

Recommendations for Treating Males: An Ethical Rationale for the Inclusion of Testicular Self-Examination (TSE) in a Standard of Care

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Abstract

The phrase “standard of care” is primarily a legal term representing what procedure a reasonable person (i.e., health practitioner) would administer to patients across similar circumstances. One major concern for health practitioners is delivering and advocating for treatments not defined as a standard of care. While providing such treatments may meet certain ethical imperatives, doing so may unwittingly trigger medical malpractice litigation fears from practitioners. Apprehension to deviate, even slightly, from the standard of care may (seem to) put the practitioner at significant risk for litigation, which, in turn, may limit options for treatment and preventive measures recommended by the practitioner. Specific to testicular treatment, certain guidelines exist for cancer, torsion, vasectomy, and scrotal masses, among others. As it relates to screening, practitioner examination is expected for patients presenting with testicular abnormalities. Testicular self-examination (TSE) advocacy, however, is discouraged by the U.S. Preventive Services Task Force, which may prompt a general unwillingness among health practitioners to promote the behavior. Considering the benefits TSE has beyond cancer detection, and the historical support it has received among health practitioners, it is paramount to consider the ethical implications of its official “exclusion” from preventive health and clinical care recommendations (i.e., standard of care). Since good ethics should lead practitioner patient care guidelines, not fear of increased malpractice risks, we recommend the development of a standard of care for counseling males to perform TSE.

Keywords

testicular cancer, men's health, standard of care, testicular self-examination, ethics

Overview of the Issue

“The difficulties inherent in treating patients once [cancer] relapse has occurred makes prevention a preferable alternative.”

—Hendry (1994, p. 289).

Barriers to Male Health Care Utilization

Research indicates that significant barriers exist for males seeking health care, including service options and access (Bertakis, Azari, Helms, Callahan, & Robbins, 2000; Pinkhasov et al., 2010), insurance/coverage (Cheatham, Barksdale, & Rodgers, 2008), and intrapersonal and interpersonal beliefs and attitudes on seeking care (Addis

& Mahalik, 2003). Societal normative values regarding male health outcomes and preventive care and treatment service activity also create obstacles in the guise of peer judgment and nonconformity for males to seek help, even if they wanted and/or needed it (Leone & Rovito, 2013). Even

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more disconcerting is the popularizing feature of current media sources to overportray males taking pride in self-help procedures, such as men being self-reliant, or more commonly termed, the "I got this mentality" (Singleton, 2003).

The aforementioned barriers could adversely affect overall male quality of life by limiting the amount of care sought from qualified, trained professionals (Courtenay, 2000; Gough, 2006). Addis and Mahalik (2003), for example, assert that males irregularly seek disease prevention, treatment, and other health services. Heidelbaugh and Tortorello (2012) indicate that nearly one third of men report not having a primary care physician. Sandman, Simantov, and An (2000) reported that nearly one of four participant men did not see a physician in the year prior to completing their survey, which was three times the rate reported for women (~8%). Furthermore, the authors highlight the gender disparity in health care accessibility by comparing the one third of men to only one fifth of women reporting that they did not have a regular doctor to go to when they were sick or needed medical advice.

Disparate Health Outcomes and Specific Threats From Testicular Cancer

Nine out of the top 10 causes of death are higher among males than their female counterparts (Centers for Disease Control and Prevention, 2012). This inequality is particularly evident among adolescent and young adult males where the risk of performing high-risk behaviors is nearly triple, suicide is nearly double, and accidental deaths and homicides are higher than females, which contributes to a 179% (15- 24-year-olds) and 128% (25- 34-year-olds) increased mortality risk than females their age, the highest among all age categories (National Center for Health Statistics, 2009; Youth Risk Behavior Surveillance System, 2011). Marcell, Ford, Pleck, and Sonenstein (2007) and Marcell, Howard, Plowden, and Watson (2010) indicate that health care-seeking behaviors are among the lowest rates of any age and gender group within this population. It is of little wonder, therefore, as to why young adult males experience some of the most disparate health outcomes.

