

Review

The Sexual Health Inventory for Men (SHIM): a 5-year review of research and clinical experience

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The Sexual Health Inventory for Men (SHIM) is a widely used scale for screening and diagnosis of erectile dysfunction (ED) and severity of ED in clinical practice and research. In reviewing the SHIM-related literature, we sought to provide a compendium of studies in which the SHIM was used, to provide a systematic framework for organizing and evaluating the studies, and to provide a status report on the SHIM and its impact on the management of male sexual dysfunction. Using a Medline search, we found that the SHIM was an integral measure in at least 21 studies on the prevalence of ED, 23 studies on the efficacy of ED interventions, and eight other (mainly correlational) studies. The quantity of research and quality of scholarship on the SHIM provide testimony to its positive impact on understanding and improving male sexual function. These scientific contributions are likely to remain influential in coming years.

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Introduction

Erectile dysfunction (ED) affects a large proportion of the adult male population. The International Index of Erectile Function (IIEF) is a widely used, multidimensional self-report instrument for the evaluation of male sexual function.^{1,2} The development and validation of the IIEF have been reported elsewhere.^{1,2} Briefly, the IIEF, which consists of 15 items and five domains, is a psychometrically valid and reliable instrument that was developed through consultations with an international panel of experts for use in determining efficacy of treatment in controlled clinical trials. The IIEF has high sensitivity for detecting real treatment effects and has been adopted as the gold standard treatment outcome measure for clinical trials in ED, regardless of the type of treatment intervention or study population under investigation. Designed originally and

specifically for use in clinical trials, the full-scale IIEF required simplification and abbreviation in order to be adopted in broad clinical practice as a diagnostic measure for ED or as a simple office screening tool.

The National Institutes of Health's Consensus Panel on ED outlined several goals for basic and clinical research on ED.³ One of these goals was to create a staging system for the quantitative and qualitative classification of ED to improve clinical decision making and patient care. With this purpose in mind, an abridged five-item version of the 15-item IIEF known as the IIEF-5—or the Sexual Health Inventory for Men (SHIM)—was developed and validated as a brief, easily administered, patient-reported diagnostic tool (Table 1).⁴

Diagnostic evaluations of the SHIM have shown it to have high sensitivity and specificity, moderate-to-high correlations with (and better reliability than) a single-item self-assessment of ED severity, and tangible correlations (as expected) with improvement in erections and with treatment satisfaction for both patient and partner.^{4,5}

The SHIM, which, like the original IIEF, has been translated into more than 30 languages, is widely used as a screening measure in clinical practice settings in the United States and other countries

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Table 1 The Sexual Health Inventory for Men

PATIENT INSTRUCTIONS

SUBJECT INITIALS: _____

DATE COMPLETED: _/_/_
DD/MM/YR

Sexual health is an important part of an individual's overall physical and emotional well-being. Erectile dysfunction, also known as impotence, is one type of very common medical condition affecting sexual health. Fortunately, there are many different treatment options for erectile dysfunction. This questionnaire is designed to help you and your doctor identify if you may be experiencing erectile dysfunction. If you are, you may choose to discuss treatment options with your doctor.

Each question has several possible responses. Circle the number of the response that **best describes** your own situation. Please be sure that you select one and only one response for **each question**.

OVER THE PAST 6 MONTHS:

1. How do you rate your confidence that you could get and keep an erection?Very Low
1Low
2Moderate
3High
4Very High
52. When you had erections with sexual stimulation, how often were your erections hard enough for penetration (entering your partner)?No sexual activity
0Almost never or never
1A few times (much
less than half the
time)
2Sometimes (about
half the time)
3Most times (much
more than half the
time)
4Almost always or
always
53. During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) you partner?Did not attempt intercourse
0Almost never or never
1A few times (much
less than half the
time)
2Sometimes (about
half the time)
3Most times (much
more than half the
time)
4Almost always or
always
54. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?Did not attempt intercourse
0Extremely difficult
1Very difficult
2Difficult
3Slightly difficult
4Not difficult
55. When you attempted sexual intercourse, how often was it satisfactory for you?Did not attempt intercourse
0Almost never or never
1A few times (much
less than half the
time)
2Sometimes (about
half the time)
3Most times (much
more than half the
time)
4Almost always or
always
5

SCORE: Add the numbers corresponding to questions 1–5. If your score is 21 or less, you may want to speak with your doctor.

around the world, and is intended to gauge sexual function over the past 6 months. In addition, the SHIM has been adopted as a standard diagnostic aid for office screening of ED. Responses to each of the five items on the SHIM (Table 1), which are based on a rating scale from 0 to 5 or from 1 to 5 (depending on the item), are summed to arrive at a total score that can range from 1 to 25, with higher scores indicating better sexual health. Patients with a score of 21 or less may have evidence of ED, and are encouraged to consult a physician for further evaluation and possible treatment of their condition. Among men in a stable relationship (ie men who had an opportunity for sexual activity), classification of ED is partitioned into five severity grades: no ED (SHIM total score, 22–25), mild (17–21), mild to moderate (12–16), moderate (8–11), and severe ED (1–7).

Since publication of the original validation studies,^{4,5} several articles on the SHIM have been published. Obtaining publications from a Medline search (January 1966–November 2004) using the key words 'Sexual Health Inventory for Men' or 'IIEF-5', we provide a comprehensive review of the SHIM with three major objectives: (1) to provide a compendium of studies in which the SHIM was used, (2) to provide a systematic framework to organize and review the studies, and (3) to provide a status report on the SHIM and its impact on the assessment of male sexual function.

