage (private and governmental) results in substantial out-of-pocket expenses in the private sector, and limited funding for basic, clinical and public health research for improving access to and treatment of male factor infertility
Socioeconomic barriers	Cultural, religious and societal perceptions of the diagnosis of infertility and its acceptance
Government and health policy barriers	Need to recognize reproduction as a disease process and a public health issue

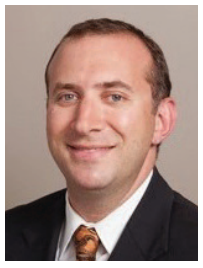
1. Petok WD:. Infertility counseling (or the lack thereof) of the forgotten male partner. Fertil Steril 2015; **104**: 260.

2. Eisenberg ML, Lathi RB, Baker VL et al: Frequency of the male infertility evaluation: data from the national survey of family growth. J Urol 2013; **189**: 1030.

3. Odisho AY, Nangia AK, Katz PP et al: Temporal and geospatial trends in male factor infertility with assisted reproductive technology in the United States from 1999-2010. Fertil Steril 2014; **102**: 469.

4. Wu AK, Odisho AY, Washington SL, 3rd et al: Out-of-pocket fertility patient expense: data from a multicenter prospective infertility cohort. J Urol 2014; **191**: 427.

Informed Refusal: The Uncomfortable Other Side of Informed Consent



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The process of informed consent has evolved over the decades from an era when physicians often singly decided what was in the best interest of the patient, known as "beneficent paternalism," to now promoting active patient involvement in health care decision making based on patient "self-determination."[1] The proper balance of these ethical poles has not yet been determined. As such, the informed consent process relies on the competent patient's ability to comprehend the choices of a given treatment and its risks and benefits, and the alternatives and their risks and benefits, as well as the risks of rejecting the recommended treatment. Taken to its logical extreme, a patient's right to self-determination is their freedom to refuse a medical treatment even when such refusal is detrimental to their health.[1] Yet, physicians can ill afford ethically to simply stand idle while a potentially poor medical decision is being contemplated by a patient.

Refusal to proceed with a recommended treatment, which may be encountered with aggressive or late stage genitourinary cancer, may initially be interpreted by the urologist as a failure to comprehend what is being expressed to the patient and may raise questions of competence. Especially in the geriatric population, competence must be assessed by the urologist in order to assure that the patient can comprehend treatment options and the risks of refusal. When a patient agrees to a certain treatment, their competency is not challenged because the physician believes the patient is making the "correct" decision. However, a patient's refusal of a recommendation is often considered a sign of their inability to make rational decisions.[1] The elderly population must be approached with greater attention to assure comprehension of medical choices as well as the assurance of sound judgment by the urologist that they can make reasonable decisions. Otherwise informed consent and more importantly informed refusal cannot be obtained.

Potentially life threatening diagnoses directly impact patient decision making. The threat of death may alter or impede one's ability to make a proper informed consent decision and heightens the concern of the physician when a potentially lifesaving but risky surgery is recommended but refused. Yet, at these anxious moments, if the physician is unwilling to carry out the potential option of refusal, then the patient's free choice has been restricted. A decision under these circumstances can be viewed as manipulated or coerced[1] and, if unforeseen complications ensue, there may be a pathway to potential litigation.

▼ Continued on page 17

Informed Refusal

▼ Continued from page 16

Therefore, how shall a urologist go about counseling and documenting "Informed Refusal"?

- Discuss and document the recommended care plan, which includes all treatments, procedures, medications and followup treatments, and the reason for the given recommendation.
- Discuss and document the risks and benefits of the proposed recommendation.
- Document discussions with family members, whether present or by telephone.
- Use multimedia, brochures or other means to convey the disease process and recommended treatments, and document that such tools were used in the office or sent home with the patient and/or family members.
- Document the patient's refusal in terms of 1) the reason for the refusal, 2) the consequences and risks of refusing the recommended treatment, 3) explanation of the risks of refusal and the patient's response confirming reasons for refusal, and 4) the patient's continued decision to refuse a recommended treatment and their comprehension of such.
- Document that alternative treatments were discussed (as well as their risks and benefits), and even any compromises in treatments the patient may partially accept.
- Document that all questions from the patient and family members were adequately addressed and answered, and that all parties acknowledged understanding of the subject matter reviewed.
- Document any witnesses, such as nursing aides, caretakers, power of attorney, who were present for the explanations of the recommended treatment and the refusal.
- Document a request to have the patient follow up in a reasonably short time to present the opportunity to readdress any treatments they may then elect; in addition, discuss and document the refusal with the referring physician, as they may wish to go over the matter independently from the surgeon.

