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Oncology Section EDGE Task Force on Cancer: A systematic review of patient-reported measures for sexual dysfunction

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Abstract

Background—Sexual dysfunction is an important and infrequently addressed issue in patients with cancer.

Purpose—To identify self-report measures for assessing sexual dysfunction and to evaluate their psychometric properties and relevance to patients with cancer.

Methods—Multiple electronic databases (CINAHL, Medline, PsycInfo) were reviewed using specific search terms to locate articles that identify self-report measures assessing sexual dysfunction. From the 1118 articles reviewed, 21 measures were selected for analysis. Each measure was independently reviewed and rated by two reviewers using the Cancer EDGE Task Force Outcome Measure Rating Form. Any discrepancies between reviewers were discussed and an overall recommendation for each measure was made using the 4-point Cancer EDGE Task Force Rating Scale.

Results—Based on the psychometric properties and relevance to patients with cancers, we highly recommend the following four measures: Sexual Function – Vaginal Changes Questionnaire; International Index of Erectile Function; Erection Hardness Score; Sexual Health Inventory for Men (aka International Index of Erectile Function-5). We recommend one measure, the Sexual Interest and Desire Inventory. We are unable to recommend eight measures based on limited psychometric information and/or clinical utility. Finally, we do not recommend an additional eight measures.

Conclusions—Five of the 21 sexual dysfunction measures demonstrated satisfactory psychometric properties and application to the cancer population and are thereby recommended for clinical use in patients with cancer.

INTRODUCTION

Sexual dysfunction is a distressing effect of surgery, radiation, and chemotherapies for treatment of cancer in women and men.¹⁻³ The term sexual dysfunction is associated with concerns or difficulties with sexual activity that negatively impact sexual enjoyment and satisfaction.⁴ The prevalence of sexual dysfunction in women with gynecologic cancers is estimated at up to 90%,^{5,6} compared to 40% in the general population.⁷ Women who undergo pelvic surgery for gynecological cancers report decreased sexual desire, impaired vaginal lubrication, dyspareunia, and decreased orgasm intensity.⁸ For men undergoing prostatectomy, nearly 60% report impotence 18 months after surgery⁹ and while survival may be their primary concern, sexual function is highly valued among this cohort.¹⁰ Interestingly, sexual dysfunction is not limited to individuals with urogenital cancers. Raggio and colleagues reported that in breast cancer survivors who were three or more years post treatment, 77% of them reported sexual dysfunction.¹¹ For women undergoing radiation therapy for breast cancer, sexual satisfaction is also a problem during treatment.¹² Sexual dysfunction and pain are associated with higher levels of depression and anxiety, and lower levels of sexual enjoyment and satisfaction.¹³ *The impact of sexual dysfunction can be debilitating and is likely multifactorial in etiology. Previous work suggests that biological factors (ie caused by cancer and/or its treatments)^{14,15}, psychosexual factors (affective and emotional variables)¹⁶, and contextual factors (relationship and/or intimacy issues)¹⁷ may contribute to this condition. While pelvic pain or dyspareunia may be an aspect of sexual dysfunction most commonly seen by physical therapists, other issues, including lack of arousal, desire, and relationship issues also accompany this condition and contribute to its maintenance.* Despite the high prevalence of sexual dysfunction in both women and men following cancer treatments, these issues are infrequently addressed. Nearly one third of men with impotence report they have not sought care for their impotence, and over 60% of gynecologic cancer survivors reported that physicians did not discuss the impacts of cancer treatments on sexual function.¹⁸

While this information is concerning, the responsibility to evaluate sexual function in individuals with cancer cannot be the physician's alone. Given the increasing numbers of cancer survivors and physical problems associated with cancer treatments, rehabilitation providers are increasingly included as part of the multi-disciplinary care team. A recent study of patients with cancer who presented to a cancer rehabilitation outpatient physical therapy clinic reported that over 40% of patients who presented there in a two-year period had been diagnosed with urogenital cancers.¹⁹ While this study did not report rates of sexual dysfunction specifically, patients diagnosed with urogenital cancers had high rates of soft tissue dysfunctions and strength deficits, in addition to urinary incontinence. Given increasing rates of cancer survivorship and mounting evidence to support the notion that sexual dysfunction following cancer treatments is an important issue to patients, healthcare providers who manage these patients should screen for sexual dysfunction and when appropriate, refer to providers with the expertise to manage this dysfunction.