Prevalence studies

The Medline search identified 23 articles based on 21 independent studies in which the SHIM was used to estimate the prevalence of ED (Table 2). Of these 21 prevalence studies, five (24%) studies involved a diverse group of men from a broad range of clinical practice settings (family services or urological clinics). Men in each study did not share a common chronic disease and could have had none, one, or multiple chronic conditions. The estimated prevalence of ED in these studies was 64% in Leon, Spain;⁶ 56% in West Virginia, USA;⁷ 54% in Porto Alegre, Brazil;^{8–10} 37% in Korea;¹¹ and 32% with severe or moderate ED in Japan.¹² Four studies involved men from the general population. The estimated prevalence of ED was 32% in France;¹³ 51% in Rancho Bernardo, California, USA;¹⁴ 51% in Singapore;¹⁵ and 36% among healthy men and 52% among men with chronic disease in Japan.¹⁶ These proportions are likely to have been influenced by the age distribution of the sample, which differed from study to study (Table 2).

The remaining 12 (57%) studies provided the estimated prevalence of ED for patients with a specific chronic disease. The estimated prevalence

of ED was 49% for men with chronic prostatitis in Anhui, China;¹⁷ 56% for men with kidney transplants in Toulouse, France,¹⁸ 55% for men with kidney transplants in Spain;¹⁹ 82% (prevalence of severe ED = 45%) for men with end-stage renal disease in Philadelphia, Pennsylvania, USA,²⁰ 88% for men with end-stage renal disease in Ontario, Canada;²¹ 69% for men with Peyronie's disease (vs 54% for men without) in Porto Alegre, Brazil;²² 47% for men with hypertension in Valencia, Spain;²³ 68% for men with diabetes in Japan;²⁴ 70% (prevalence of severe ED = 25%) for men with chronic stable coronary artery disease in Southern California, USA;²⁵ 81% for men with systemic sclerosis and 48% for men with rheumatoid arthritis in the United States and Canada;²⁶ and 46% for men with essential hypertension in Spain.²⁷ Among patients with ED in Beijing, China, 7% had neurogenic ED.²⁸

The prevalence of ED was generally based on a SHIM score of 21 or less, as recommended,^{4,5} and, when assessed, severity of ED also followed guidelines (no ED, 22–25; mild, 17–21; mild to moderate, 12–16; moderate, 8–11; and severe, 1–7). A few exceptions were noted. Authors of one study specified a SHIM score above 20 as no ED, between 16 and 20 (inclusive) as mild ED, between 11 and 15 as moderate ED, and less than 10 as severe ED.¹³ Authors of another study used a variant of the SHIM (the first four questions on the IIEF-5 that address erectile functioning) with severity grades of ED as complete (score of 4 or less), severe (5–10), moderate (11–14), and mild (15–18), as well as no ED (19–20).¹⁴ One group of researchers used a score of less than 21 for ED and subdivided ED arbitrarily into mild (16–20), moderate (11–15), and severe or complete (10 or less).¹⁵ Another group used scores of 17–21 for mild, 11–16 for mild-to-moderate, 8–10 for moderate, and 7 or less for severe ED.²⁵

In general, a common theme among the 21 studies reviewed was a relatively high prevalence rate of ED that signified a common and major health problem. When the relationship between ED and its potential risk factors was examined, a higher prevalence of ED was found to be associated with diabetes, depression, vascular disease, hypertension, and increased age, as predicted. Researchers and patients noted that the SHIM was user-friendly, easy to administer, quick, and inexpensive.

Intervention studies

The SHIM was applied as an efficacy measure in 23 studies evaluating an intervention for ED or related conditions (eg Peyronie's disease) (Table 3). In four (17%) of these studies, the sole intervention was surgery and comprised Nesbit operation for Peyronie's disease,²⁹ venous stripping surgery,³⁰ prosta-