There are several useful tips when obtaining informed refusal or consent. [2]

- Build a good rapport; effective communication has been shown to reduce the likelihood of litigation.
- Discuss all treatment options regardless of ability to pay or level of insurance coverage.
- Discuss how test results will be communicated to the patient; recommend the patient call within 1 to 2 weeks if they do not hear from the physician or office about results; overlooked, lost or misfiled results are low hanging fruit for potential litigation.
- Avoiding making guarantees regarding outcomes (good or bad) of treatments, as these can be seen as broken promises and a potential cause for a claim.
- Documentation is the only proof a discussion occurred. Take the time to create well written and comprehensive templates that can be used in electronic medical records and consent forms, as they may be used as mental prompts of the subject matter for discussion. ◆

1. Mars FH: Informed consent and the elderly patient. Clin Ger Med 1986; **2**: 501.
2. Kaibara PD: 8 Ways to improve the informed consent process. J Fam Prac 2010; **59**: 373.

HAVE YOU *Read?*

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Hamdy FC, Donovan JL, Lane JA et al: 10-Year outcomes after monitoring, surgery, or radiotherapy for localized prostate cancer. N Engl J Med 2016; 375: 1415-1424.

Management of clinically localized prostate cancer detected by prostate specific antigen (PSA) is currently controversial with critics of therapy claiming that overtreatment of this group leads to a reduced quality of life for the less aggressive cancers. The authors extracted data from the ProtecT (Prostate testing for cancer and Treatment) trial, which is a prospective randomized trial and patient reported outcomes using validated questionnaires. This trial involves using PSA to detect prostate cancer and offering those diagnosed with cancer the option of participating in a study with 3 arms of therapy, including active monitoring, radical prostatectomy (RRP) or radiation therapy (RAD). A total of 1,643 people entered this trial and the 10-year outcome data are presented.

There were only 17 deaths due to prostate cancer, including 8 in the active monitoring group, 5 in the RRP group and 4 in the RAD group, and the differences were not significant. Metastases developed in significantly more men in the monitored group (33 men) compared to the RRP group (13) and the RAD group (16) (p=0.004). Higher rates of disease progression also occurred in the actively monitored group (112 men) compared to the surgery group (33) and RAD group (33) (p ≤0.001). Although the overall number of deaths was low at 10 years, disease progression was significantly greater in the monitored group.

For more than 40 to 50 years it has been well known that the number of prostate cancer deaths among treated patients is low until 13 to 15 years after treatment, and this study reaffirms that finding. The increased number of men with disease progression at 10 years in the monitored group will ultimately translate into more deaths than the treated subjects, and is something to be considered when informing patients about active monitoring. The 15-year results of this trial will be interesting. Overall this is a good study and positively addresses the value of PSA screening. The quality of life issues from this trial are presented next.

Donovan JL, Hamdy FC, Lane JA et al: Patient-reported outcomes after monitoring, surgery, or radiotherapy for prostate cancer. N Engl J Med 2016; 375: 1425-1437.

In an era when many claim overtreatment of less aggressive prostate cancer, the data presented in this report extracted from the ProtecT trial provide useful information to aid clinicians in counseling newly diagnosed patients in regard to what options are available as well as the quality of life outcomes they can expect from the possible choices. Erectile dysfunction and urinary incontinence were reported out to 6 years after study entry. Incontinence and erectile dysfunction increased initially (primarily in the treated groups) followed by some recovery and then stabilization at 6 to 12 months. Normal erectile function was defined as erections firm enough for intercourse and incontinence was defined as having to wear pads. At baseline 67% of the men reported normal erections. After 6 years normal erectile function was noted in 17% of the men in the RRP group, 27% in the RAD group and 41% in the active monitoring group. There was a gradual natural decline in erectile function but also men with disease progression in the actively monitoring group received treatment. Incontinence rates after 6 years were 17% in the RRP group, 4% in the RAD group and 8% in the monitored group. The rate of incontinence increased in the monitored group as the men gradually received radical treatment.

Unger JM, Till C, Thompson IM Jr et al: Long-term consequences of finasteride vs placebo in the Prostate Cancer Prevention Trial. J Natl Cancer Inst 2016; 108: djw168.

The finasteride trial was originally initiated to determine if this drug could reduce cancer risk. It did reduce the risk of low grade cancer but it did not affect overall survival. But were there other and perhaps adverse risks of long-term finasteride use? Unger et al linked data from finasteride trial participants with Medicare claims for about 13,935 people, and compared those on drug vs placebo with a median

▼ Continued on page 18