Although many measures exist to assess sexual dysfunction, few studies have appraised these measures as a whole. Woodward et al reviewed the advantages and disadvantages of measures of physiologic sexual function measures for women and reported that while many

measures exist, most had not been validated and the measures did not correlate well with self-reported sexual arousal.²⁰ Others have evaluated the psychometric properties of sexual function measures in specific populations, including women,²¹ gay men,²² and patients using antipsychotics,²³ for example. White et al reported on the appraised quality and clinical utility of sexual dysfunction measures in women with cervical or endometrial cancers and reported that the Female Sexual Function Index was the most robust and clinically useful measure for this population.²⁴ Similarly, Jeffery et al. reported their recommendations on use of sexual function measures for females with cancer.²⁵ They concluded that while some quality of life measures do include questions specific to sexual function, measures designed to specifically address sexual function would provide clinicians with a deeper understanding of the extent of sexual problems in these patients. Thus, the purpose of this review is to expand on existing work to critically appraise patient-reported sexual dysfunction measures to provide recommendations on the most robust and clinically useful measures to evaluate sexual dysfunction in patients with cancer.

METHODS

To generate an initial list of outcome measures, the authors with the help of a Creighton University librarian systematically searched the literature for outcome measures that assessed sexual function, urinary incontinence, and/or fecal incontinence and proceeded to evaluate the psychometric properties and clinical usefulness of those measures. For purposes of this manuscript, only measures that related to sexual function were reviewed and evaluated. The urinary and fecal incontinence measures have been reported in another manuscript (Jeffrey et al, in review). The primary search was conducted in CINAHL, Medline, and PsycInfo. Terms specific to the search strategies used both alone and in combination are listed in Table 1. Research articles were included for consideration if the text was available in English, if they were related to sexual function and from the year 1995 to August 2015 (time at which search was conducted). Exclusion criteria were that the text was not available in English or not related to sexual dysfunction. The initial search of the literature returned 1118 articles. Eight hundred and ninety of these did not meet the inclusion criteria leaving 228 articles to be included in the primary review. Of these articles, 21 articles were specific to measures of sexual function and were selected for review.

For the purposes of this paper, the authors comprised the EDGE Task Force. Each outcome measure was independently reviewed by two members of the task force using the Cancer EDGE Task Force Outcome Measure Rating Form.²⁶ This form details information about psychometric properties including reliability, validity, minimal detectable change (MDC), and minimal clinically important differences (MCID) as available. Clinical utility was also addressed which included: availability of the measure, length of the questionnaire, cost, time required to complete, and scoring and interpretation. As a part of the assessment, each reviewer ranked the outcome measure using the Cancer EDGE rating scale described in Table 2. Discrepancies between reviewers were discussed and a consensus was reached for all ratings and recommendations.

RESULTS

A comprehensive review of the literature yielded 21 outcome measures that assessed sexual dysfunction in individuals diagnosed with cancer. Of these, four measures received the highest rating (4= Highly Recommend) and one received the second highest rating (3= Recommend). Eight outcome measures were unable to be recommended at this time due to either weak supporting evidence or lack of clinical utility, including time to complete and insufficient access to the measure, including cost. Seven of these measures were given a score of 2A, indicating that they had been used in research in individuals with cancer, however did not achieve the standards for recommendation for clinical use. *One measure was given a score of 2B, indicating that it had not been used in individuals with cancer.* Eight of the 21 outcome measures are not recommended (score of 1) due to insufficient psychometric data, response burden, or scoring burden. The ratings of the 21 outcome measures are presented in Table 3.