Table 2 21 Prevalence studies on ED using the SHIM

<i>Authors</i>	<i>Subjects and setting</i>	<i>Results on prevalence of ED</i>	<i>Conclusions</i>
Sánchez Merino <i>et al</i> ⁶	830 men aged 19–90 y; urology and family services; Leon, Spain	Overall prevalence = 63.9%; marked increase in prevalence after age 50	Prevalence very high; risk factor for ED: age, depression, and vascular disease
Hakim <i>et al</i> ⁷	102 patients aged 20–80 y; university-based urology clinic; West Virginia, USA	Prevalence = 56%; 58% of patients screened initiated discussion with their physician; average SHIM score = 17.24	Screening for ED using the SHIM should be performed on patients with any identifiable risk factor
Rhoden <i>et al</i> ^{8–10}	965 patients (mean age 60.7 y); prostate exam; Porto Alegre, Brazil	Prevalence: 53.9% for any ED, 21.5% for mild, 14.1% for mild to moderate, 6.3% for moderate, and 11.9% for severe	ED correlated with age, but ED and severity of ED did not correlate with testosterone serum levels; SHIM was easy method to evaluate ED in this large study
Cho <i>et al</i> ¹¹	3501 men at 32 family practices; Korea	Prevalence: 1.6% for severe ED, 10.2% for moderate, and 24.7% for mild	ED is a major health problem in primary-care settings; risk factors for ED: age, 30+ pack-years of smoking, low educational status, low income, high job-related physical activity, depression, and anxiety
Sasayama <i>et al</i> ¹²	6112 men from 447 outpatient clinics throughout Japan	81% of men (<i>n</i> = 4951) evaluated; prevalence of severe or moderate ED = 32%; severity of ED related to depression, dysuria, and perceived poor health condition	ED is common among male ambulatory patients; physicians should be encouraged to ask their patients about their ED to identify an unmet need for treatment
Giuliano <i>et al</i> ¹³	1004 aged 40 y and older (mean age 57.3 y); telephone survey; France	Prevalence = 31.6%; majority of men suffering from ED expressed dissatisfaction with their partner	Confirms high prevalence of ED in France; SHIM proved to be a satisfactory in general
Monga <i>et al</i> ¹⁴	976 men in an established community-based cohort of older men (mean age 64.5 y); Rancho Bernardo, California, USA; mailed survey	51% of 660 sexually active men reported complete (3%), severe (10.5%), moderate (12.6%), or mild (24%) ED	Confirms strong correlation of advancing age with prevalence and degree of ED
Tan <i>et al</i> ¹⁵	729 men aged 30 y and above completed a comprehensive survey that included the SHIM; Singapore	Prevalence: 51.3% for any ED, 23.2% for mild, 8.8% for moderate, and 19.3% for severe	ED is common among men in Singapore; age is factor most affecting ED; prevalence and severity of ED increased substantially after 50
Naya <i>et al</i> ¹⁶	640 healthy men and 396 men with chronic disease; mean age = 43.6 y; Japan (Tokyo, Kyoto, Osaka)	Prevalence (called ‘incidence’ in article) of ED among healthy men = 36.15%; prevalence of ED among men with chronic disease = 52.3%	Likelihood of ED increases with presence of cardiac disease, diabetes mellitus, chronic renal failure, and hypertension
Liang <i>et al</i> ¹⁷	2000 men with chronic prostatitis; Anhui, China	Prevalence = 49%	Prevalence is high and negatively correlated with age and course of chronic prostatitis
Malavaud <i>et al</i> ¹⁸	212 sexually active patients; kidney transplant recipients; Toulouse, France	Prevalence = 55.7%; ED status linked to age, time on dialysis, and iterative transplants	Unveiled high prevalence; negative impact of time on dialysis is emphasized
Rebollo <i>et al</i> ¹⁹	199 men with kidney transplants; median age = 52 y; mean time with transplant = 70.5 months; Spain	Prevalence: 54.9% for any ED, 20.7% for severe, 10.9% for moderate, 11.4% for mild to moderate, and 11.9% for mild	Ask patients about ED because of its high prevalence; design intervention strategies to decrease damage caused by dialysis
Rosas <i>et al</i> ²⁰	302 patients with end-stage renal disease (mean age 59.5 y); Philadelphia, Pennsylvania, USA	Prevalence of any ED = 82%; prevalence of severe ED = 45%	Increasing age and diabetes associated with higher prevalence of ED; high prevalence even among patients with good functional status

Table 2 Continued

Authors	Subjects and setting	Results on prevalence of ED	Conclusions
Krishnan <i>et al</i> ²¹	44 patients with chronic end-stage renal disease on peritoneal dialysis (PD); mean age 61.8 y; Ontario, Canada	Prevalence of ED = 88%; all patients with diabetes had ED	ED is highly prevalent in patients on chronic PD; diabetes and increasing age are associated with higher percentage of ED
Rhoden <i>et al</i> ²²	974 older than age 50 y (mean 60.7 y); prostate exam; Porto Alegre, Brazil	Prevalence of ED for men with and without Peyronie's disease were 68.6 and 53.5%, respectively ($P > 0.05$)	Other epidemiological studies with different designs and age stratification are needed for confirmation
Cuéller de León <i>et al</i> ²³	512 patients (mean age 63.4 y) with hypertension from educational primary care center; Valencia, Spain	Prevalence = 46.5%; ED correlated with age, diabetes mellitus, and ischemic heart disease	High prevalence of ED in patients with hypertension
Naya <i>et al</i> ²⁴	62 patients (mean age 59.6 y) with diabetes mellitus, of whom 25 were treated with hemodialysis (chronic renal failure, CRF); SHIM self-administered at home; Kyoto, Japan	Prevalence: 0% for control ($n = 20$), 51.0% for the non-CRF group, 92.0% for the CRG group, and 67.7% for all patients with diabetes	Level of erythrocyte aldose reductase may be a useful modality for prediction of ED in patient with diabetes
Kloner <i>et al</i> ²⁵	76 patients with chronic stable coronary artery disease during routine outpatient cardiology visits; mean age = 64 y; Southern California, USA	Prevalence: 70% for any ED, 25% for severe, 5% for moderate, 21% for mild to moderate, and 18% for mild	ED is extremely common in this population; SHIM is useful, quick, and inexpensive
Hong <i>et al</i> ²⁶	43 men with systemic sclerosis and 23 with rheumatoid arthritis; mean age = 53 y; USA and Canada	Prevalence: 81% with systemic sclerosis (SSc), 48% with rheumatoid arthritis (RA)	ED is frequent in SSc, more common than RA, and occurs on average 3 y after disease onset
Aranda <i>et al</i> ²⁷	2130 men (mean age 55.5 y) with essential hypertension under treatment were recruited in the first phase of the study; Spain	Prevalence of ED = 45.8% ($n = 975$); these 975 patients were invited to start treatment with sildenafil in second phase of the study	ED is common in this population
Bai <i>et al</i> ²⁸	201 patients with ED were evaluated by physical examination; Beijing China	13 cases of neurogenic ED and 188 cases of miscellaneous (and unknown cases) of ED were diagnosed	Neurogenic ED is common disorder; diagnostic approaches should be based on the patient's condition