Specific to genitourinary health, more than 8,000 cases of testicular cancer (TCa) are diagnosed each year in the United States with approximately 400 deaths attributed to the disease (U.S. Cancer Statistics Working Group, 2015). The 5-year survival rate for TCa is 99% for localized cases (American Cancer Society [ACS], 2015a, 2015b), suggesting the disease is highly treatable with the tendency to have very favorable outcomes, even when discovered in later stages. When compounded over the course of a given decade, however, where ~90,000 TCa cases and ~4,000 TCa deaths occur, primarily in young males ages ~15 to 40 (Akar & Bebiş, 2014; Rosella, 1994; Trumbo, 2004), the disease becomes a much more concerning issue.

Making this issue increasingly pressing is the threat TCa poses to "years of potential life lost" (YPLL) within young adult and adolescent males as they experience the highest incidence and mortality rates of the disease (Giannandrea et al., 2013; Palmer, 2013; Walschaerts et al., 2008). Li, Ekwueme, Rim, and Tangka (2010) indicate that TCa has the highest average number of YPLL (~40) than all other male genital cancers. Although TCa affects significantly fewer males in terms of crude death count as compared with prostate cancer, for example, that gap closes considerably when factoring the years of life lost (Kamel, Moore, Bissada, & Heshmat, 2012; Siegel, Miller, & Jemal, 2015). In other words, males dying of TCa are significantly younger than in the majority of other causes of death, which increases the urgency to promote knowledge and awareness of the disease.

An Emerging Need Regarding TCa Risk Among Young Males

Considering this widening gap in gender health outcomes, irregular care, and the unique risk posed by TCa, it is important to revise current guidelines for young adult male health care treatment and prevention services. Most literature suggests a knowledge gap within young adult and adolescent males on what the disease is, who is most at-risk, and prevention/treatment options (Rosella, 1994; Trumbo, 2004; Walschaerts et al., 2008; Wanzer, Foster, Servoss, & LaBelle, 2014). Most interventions modestly affect some of the aforementioned variables but few, if any at all, report on long-term successes in making males more efficacious as it pertains to becoming aware of the disease and/or preventing late-stage diagnosis of TCa (see Rovito et al., 2014).

Perhaps amending both the manner in which preventive and treatment services are rendered and the scope of what said services intend to achieve will encourage these males to seek care, have that care be more amenable to their needs and comfort level, and, ultimately, promote better health outcomes. To counteract these negative portrayals and their effects on male health outcomes, we argue that future discourse should focus on balancing the preservation of autonomous decision making regarding health care navigation and adaptive self-agency with communication strategies and promotion of behaviors from external entities (see Kwon, Olliffe, Bottorff, & Kelly, 2014, for a similar discussion).

Current Standards for Treating Young Adult Males

The literature suggests a lack of unanimity regarding a standard of care (e.g., Boccon-Gibod et al., 2003), or even gender-equitable practice (e.g., Courtenay, 2000), for male health and wellness services. Heidelbaugh and Tortorello (2012) discuss the ambiguity of methods to

conduct comprehensive physical examinations on male patients. Odgers et al. (2007) go so far as to indicate that the *Diagnostic and Statistical Manual of Mental Disorders—Fourth edition* may not be as robust in its criteria for properly diagnosing certain mental health conditions among males as once thought, thus leading to false-positive results. It appears that existing treatment protocols are perhaps not as efficient and effective as they need to be or that there is a general lack of tried and true guidelines shepherding health practitioners on how to properly screen, examine, and treat males.

Regarding testicular health, treatment standards of cancer, torsion, vasectomy, and scrotal masses are historically well established (see, e.g., Albers et al., 2005; Albers et al., 2011; Cornett & Dea, 2014; Hendry, 1994; Martin, 1991). Prevention and screening standards, however, remain ambiguous at best, specifically those referencing testicular self-examination (TSE).

Arguments Against TSE

In 2011, the U.S. Preventive Services Task Force (USPSTF, 2011a, 2011b) gave TSE a “D” rating in their final recommendation statement for TCa screening, concluding that there is “moderate certainty that screening for TCa has no net benefit.” This recommendation extends to both testicular examination by a clinician, as well as TSE, due to either method being unlikely to yield health benefits and that potential harms include “false-positive results, anxiety, and harms from diagnostic tests or procedures.” Four core issues served as the impetus behind the D-rating: the relative rarity of TCa, highly favorable treatment outcomes, accuracy concerns of clinical or self-examination, and a dearth of evidence for TSE’s capacity to reduce deaths associated from TCa.