DISCUSSION

The purposes of this review were to systematically identify and analyze outcome measures for assessing sexual dysfunction in the individuals with cancer and to recommend outcome measures with adequate psychometric properties and clinical usefulness. Four measures were highly recommended and one additional measure was recommended. These measures are described below and clinical usefulness is available in Table 4.

Sexual Function – Vaginal Changes Questionnaire (SVQ)

EDGE Rating: 4 (Highly Recommended)—The SVQ was developed to evaluate sexual and vaginal dysfunction within the gynecological cancer population.²⁷ The *self-report* measure consists of 20 core items *scored on a 4-point Likert scale that evaluates five primary areas of sexual dysfunction: sexual interest/desire, lubrication, orgasm, pain, and sexual satisfaction. There is no total score calculated but rather the subscale scores have been reported individually.*^{28–30} Additionally, there are seven items that can be used to compare current levels of dysfunction to pre-cancer diagnosis for a longitudinal comparison and analysis in a specific patient. The SVQ has been validated in patients with gynecological cancer and demonstrates high test-retest reliability (0.84–0.96) and internal consistency (Cronbach's $\alpha = 0.76–0.83$).²⁷ This measure's sound psychometric properties along with its moderate length make it a good candidate for clinical use. The MDC and MDIC have not been reported for the SVQ, limiting the information about its responsiveness to change.

International Index of Erectile Function (IIEF)

EDGE Rating: 4 (Highly Recommended)—The IIEF is a 15-item, self-report questionnaire covering 5 domains: erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction.³¹ Each question is rated 0 to 5 on a Likert scale. Subscale scores for each domain are determined for each domain and a total score (range 0–75) is reached from the sum of those values. The measure demonstrates good internal consistency for the total scale (Cronbach's $\alpha = 0.91–0.96$) as well as the individual domains, the highest being the erectile function and orgasmic function domains. Test-retest

reliability was high for the erectile function and intercourse satisfaction domains as well as the total scale (0.84, 0.81, and 0.82 respectively), and was moderately high for the other domains. All five domains demonstrate sensitivity to change, although the magnitude of change was highest for the erectile function domain and lowest for the sexual desire domain. The MCIDs for this measure have been established but varies based on baseline erectile dysfunction.³² Specifically, the MCID is positively associated with baseline erectile dysfunction severity. For those with mild, moderate, and severe erectile dysfunction, the corresponding MCIDs are 2, 5, and 7, respectively.

Erection Hardness Score (EHS)

EDGE Rating: 4 (Highly Recommended)—The EHS was developed as a self-report, single-item questionnaire for scoring erection hardness reported using a 0 to 4 Likert scale (0: penis does not enlarge, 1: penis is larger but not hard, 2: penis is hard but not hard enough for penetration, 3: penis is hard enough for penetration but not completely hard, 4: penis is completely hard and fully rigid). A score of 3 or less indicates presence of erectile dysfunction and can be confirmed by comparing scores to the IIEF erectile function domain (score of ≥ 25).^{33,34} This measure demonstrates good test-retest reliability ($r = 0.76$) and an MCID of 0.86, and has been shown to differentiate between men with and without erectile dysfunction and varying levels of ED severity.³³ The EHS has been used as an outcome measure in several studies with individuals with erectile dysfunction following treatment for male genitourinary cancers and has been validated in several languages.^{34–37}

Sexual Health Inventory for Men (SHIM)/(aka IIEF-5)

EDGE Rating: 4 (Highly recommended)—The SHIM is 5-item self-report measure assessing erectile function with good reported reliability and validity.^{38,39} This measure is an abridged version of the International Index of Erectile Function (IIEF)³⁸ and is widely used for screening and diagnosis of erectile dysfunction (ED) and severity of ED over the previous six months. *The IIEF-5 has high internal consistency (Cronbach's alpha, range=0.73–0.99) and moderate to high test-retest reliability (r , range= 0.64–0.84).*^{31,38,40} A cutoff score of less than or equal to 21 is indicative of ED. While there are no reported MCID or MCDs, reference values for scoring include severe ED (5–7), moderate ED (8–11), mild to moderate ED (12–16), mild ED (17–21), and no ED (22–25).³⁸