Note: Only the four questions on erectile functioning of the SHIM were employed in one study.¹⁴

tectomy,³¹ and surgery for penile fracture.³² In seven (30%) of the 23 studies, the active interventions included sildenafil for patients with ED,^{5,33} sildenafil plus patient education for patients with ED,^{34–36} sildenafil for patients with ED and arterial hypertension,³⁷ and, in one study, sildenafil in young healthy men.³⁸ Five (22%) of the 23 studies featured the evaluation of other oral agents: *Butea superba* for patients with ED,³⁹ alpha-blockers or finasteride for patients at high risk for ED,⁴⁰ intraurethral alprostadil for patients with ED who were nonresponders to sildenafil,⁴¹ atorvastatin for patients with hypercholesterolemia as the only risk factor for ED,⁴² and herbal and vitamin supplements for men who visited a prostate cancer screening clinic.⁴³ Six (26%) intervention studies involved surgery followed by sildenafil.^{44–49} One (4%) study involved intracorporeal injection for ED caused by radical prostatectomy.⁵⁰

In general, the results of the intervention studies using the SHIM indicated a substantial benefit with

sildenafil alone, sildenafil plus patient education, and surgical procedures.

All but two studies strictly followed the guidelines proposed for the SHIM from its validation studies.^{4,5} In one study, the 'normal' score used for no ED (26–30) suggested that the Erectile Function (EF) domain of the IIEF was used instead of the SHIM (or 'IIEF-5').³⁸ In another study, a score of less than 21 (instead of less than or equal to 21) was used to classify ED.⁴⁰

Other studies

In eight other studies, which were neither prevalence studies nor intervention studies, the SHIM was used to (1) determine patient inclusion in one study, (2) examine or test correlational hypotheses with potential risk factors of ED in six studies, and (3) evaluate its measurement properties in a specific

Table 3 23 Intervention studies using the SHIM

Authors	Subjects and interventions	Results	Conclusions
Savoca <i>et al</i> ²⁹	157 patients assessed on sexual function at long-term follow-up (mean 72 months) after Nesbit operation for Peyronie's disease; Trieste, Italy	136 patients (86.7%) had good erectile function (SHIM score > 21); 20 patients (12.7%) had partial ED (SHIM range 10–21); one patient (0.6%) had complete loss of erectile function	Nesbit operation is a simple and safe method to correct penile deformity due to Peyronie's disease; the operation results in the greatest amount of patient satisfaction about sexual function
Hsu <i>et al</i> ³⁰	148 patients who underwent venous stripping surgery; SHIM measured before and after months after surgery; Taipei, China	Mean SHIM score was 9.3 at preoperative stage and increased to 22.7 after the operation	Substantial improvement in erectile function occurred after venous surgery, which patients believe is a worthwhile treatment modality
Noldus <i>et al</i> ³¹	366 patients underwent uni- or bilateral nerve-sparing radical retropubic prostatectomies for clinically localized prostate cancer; mean age = 62.5 y; Hamburg, Germany; 12-month follow-up	Men who had good erections ('grades 4 and 5') had a higher SHIM score (mean of 19.2 for unilateral and 20.2 for bilateral) than those with or without tumescence (mean of 5.2 for unilateral and 7.0 for bilateral)	Bilateral procedure reveals better results on recovery of erections sufficient for sexual intercourse; SHIM now mailed preoperatively to patients
Zargooshi <i>et al</i> ³²	170 patients (mean age 27 y) with penile fracture who underwent surgery; long-term potency (>6 months after surgery) was evaluated; SHIM classified grades of ED; Kermanshah, Iran	162 reported satisfactory and painless erectile function; in sexually active men, mean SHIM score was 23.2 ($n = 162$) and not statistically different from 22.8 for controls ($n = 194$)	Surgery for a fracture penis is safe and effective, restoring erectile function to that of controls; surgical treatment is strongly recommended
Cappelleri <i>et al</i> ⁵	247 male outpatients (mean age 59 y) were randomized to sildenafil or placebo for 12 weeks; USA	Mean (median) SHIM score in sildenafil group was 16.5 (20.5) vs 9.2 (6.0) in placebo group ($P < 0.001$); SHIM scores correlated moderately with treatment satisfaction from patients ($r = 0.68$) and partners ($r = 0.56$) as well as with global efficacy ($r = 0.69$)	SHIM showed meaningful and substantial differences between sildenafil and placebo; SHIM correlated as expected with treatment satisfaction and global efficacy on improved erections
Martínez-Jabaloyas <i>et al</i> ³³	213 eligible patients with ED (mean age 58 y); Valencia, Spain; efficacy with sildenafil based on Questions 2 and 3 of SHIM and global assessment question; patients also evaluated with five-item SHIM; Assessments at baseline and 2 months after sildenafil	Sildenafil was efficacious in 56.8% of patients	Sildenafil is rather effective and well tolerated; baseline severity of ED (baseline SHIM) and etiological factors are most associated with treatment outcome
Guirao Sanchez <i>et al</i> ³⁴	125 patients with ED as measured by a SHIM score below 21; Murcia, Spain; intervention: health education with sildenafil (no control group)	Erectile function improved by 74% with sildenafil	Two of three patients with ED presented associated diseases; one of three were ignorant of their health problem; three in every four responded to sildenafil
Atiemo <i>et al</i> ³⁵	253 sildenafil nonresponders (mean age 59.8 y) received patient reeducation over a 2-y period; Baltimore, Maryland, USA	98 patients were responders to sildenafil based on a global assessment question on sildenafil failures referred from primary improved erection; compared with nonresponders, responders had an average increase in SHIM score per question of about two points	Approximately 40% of patients with care providers can be converted to responders through re-education
Jiann <i>et al</i> ³⁶	60 patients with ED (mean age 64.5 y) who failed on sildenafil	Based on a global assessment question, the response rate to	Efficacy of sildenafil could be improved to a great extent by