Casey, Grainger, Butler, McDermott, and Thornhill (2011) and Hopcroft (2012) discuss false-positives and possible resultant invasive procedures and anxiety stemming from a misdiagnosis. A false-positive diagnosis could potentially lead to unnecessary invasive confirmatory procedures to confirm the diagnosis, which could potentially drive up costs. Furthermore, Casey et al. (2011) and Hopcroft (2012) claim that because of TCa’s receptiveness to treatment, even in later stages, coupled with the notion that the disease is very rare, to cause alarmingly high levels of caution, fear, and/or anxiety about the disease to males who probably will never present with cancer does more harm than good. Lin and Sharangpani (2010), among others, mirror this position. Officially, the claim is that self-screening harm outweighs its benefit.

Arguments for TSE

The aforementioned USPSTF recommendation and arguments against TSE promotion, however, stands in contrast

to historical and contemporary support for TSE patient education efforts in a variety of clinical settings. Martin (1991), for example, provides an overview of oncological nursing TCa guidelines supporting TSE advocacy. Rosella (1994) advocates for using school nurses as a conduit for TSE patient education. Furthermore, Akar and Bebiş (2014) suggest that patient care personnel should be taught how to properly conduct TSE in order to facilitate interactive education with their patients. The American Urological Association officially includes TSE as part of their “Men’s Health Checklist” (American Urological Association, 2014), which is meant to serve as a reference for urologists and other health practitioners to improve patient care. The checklist does make mention, however, of the USPSTF’s recommendation against the procedure in the document. The ACS does not currently have a recommendation for or against TSE, but does recommend a testicular exam as part of a routine cancer-related checkup. The ACS also states that “most doctors agree that examining a man’s testicles should be part of a general physical exam.”

Although there is a potential argument that TSE could promote self-help within males and possibly lead to a decrease in physician visitation, we posit that the behavior would actually serve as the aforementioned balance wherein a male would be counseled on TSE by his physician but then have the autonomy to execute the practice. Part of the counseling of TSE is to promote a male to feel more comfortable with his body and to have a conversation with his physician regarding any concerns.

Taking into consideration the overwhelming support from public health literature for TSE advocacy (see, e.g., McGilligan, McClenahan, & Adamson [2009]; Morman [2000]; Trumbo [2004]; Wanzer et al. [2014], for discussions of increasing knowledge of, and awareness to, testicular health issues, as well as the development of more positive dispositions toward proactivity in practicing healthy behaviors), there appears to be a disconnect or polarization of positions from scholars and practitioners on the benefits of TSE and whether or not it should be included in a standard of care for treating boys and men. This heterogeneity of preventive health and clinical care recommendations (informal and formal) may create confusion among health practitioners as to which behavior(s) they should recommend to male patients. On one hand, you have clinical and community health entities advocating for TSE’s inclusion, and on the other, the USPSTF recommends against promoting the behavior. There are conflicting messages, which can possibly affect the quality of care provided. It is therefore essential that we revisit the official policies and standards in order to provide continuity on what protocols are created and utilized in caring for males, particularly as it pertains to testicular health.

Standard of Care and Clinical Practice Guidelines

The concept of standard of care has developed as legal theory has evolved over the years, beginning, *inter alia*, with the landmark legal case on informed consent *Schloendorff v. Society of New York Hospital* in 1914. Due to the evolving nature of tort law, the legal definition of the term “standard of care” is not always precisely understood. It is, therefore, important to define to what standards physicians are being held as there is a possibility that they were created without proper scientific vetting (i.e., rigorous, proper evaluation of existing evidence), and thus would serve as a detriment instead of a benefit.