Sexual Interest and Desire Inventory for Females (SIDI-F)

EDGE Rating: 3 (Recommended)—The SIDI-F is a 13-item, clinician administered scale validated in women diagnosed with hypoactive sexual desire disorder (HSDD) designed to measure the severity of sexual dysfunction with its total score ranging from 0–51, with scores less than or equal to 33 indicating the presence of HSDD.⁴¹ Clayton et al reported high internal consistency of this measure with a Cronbach's α of 0.90 and test retest reliability ranged from 0.85 to 0.90.⁴² These authors also reported on the discriminant validity of this measure, evidenced by its ability to distinguish between women clinically diagnosed with HSDD compared to women who did not meet the criteria for sexual dysfunction or orgasmic disorder. Although the measure has not been used in the cancer population to date, the SIDI-F may be relevant for women with different types of cancer who

have been diagnosed with HSDD. One potential limitation of the clinical utility of this measure is that it requires the clinician to administer the questions to the patient rather than allowing the patient to complete this measure as part of intake or other self-report questionnaires. Alternatively, administration of this measure is estimated at five to ten minutes.⁴¹

The results of this literature analysis demonstrate the need for increased scrutiny to determine the reliability and validity of existing outcome measures for sexual dysfunction, as it is apparent that the five highly recommended and recommended measures discussed are not sufficient to provide a comprehensive list of outcome measures from which to choose. The limited amount of high quality studies validating the use sexual dysfunction outcome measures in the cancer population begs the question as to whether sexual dysfunction is inherently different in individuals with different types of cancer and between patients with cancer and cancer-free patients. For example, does sexual dysfunction differ after undergoing a hysterectomy for chronic pelvic pain compared to someone who had the same surgery for uterine cancer? Is sexual dysfunction different in the woman with uterine cancer compared to a woman who underwent a double mastectomy for breast cancer? Future research in this area can help to clarify the clinical utility of these outcome tools and may provide information to strengthen the evidence of some of these measures as they relate to individuals with different types of cancers.

When interpreting the Task Force's recommendations, there are several key considerations. The primary limitation is the time component between the literature search (August 2015) and the publication of this paper. New studies may have been published after the literature search was conducted which may provide evidence to support measures that could not be recommended at this time. Future expansions on the clinical utility and strength of outcome measures for sexual dysfunction will include this increased body of evidence as well as focusing on the validity of the measures within the cancer population specifically. The literature search was restricted to journals and articles in English. This may have limited the number of measures reviewed that could have been available in journals in other languages. The recommendations of the Task Force are intended to serve as a guide to increase evidence-informed practice in selection of outcome measures. Practitioners are encouraged to consult the overall recommendations as well as the individual information for each outcome measure and any new literature in order to select appropriate measures of incontinence and sexual dysfunction.

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Figure 1.
PRISMA flow diagram

Table 1

Search terms for initial review of literature

Search Strategy	Cancer	Sexual Function	Outcome Measures
Search Terms & Strings	"Neoplasms+", "Prostatic Neoplasms+", "Testicular Neoplasms+", "Colorectal Neoplasms+", "Breast Neoplasms+", "Bladder Neoplasms+", "Urethral Neoplasms+", "Carcinoma, Renal Cell+", "Vulvar Neoplasms+", "Vaginal Neoplasms+", "Ovarian Neoplasms+", "Uterine Neoplasms+", "Urinary Bladder Neoplasms", "Benign Neoplasms", "Endocrine Neoplasms", "Leukemias", "Nervous System Neoplasms +", "Terminal Cancer", cancer, neoplasm, carcinoma, leukemia, lymphoma, melanoma, sarcoma	"Dyspareunia", "Frigidity", "Impotence", "Premature Ejaculation", "Sexual Dysfunction, Male+", "Sexual Dysfunction, Female+", "Sexual Dysfunction, Physiological+", "Sexual Dysfunctions, Psychological+", "Sexual Function Disturbances", "Erectile Dysfunction", "Female Sexual Dysfunction", "Inhibited Sexual Desire", "Priapism", "Vaginismus", sexual, dyspareunia, erectile dysfunction, erectile function, impotence, ejaculate, vaginismus, psychosexual, frigid, orgasm, sexual dysfunction, sexual function, sexual disorder, sexual distress, sexually active	"Reproducibility of Results+", "Reliability and Validity+", "Psychometrics", "Data Collection", "Focus Groups", "Interviews+", "Self Report", "Surveys", "Clinical Assessment Tools+", "Research Instruments +", "Factor Analysis, Statistical", "Geriatric Assessment", "Health Surveys", "Health Status Indicators+", "Health Care Surveys", "Interviews as Topic", "Questionnaires+", "Testing+", "Measurement+", "Statistical Analysis+", "Statistical Reliability", "Consistency (Measurement)", "Interrater Reliability", "Test Reliability", "Test Validity", reliability, valid, psychometric, clinimetric, questionnaire, survey, index, indices, scale, assess, evaluate, measure, inventor, test