Table 3 Continued

Authors	Subjects and interventions	Results	Conclusions
	were eligible to be rechallenged with sildenafil; 44 consented to the rechallenge and received appropriate patient education; Taiwan, China	rechallenge was 58.5%; mean improvement in SHIM score education of patients and continuing from baseline was 8.4 for responders and 1.4 for nonresponders; SHIM also used to classify moderate and severe ED	adequate medical education given to primary care physicians
Martínez Jabaloyas <i>et al</i> ³⁷	103 eligible patients with ED plus arterial hypertension; Valencia, Spain; intervention: sildenafil; efficacy measured by SHIM and global assessment questionnaire	Sildenafil was efficacious in 59.2% of patients	Sildenafil is rather effective and well tolerated; baseline severity of ED (baseline SHIM) and diabetes mellitus are most associated with treatment outcome
Mondaini <i>et al</i> ³⁸	92 young healthy men (aged 20–40 y) were initially evaluated with the ‘SHIM’; only the 60 men whose ‘SHIM’ score was in the normal range qualified; randomized placebo-controlled double-blind trial with sildenafil; Florence, Italy	No difference between groups on erectile quality and improvement of erection; sildenafil caused a significant reduction of the postejaculatory refractory time (12/30 vs 4/30, $P = 0.04$)	Sildenafil does not improve sexual function in men without ED but does appear to reduce the postejaculatory refractory time
Cherdshewasart and Nimsakul ³⁹	39 patients with ED (aged 30–70 y); 3-month double-blind clinical trial; treatments: <i>Butea superba</i> ($n = 25$) and placebo ($n = 14$); Bangkok, Thailand	17 of 25 patients in <i>Butea superba</i> completed the trial and they had significant upgrading in four of five questions on SHIM; no patients in the placebo group completed the SHIM	Plant preparation appears to improve erectile function in ED patients without apparent toxicity
Sadeghi-Nejad <i>et al</i> ⁴⁰	123 patients who were taking alpha-blockers or finasteride and who had risk factors for ED; mean age = 68 y; Newark, New Jersey, USA	81% had SHIM scores <21, indicating some degree of ED; average SHIM score indicated no significant difference among alpha-blockers, finasteride, and an age-matched group on neither medication; inverse linear relationship between number of ED risk factors and SHIM scores	No difference between alpha-blockers and finasteride as independent risk factors for ED; age and other risk factors (heart disease, hypertension, smoking, and hypercholesterolemia) tend to have a much stronger influence on severity of ED
Jaffe <i>et al</i> ⁴¹	44 patients (aged 41–74 y) with ED in whom treatment with sildenafil failed were later treated with intraurethral alprostadil SHIM administered before and after treatment with intraurethral alprostadil; Philadelphia, Pennsylvania, USA	13 (29.5%) responded successfully to intraurethral alprostadil (follow-up range: 2–15 months) based on improved SHIM score and another subjective measure; SHIM used to determine quality of erections and any improvement in erectile function	Although sildenafil remains the most common initial therapy in men with ED, intraurethral alprostadil may be a reasonable treatment option for sildenafil nonresponders
Saltzman <i>et al</i> ⁴²	9 men (mean age 49.7 y) were determined to have hypercholesterolemia as the only risk factor for ED and agreed to participate; organic ED verified in part by SHIM; intervention = atorvastatin; Peabody, Massachusetts, USA	Mean length of treatment with atorvastatin was 3.7 months; eight of nine men had improved erection adequate for penetration during sexual intercourse; mean SHIM scores improved from 14.2 to 20.7 ($P < 0.001$).	Treating hypercholesterolemia may improve ED while promoting primary cardiac prevention
Barqawi <i>et al</i> ⁴³	12 457 men (mean age = 60 y) completed the SHIM and the American Urological Association Symptom Score (AUA-SS) in order to examine the relationships of SHIM and AUA-SS with observed usage	SHIM scores did not differ between men who took herbs/vitamin supplements and those who did not; AUA-SS was greater (poorer) for men who took the herb/vitamin compared with those who did not	An additional investigation is warranted on why some men are not receiving standard prescription medications for lower urinary tract symptoms and whether reliance on alternative treatment plays a role