Clinical practice guidelines (CPGs) and recommendations are being used more frequently as support for standard of care, although they may vary among advisory bodies and change over time (Moffett & Moore, 2011). One modern definition of standard of care is “that which a minimally competent physician in the same field would do under similar circumstances,” (Moffett & Moore, 2011, p. 111). Disclaimers are usually included in CPGs and recommendations put forth by professional societies to inform the audience that said endorsements are not intended to represent the standard of care (McGuire, Knoppers, Zawati, & Clayton, 2014), as discussed previously regarding the American Urological Association’s referencing the USPSTF’s dissenting opinion on recommending TSE. Yet in the event of a lawsuit, these types of documents may be relied on to determine professional practice (McGuire et al., 2014). When the scientific evidence base from which CPGs are formulated is lacking, it becomes especially important to acknowledge this limitation in regard to incorporating those guidelines in a standard of care (Moffett & Moore, 2011)

The Institute of Medicine defines CPGs as “statements that include recommendations intended to optimize patient care that are formed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options,” (Institute of Medicine, 2011, p. 4). CPGs have evolved over the years, going from mainly a panel of experts who develop consensus statements to evidence-based medicine with a focus on effectiveness and lowering costs. More recently, evidence-based guidelines have been criticized for lacking foundation, relying too heavily on randomized controlled trials, and not being tailored to the individual patient (Francis, 2013).

The USPSTF considers randomized controlled trials as paramount for conducting a harm–benefit analysis on interventions (USPSTF, 2013). It would be expected that the current recommendations against TSE would be based on such robust evidence. However, a 2010 systematic review identified no randomized controlled trials, cohort, nor case control studies that looked at the benefits and harms of the effectiveness of TSE in reducing mortality

due to TCa in asymptomatic men (Lin & Sharangpani, 2010). This recommendation against TSE based on a limited amount of evidence poses a number of problems.

First, the absence of sufficient evidence of effectiveness is often misinterpreted to mean “evidence of absence of effectiveness,” (Francis, 2013, p. 357). CPGs and recommendations should not be perceived as the definite standard of care for decisions at the point of care, but rather fluid, working documents that aid providers in patient care and are subject to regular updates as new evidence becomes available (Francis, 2013; Institute of Medicine, 2011). Nevertheless, CPGs are becoming more pervasive in shaping health policy (Francis, 2013). In fact, now more than ever, CPGs and recommendations are being incorporated into decisions that guide policies affecting the payment and delivery of health services. This is perhaps best demonstrated by the inclusion of the USPSTF recommendations in the Affordable Care Act, under which most insurers are required to cover the costs of “A” and “B” services with no cost sharing to the patient (Henry J. Kaiser Family Foundation, 2011).

The second problem concerns the tension between legal and ethical standards. The legal basis for the concept of standard of care (as well as CPGs, which provide the foundation from which a standard of care could be defined) can change based on the legal climate of torts like negligence and medical malpractice and clinical evidence, respectively. Rather than pin ethical analysis on esoteric ethical theories, especially for offering practical and implementable ethical recommendations, this article concentrates on analysis of the ethical principles or values, which have remained stable, that undergird the concept of standard of care and CPGs.

The core ethical value to positively benefit individual patients—beneficence—must always be at the forefront of any clinical intervention or recommendation. As clinical evidence mounts for particular interventions or recommendations, the ethical principle of nonmaleficence, a corollary of beneficence—the duty to do no further harm—becomes paramount. CPGs and recommendations should not introduce additional harms to individual practitioner recommendations to patients; in fact, they should lessen them. Nevertheless, this duty to do no further harm, as a corollary to beneficence, maintains an uneasy balance with positive benefit. For instance, as long as the potential for harm can be kept low, should not an intervention or recommendation that will benefit the patient be ethically justified (if not required)?

(Re)Defining a Standard of Care Inclusive of TSE

The potential for harms (either perceived or real) of TSE are minimal and can be mitigated by increased practitioner education to patients and management of patient expectations.

The benefit (i.e., the early detection of TCa) may yield concurrent benefits in terms of early treatment and decreasing the proportionally disparate YPLLs associated with the disease. It seems that, at least in terms of the current justification against TSE, the principle of nonmaleficence has trumped beneficence (and wrongly so, as the potential for harms are low and mitigable). On both ethical and clinical arguments, therefore, one could make a claim that a practitioner is not performing at peak proficiency by not recommending TSE to patients and, by extension, for CPGs and recommendations not to include a positive TSE recommendation, even in the absence of clinical evidence as to its effectiveness.