Table 2

Cancer EDGE Taskforce Outcome Measure Rating Form

4	Highly Recommend	Highly recommended; the outcome has good psychometric properties and good clinical utility; the measure has been used in research on individuals with or post cancer.
3	Recommend	Recommended; the outcome measure has good psychometric properties and good clinical utility; no published evidence that the measure has been applied to research on individuals with or post cancer.
2A	Unable to Recommend at this time	Unable to recommend at this time; there is insufficient information to support a recommendation of this outcome measure; the measure has been used in research on individuals with or post cancer.
2B	Unable to Recommend at this time	Unable to recommend at this time; there is insufficient information to support a recommendation of this outcome measure; no published evidence that the measure has been applied to research on individuals with or post cancer.
1	Do Not Recommend	Poor psychometrics &/or poor clinical utility (time, equipment, cost, etc.).

Table 3

Results of Task Force Literature Review by Rating

Rating	Measure Name
4 – Highly recommend	<ul style="list-style-type: none"> • Sexual Function – Vaginal Changes Questionnaire • International Index of Erectile Function • Erection Hardness Score • Sexual Health Inventory for Men (IIEF- 5)
3 – Recommend	<ul style="list-style-type: none"> • Sexual Interest and Desire Inventory for Females
2A – Unable to recommend at this time	<ul style="list-style-type: none"> • PROMIS-Sexual Function • Female Sexual Function Index • Arizona Sexual Experience Scale • Golombok-Rust Inventory of Sexual Satisfaction • Psychological Impact of Erectile Dysfunction • Sexual Function Questionnaire • Changes in Sexual Functioning Questionnaire
2B – Unable to recommend at this time	<ul style="list-style-type: none"> • Female Sexual Distress Scale
1 – Do not recommend	<ul style="list-style-type: none"> • Dyadic Adjustment Scale • Brief Sexual Function Questionnaire for Men • Sexual Concerns Questionnaire-Gynecological Cancer • Watts Sexual Function Questionnaire • Sexual Problems Scale • Brief Index of Sexual Functioning in Women • Brief Sexual Function Inventory for Men • Radiumhemmet Scale of Sexual Function

Clinical Usefulness of Sexual Dysfunction Outcomes Highly Recommended (4) and Recommended (3) Measures

Table 4

Measure	Equipment Needed	Cost	Ease of Use	Scoring/Interpretation	Normative Data
Highly Recommended (4)					
Sexual Function – Vaginal Changes Questionnaire (SVQ)	Paper & pencil	Free	Easy	Easy	Yes
International Index of Erectile Function (IIEF)	Paper & pencil	Free	Easy	Easy	Yes
Erection Hardness Score (EHS)	Paper & pencil	Free	Easy	Easy	Yes
Sexual Health Inventory for Men (SHIM) (also known as: IIEF-5)	Paper & pencil	Free	Easy	Easy	Yes
Recommended (3)					
Sexual Interest and Desire Inventory for Females (SIDI-F)	Paper & pencil	Free	Easy	Easy	No