Table 3 Continued

<i>Authors</i>	<i>Subjects and interventions</i>	<i>Results</i>	<i>Conclusions</i>
	trends of herbal and vitamin supplements among men who visited a prostate cancer screening clinic; USA		
Raina <i>et al</i> ⁴⁴	43 sexually active patients (mean age 66.7 y) who underwent ¹²⁵ I seed implantation to treat low-volume prostate cancer and who initiated sildenafil therapy; Cleveland, Ohio, USA	Mean SHIM score of 20.17 before brachytherapy, 9.82 after ¹²⁵ I seed insertion (before sildenafil use), and 18.30 after sildenafil at 4 y	ED is a major long-term issue after ¹²⁵ I seed radiotherapy; sildenafil improves erections in most patients after ¹²⁵ I seed implantation
Raina <i>et al</i> ⁴⁵	48 patients with ED after radical prostatectomy (RP) who responded positively to sildenafil were surveyed 3 y later; Cleveland, Ohio, USA	Mean SHIM score of 5.18 at baseline after surgery, 18.52 at 1 y of sildenafil use, and 20.01 at 3 y of sildenafil use	Vast majority of patients with ED after RP who initially responded to sildenafil continue to do so at 3 y and remained satisfied and compliant
Raina <i>et al</i> ⁴⁶	49 patients (mean age 60.9 y) with ED after radical prostatectomy were identified as long-term users of intracavernous (IC) injections; patients received open-label treatment with sildenafil for a minimum of 4 weeks or five attempts; Cleveland, Ohio, USA	Patients who switched to oral therapy had a greater mean SHIM score with IC injections than those who did not switch; three predictive factors for a successful switch: high preoperative SHIM score, high post-IC injection SHIM score, and type of IC medication used	Long-term users of IC injection therapy can potentially switch to sildenafil with acceptable sexual satisfaction
Raina <i>et al</i> ⁴⁷	174 patients (mean age 61.8 y) with ED were prescribed sildenafil after radical prostatectomy (RP); SHIM used to assess erectile function at baseline and 1 y after sildenafil use; Cleveland, Ohio, USA	100 of 174 patients reported successful vaginal intercourse and had a mean SHIM of 19.46; SHIM scores indicated that improvement was greater in the bilateral nerve-sparing (NS) group than in unilateral NS or non-NS groups	Efficacy of sildenafil after RP correlated with degree of neurovascular bundle preservation, preoperative erectile function status, and interval from RP to sildenafil use
Oguara <i>et al</i> ⁴⁸	43 eligible patients (mean age 62.5 y) were prescribed sildenafil at their request after they had a radical retropubic prostatectomy for localized prostate cancer; Kurashiki, Japan	27 of 43 completed the SHIM; sildenafil 50 mg had a better effect on sexual function than 25 mg in most patients; mean SHIM score increased from 4.3 at baseline to 11.4 at follow-up; sildenafil yielded improvements in all questions of the SHIM	Sildenafil is well tolerated and should be initially used for treatment of Japanese men with ED after radical retropubic prostatectomy
Liu <i>et al</i> ⁴⁹	170 married males (aged 26–50 y) who received kidney transplants were considered; 53 of them with ED received sildenafil for 6 months; SHIM used to measure sexual n function at baseline and after 6 months; Chongqing, China	At the end of treatment, each question in SHIM increased significantly; no interactions between sildenafil and cyclosporine; no significant adverse effects of sildenafil on graft function	Sildenafil is an effective and safe agent for treatment of ED in kidney transplant recipients
Raina <i>et al</i> ⁵⁰	102 patients using intracorporeal (IC) injection for ED caused by radical prostatectomy; mean age = 60.4 y; Cleveland, Ohio, USA	Mean presurgery SHIM (baseline) score was 21.75, decreased to 4.23 after surgery (mean interval = 9 months), and increased to 19.46 post-treatment (mean use = 3.7 y); no difference on SHIM between nerve sparing (NS) and non-nerve sparing	IC injections can provide long-term efficacy and compliance in up to 70% of patients; IC injections are an excellent salvage option in NS patients who fail oral therapy and first option in non-NS patients

Note: The EF domain of the IIEF was probably used instead of the SHIM in one study.³⁸

Table 4 Eight other studies using the SHIM

Authors	Subjects and settings	Results	Conclusions
Guest and Das Gupta ⁵¹	23% of the 5000 sampled ($n = 1141$) mailed a completed SHIM (IIEF-5), used to diagnose ED and determine patient inclusion into the study; UK	Of the 1141 respondents, 82.2% ($n = 939$) met the criteria for ED (SHIM score of 21 or less); mean age = 60.4 y	Health-related quality of life (EuroQoL) among men with ED is poorer in those with comorbid illnesses and improves with age
Day <i>et al</i> ⁵²	SHIM questionnaires on 31 054 men were used for analysis from more than 600 general practitioners and urologists throughout the United States; ED status (measured by SHIM) expressed as function of known risk factors for ED (age, current smoking status, diabetes, depression, hypertension, prostate disease, cholesterol levels)	Risk of ED can be reasonably predicted using known risk factors for ED (sensitivity = 81.8%, specificity = 57.7%)	The SHIM Score Indicator showed significant relationships between risk factors for ED and an increased risk for at least mild ED; The Indicator is a convenient way to rapidly identify patients at high risk of ED who should be further assessed
Mondaini <i>et al</i> ⁵³	67 men (median age of 27 y old) who complained of 'short penis' and requested surgical correction; clinical history, including the SHIM (IIEF-5) and an accurate physical exam, were obtained; Italy	No patient had ED according to history and SHIM scores; examinations failed to detect anatomical genital abnormalities in it reassures some men that they in any patient	Use of nomogram to compare penile dimensions is a useful tool; not abnormal and may reduce the demand for unproven surgical procedures
Kassouf and Carrier ⁵⁴	80 patients (mean age = 45.2; mean duration of ED = 3.5 y) who underwent a complete history and physical examination; Montreal, Canada	No significant differences in 'IIEF-5' ('SHIM') scores among patients with a normal vascular response, arterial insufficient, and venous leakage	'SHIM' should not be used as a method of diagnosing or comparing specific causes of ED
Elliott <i>et al</i> ⁵⁵	181 male veterans (mean 68.2 y) completed the SHIM and the International Prostate Symptom Score (IPSS) questionnaire to examine whether severity of lower urinary tract symptoms (LUTS), when controlled for other factors, was related to ED; California, USA	Correlations of SHIM with total IPSS was -0.17 ($P = 0.023$), obstructive IPSS was -0.20 ($P = .006$), irritative IPSS was -0.05 ($P = 0.492$); age was the only other factor with a statistically significant correlation with the SHIM score ($r = -0.23$, $P = 0.002$)	Obstructive LUTS correlated with and was predictive of ED, even after controlling for age and comorbidities; although age correlated with ED, age did not add to the model composed of obstructive IPSS and depression
Fung <i>et al</i> ⁵⁶	570 men completed the 'SHIM' to examine whether common coronary heart disease (CHD) factors measured in mid-life predict ED 25 y later; mean age = 45.6 Y; Rancho Bernardo, California, USA	Mean age, body mass index, cholesterol, and triglycerides were each significantly associated with increased risk of ED; blood pressure and fasting blood glucose were not statistically associated with ED, likely due to selective mortality	Improving CHD risk factors in mid-life may decrease the risk of ED as well as CHD; ED should be included as an outcome in clinical trials of lipid-lowering agents and lifestyle modifications
Mulhall <i>et al</i> ⁵⁷	534 presented to one of three prostate cancer screening centers completed the SHIM, provided medical history, and underwent physical examination; diagnosis of Peyronie's disease was based on palpable penile plaque; USA	48 patients (8.9%) had Peyronie's disease (mean age = 68.2 y); these patients has significantly lower values for responses to each of the five questions on the SHIM; increased and decreased total SHIM score were significantly related to a greater probability of Peyronie's disease	Prevalence of Peyronie's disease is greater than most previously reported series; significant associations were found between Peyronie's disease aging, hypertension, diabetes, and self-reported ED
Lim <i>et al</i> ⁵⁸	Validation study on IIEF and SHIM for use in Malaysia; 136 patients in one study and 26 ED patients in another study were evaluated; mean age = 54 y	Area under the curve of the Malay IIEF-5 (SHIM) was 0.86; the optimal cutoff score of 17 had a sensitivity of 85% and specificity of 75%	While the Malay IIEF requires more work, the Malay IIEF-5 (SHIM) has acceptable measurement properties to recommend it use in clinical practice and research