An assumption made about CPGs and recommendations (which are geared toward the individual practitioner–patient interaction), is that the health outcomes of the population can be improved as a result of large numbers of practitioners following particular CPGs. When viewed from this policy level, the ethical justification remains the same—TSE should be recommended—but interestingly, the reasons behind it are different. This difference occurs because when taking a public health orientation to any health problem, the ethical principles of beneficence and nonmaleficence take a back seat to other ethical considerations—namely, justice and the principle of utility (Jennings, 2003). The justice concerns (namely, the disparities that exist in the health of young males) have already been discussed. The principle of utility (best formulated as “doing the greatest good for the greatest number”) is at the core of public health ethics. Public health is less concerned with benefiting individual members of the population (as in the principle of beneficence); what matters is the net benefit to the entire population.

A quick example distills the distinct features of an ethics of health care from an ethics of public health. If the Hoover Dam were to suddenly and unexpectedly burst, an individual health care ethics approach would recommend saving as many people as possible in immediate danger. A public health ethics approach might sacrifice the people in immediate danger (who likely have a small chance of survival anyways) in order to stem the flow of water to the surrounding greater Las Vegas population. To extend the example to TSE, a public health ethics perspective would mandate CPGs recommend TSE and thus individual practitioners to teach TSE to young adult male patients. In other words, despite what might seem small risks, the benefits vastly outweigh these risks. Furthermore, the compounding benefits TSE promotion would lend to the aggregate male population through their lifespan would prove to be invaluable both in terms of YPLLs and dollars spent (see Aberger, Wilson, Holzbeierlein, Griebeling, & Nangia, 2014).

The only way that such a recommendation could be excluded or removed is in the face of overwhelming,

positive evidence that TSE is *not* beneficial. The absence of such evidence does not justify a negative or non-existent recommendation about TSE. In our view, the ethical arguments are just too strong to allow the exclusion of TSE in CPGs for the health of young adult males. Frankly, the evidence does not exist to suggest that TSE should not be promoted. This, of course, in the joint opinion of these authors poses ethical concerns that need to be expeditiously considered and appropriately addressed.

Next Steps and Future Implications

Reflecting on the fact that testicular health abnormalities tend to manifest during adolescence and young adulthood, defining a standard of care for testicular health centered on this population is obligatory. The need for TSE advocacy and education as an integral part of this new standard of care is demonstrated by the current inconsistencies surrounding testicular health at the point of care. In other words, if adolescent and young adult males are not getting care as frequently as recommended, should they not be empowered with self-help tools to promote health and wellness?

Considering both clinical and community health support for the behavior, coupled with the idea that there is a complete lack of robust evidence demonstrating that TSE harms more than benefits, it is unethical for health practitioners to not recommend the procedure. We further call on the USPSTF to review the criteria and evidence used to grant a D-rating for TSE as it is inconclusive at best. In our collective opinion the D-rating should be rerated as “I,” which essentially suggests that there is insufficient evidence to assess the balance of benefits and harms of the behavior. Any future recommendation should expand from the RCT-only rule of thumb to include other analytical study designs, inclusive of cohort and case-control designs.

As TSE received a “D” rating from the USPSTF, the service alone would probably not be covered as part of preventive health under the tenets of the Affordable Care Act. If TSE were to be incorporated into a routine yearly medical visit, however, it may be covered at 100% as an adult well male examination. But, there are virtually no costs associated with TSE, save the few minutes of patient–provider dialogue that would result from an explanation on how to conduct TSE, the importance of the procedure, and the fielding of any questions, if prompted. These authors suggest that effective communication about TSE can occur within the first few minutes of the general exam of patient vitals and would cost little to nothing to complete this service. This consult will allow males to become more knowledgeable about their bodies, and thus more aware of potential issues.

Wenger and Oliffe (2013) discuss "Moving Beyond the Prostate," which is essentially a call for researchers to expand their scope of research on men and cancer. The authors not only mean researching other cancers besides prostate but also that we need to be innovative in our approach. We take it one step further by suggesting that health practitioners reframe their approach to treatment with a more lifecourse perspective. Considering the changing and evolving medical care system (i.e., increasing costs, access concerns, among others), it is essential to promote interventions grounded in the patient education model that are easy to implement and are cost effective. There are few better examples than TSE.

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