Note: Only the four questions on the erectile functioning of the SHIM were employed in one study.⁵⁶ Authors of another study⁵⁴ apparently confused the severity classes of the SHIM with that of the six-item EF domain of the IIEF; scores for their severity classes seem to belong to neither the SHIM nor the EF domain.

population (Table 4). Specifically, one of the eight studies used the SHIM to diagnose ED for the purpose of including patients with a positive diagnosis into the study.⁵¹ Six studies, which were correlational studies, addressed the relationship of ED (as measured by SHIM) with a set of risk factors for ED (age, current smoking status, diabetes, depression, hypertension, prostate disease, and cholesterol levels)⁵² and with the following: anatomical genital abnormalities;⁵³ normal response, arterial insufficiency, and venous leakage;⁵⁴ the International Prostate Symptom Score;⁵⁵ age, body mass index, cholesterol, triglycerides, blood pressure, and fasting blood glucose;⁵⁶ and Peyronie's disease.⁵⁷ Another study involved the validation of the SHIM for use in Malaysia, and its authors recommended its implementation in clinical practice and research.⁵⁸

Authors of one study applied Questions 1–4 on the SHIM (four items on erectile function) rather than all five SHIM items.⁵⁶ They partitioned ED into complete (≤ 4), severe (5–10), moderate (11–14), mild (15–18), and none (19–20). Authors of another study apparently confused the severity classes of the SHIM with that of the six-item EF domain of the IIEF.⁵⁴ Scores for their severity classes seem to belong to neither the SHIM nor the EF domain.

Discussion

In a few published commentaries, issues were raised concerning the clinical validation and potential applications of the SHIM for diagnostic classification of ED severity.^{59–63} Among the issues discussed were potential cultural differences on how the specific terms in the SHIM are viewed and the application of findings from the SHIM to general practice settings based on scores from men in clinical trials.^{59–62} Also discussed was a lack of difference in SHIM scores among disparate group of patients.^{54,63} As there appears to be some confusion in the literature regarding the selection of items, scoring, and interpretation of the SHIM, we take this opportunity to address and clarify five key areas.

First, among men who attempted sexual intercourse and activity, the original scores of SHIM on disease severity are 22–25 (inclusive) for no ED, 17–21 for mild, 12–16 for mild-to-moderate, 8–11 for moderate, and 5–7 for severe.⁴ The score range of 1–7 for severe ED is applicable to men who had the opportunity to engage in sexual activity and intercourse, but whose sexual functioning is so poor that they did not even bother to attempt sexual activity and intercourse.^{4,5,61–62} In clinical practice, health-care professionals should ask patients about their desire and opportunity for sexual activity in order to ensure that low SHIM scores are truly indicative of severe ED. The SHIM is not applicable to men who

do not seek or have an opportunity to engage in sexual activity.^{61,62} A low score may be a consequence of a patient having an absence of opportunity or lack of interest in sex, rather than ED *per se*. Scores on the SHIM should always be placed in the context of the individual patient's circumstances in interpreting the diagnostic significance of the overall score.⁶²

Second, some confusion exists in the literature concerning the similarities between the SHIM and the full-scale IIEF or its EF domain.^{1,2} For instance, one article mistakenly referred to the five domains of the 15-item IIEF as the IIEF-5 (SHIM).⁶⁴ Four of the five items on the SHIM are taken from the six-item EF domain of the IIEF, a validated measure of treatment efficacy. Of the five items on the SHIM, only Item 7 (intercourse satisfaction) is not included in the EF domain. The diagnostic findings, therefore, between the EF domain and the SHIM are expected to be similar. Nonetheless, there are a few methodological differences between the two diagnostic measures. The inclusion of Item 7 on sexual intercourse satisfaction is a distinguishing feature of the SHIM that is absent from the EF domain. Intercourse satisfaction gives a high level of discrimination and addresses a central element in the NIH definition of ED.³ Items on the SHIM are referenced to the prior 6-month period, which conforms to the NIH's reference period for establishing a diagnosis of ED; in contrast, items in the EF domain have a reference period of 4 weeks. Although the SHIM has merit as a measure of efficacy to evaluate interventions, its primary and intended purpose is for screening and diagnostic severity assessment in clinical practice and in clinical trials as part of study inclusion criteria for ED. The EF domain of the IIEF, which has its own established diagnostic cutoff and severity grades for ED, is preferred over the SHIM to evaluate the efficacy and to assess changes associated with medical treatment of ED in clinical trials.^{65,66}

Third, subtle issues exist concerning the validation of the SHIM.^{59–62} Cultural differences on how terms are viewed on the SHIM can be addressed by briefly defining the terms to alleviate the potential ambiguity of words in any screening instrument used in different cultures. Separate validation studies in different countries can also be conducted, as has been done in Malaysia.⁵⁸ The cutoff score of 21 on the SHIM was based on diagnostic evaluations of samples from populations in the United States and the United Kingdom. The cutoff score may be the same or differ somewhat in other populations. Although the diagnostic validation of the SHIM included men with ED from clinical trials, the control (non-ED) samples were not part of clinical trials. In addition, many studies from general practice settings covered in this review article suggest that the SHIM has merit for large subpopulations of men, with and without ED, who are similar

to those enrolled in the primary validation samples—namely, men in a stable heterosexual relationship who have an opportunity to engage in sexual activity and intercourse. The SHIM is not applicable, however, for use by *all* men in the general population; for example, it is not designed for use by men who are not sexually active. Another limitation of the SHIM is that, being focused on erectile function, it does not assess sexual desire or orgasm.

Fourth, neither the SHIM nor the IIEF were designed to diagnose the etiology of ED, only its presence and level of severity. Diagnostic tools like the SHIM are not expected to correlate with pharmacological testing and physiologically based assessments, such as Doppler ultrasonography. A body of compelling scientific evidence indicates that pharmacological testing and the duplex Doppler ultrasonography are neither valid nor reliable measures for determining the presence or severity of ED.⁶⁷ These tests are known to have low sensitivity, specificity, and reproducibility.⁶⁷ Therefore, it is not surprising that physiological or pharmacological tests may be at odds with validated patient reports of sexual dysfunction, including the SHIM.^{54,63} Even if such laboratory tests were accurate for a limited purpose, sexual (and even erectile) dysfunction has multiple facets that extend beyond the limited range of function measured by such laboratory tests.

Fifth, research is lacking on how the SHIM compares with other diagnostic assessments for ED in the same population. Authors of one study reported that the SHIM had relatively high agreement with but better reliability than a single-item self-assessment of ED severity among 247 patients with ED in a double-blind placebo-controlled clinical trial with sildenafil.⁵ Authors of another study, in Medline but not captured with the keywords employed in this review, reported that the prevalence of moderate or complete (severe) ED was 36% with the SHIM and 40% with a single self-assessment question for 199 men (mean age = 59 y) selected from general medical practices in Pennsylvania, USA.⁶⁸ We recommend more research on how the multiple-item SHIM compares with single-item prevalence measures such as the ones in the MALES study⁶⁹ and the MMAS study,^{70,71} as well as multiple-item assessments such as the EF domain of the IIEF.^{65,66} A diagnostic measure that results in a graded severity of ED is favored over a measure that is limited to a categorical measure of the presence or absence of ED. A single-item self-assessment of ED, on the other hand, is likely to yield a higher rate of compliance than a multiple-item assessment in community-based epidemiologic studies.

In addition to the five key areas mentioned above, we note that several articles in which the SHIM was a prominent measure, be they published before or after our Medline search, may not have been included in our review because they were not

identified by our Medline search. Excluded articles may have been part of other literature databases, a chapter of a book, or published after our review. For example, the SHIM was administered in a survey of 7689 patients in a recent publication,⁷² published in December 2004 and hence after our search of articles. In this survey, the SHIM was pivotal in determining that patients with diabetes or hypertension or both have a high prevalence of bothersome untreated ED who wish their general practitioner to initiate a discussion and provide treatment.⁷² Although it is likely that this review covers most studies in which the SHIM was an integral assessment or outcome measure (at least 52 studies of which at least 21 were prevalence studies, 23 were intervention studies, and eight were other clinical (mostly correlational) studies), the reader should realize that not all articles using the SHIM are included. Therefore, the number and scope of the articles in this review can be viewed as a lower-bound contribution that the SHIM has had on male sexual function.

Conclusions

The SHIM is intended to serve as a screening and diagnostic aid and to complement, not supplant, clinical judgment. Although its screening properties are impressive when properly used, it should not be viewed as a perfect diagnostic discriminator. The SHIM is intended to enhance the decision making of clinicians who are likely to perform more detailed evaluations in individual cases.

In this regard, the results using the SHIM and its positive impact on the assessment of male sexual function are well documented in this review. At least 21 studies have used the SHIM to determine the prevalence of ED. In general, researchers noted that the prevalence rate of ED was relatively high and that ED is a common, major health problem. As expected, a higher prevalence of ED was associated with diabetes, depression, vascular disease, hypertension, and increased age. Researchers and patients found the SHIM to be useful, quick, and inexpensive.

Furthermore, the SHIM was incorporated to assess the efficacy of interventions in at least 23 studies. In general, substantial efficacy was found with sildenafil, sildenafil plus patient education, and surgical procedures. The SHIM was also employed in eight other (mainly correlational) studies, which helped to increase understanding of the psychometric properties of the scale. Researchers in some studies investigated and quantified the relationships of ED (as measured by the SHIM) with potential or known risk factors for ED.

We expect the SHIM to continue to enjoy widespread use and clinical utility as a brief screening

tool for ED. The quantity of research and the quality of scholarship on the SHIM provide testimony to the utility of the SHIM and its positive scientific impact on understanding and improving male sexual function that, given current trends, is likely to remain influential in coming years.

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