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Title: The feasibility of patient reported outcome measures for the care of penile

cancer

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Contribution: PB, CH, KN, IV, OK, IE and AH designed the study. CH and

CM were psychology placement students supervised by PB. CM double entered and

checked data. EW, EB, CM and PB analysed the data. PB and EW wrote the

manuscript.

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#### **Abstract**

When used in routine clinical practice, Patient Reported Outcomes Measures (PROMS) can give patients tacit approval to discuss embarrassing topics, which could be particularly useful for urological nursing. The aim of this study was to assess whether it would be feasible to use two such measures for penile cancer; one for body image (the Male Genital Self-Image Scale; MGSIS-5) and another for lymphedema (the Groin and Lower Limb Lymphedema questionnaire; G3L-20). Study packs were posted to penile cancer patients who had received i) sentinel node biopsy only, ii) inguinal node dissection only, and iii) inguinal node dissection with post-operative radiotherapy with or without chemotherapy. The two measures (MGSIS-5 and G3L-20) were complemented with those specific to sexual function (IIEF) and cancer (EORTC-QLQ-C30 version 3) and a modified Lymphoedema Genitourinary Cancer Questionnaire (mLGUCQ). Twenty patients returned questionnaires. Validity and reliability analyses are presented but low participant numbers mean that results need treating with caution. Results show sufficient feasibility for the MGSIS-5 and the G3L-20 to warrant another study to attract larger numbers of participants, either over a longer time frame or at multiple sites. In these further studies, we would recommend adding 1) more Likert responses, 2) the timeframe to the MGIS and 3) exploring either the use of sexual desire psychometric measures or the addition of sexual desire items to the MGSIS for this patient group.

# What is known about this topic

The Male Genital Self-Image Scale (MGSIS-5) and the Groin and Lower Limb Lymphedema questionnaire (G3L-20) have shown feasibility in a community sample of men aged 40 years and older.

When used in routine practice, Patient Reported Outcome Measures can be useful in urological nursing for prompting patients to discuss specific topics, particularly those that may be embarrassing or unanticipated.

# What this paper adds

The Male Genital Self-Image Scale (MGSIS-5) shows some feasibility in penile cancer patients but may need more response options and the inclusion of questions on sexual desire.

The Groin and Lower Limb Lymphedema questionnaire (G3L-20) shows some feasibility in penile cancer patients and may be able useful as a diagnostic tool.

*Keywords:* quality of life; genital body image; psychometric measures; lymphedema; penile cancer

# The feasibility of patient reported outcome measures for the care of penile cancer

#### Introduction

Penile cancer is a rare condition that despite good survival<sup>1</sup> can have detrimental long-term impact on sexual and gender identity<sup>2–7</sup>. Men's experiences of their penis after surgical treatment, for example, can be visceral and traumatic 8. The impact on quality of life can be challenging to tackle in urological nursing because many patients are too embarrassed<sup>9</sup> or traumatised<sup>8</sup> to talk about their experiences; or they talk in general terms<sup>10</sup> that is often couched in humour<sup>4,11,12</sup>. Consequently, there is a need to explore approaches that can support patient well-being. Patient Reported Outcome Measures (PROMS) are one such tool. When used prior to a healthcare appointment, PROMS can prime patients and clinicians to discuss topics pertinent to the healthcare interaction <sup>13,14</sup>. Furthermore, when used in routine practice, PROMS are not just outcome measures but offer what is called a virtual evidence-basedpractice-based cycle <sup>15,16</sup>. When patients consent, routinely collected quality of life data can help evaluate treatments, minimizing the cost of clinical trials. For example, the International Penile Advanced Trial (InPACT; ISRCTN13580965) includes a quality of measure but this adds to the financial burden of research that already struggles to attract funding.

This study considers two different types of quality-of-life PROMS for routine urological nursing. First, a genital body image measures offers a balance between a tool that is general enough to apply to a range of contexts and conditions, while still specific enough to urological nursing that it is likely prompt patients to talk about

relevant aspects of their experiences. Second, a lymphedema measure focuses on the subjective experience of a specific set of physical symptoms often due to cancer. This can prompt patients to talk about these symptoms and, if a clinical threshold is met, help clinicians decide if a particular course of action should be followed, such as a physical assessment. A study testing the Male Genital Self-Image Scale (MGSIS-5) and the Groin and Lower Limb Lymphedema Scale (G3L-20) in a community population of men aged 40 years and older concluded that feasibility studies of using these measures in clinical populations would be justified 15.

#### **Aims**

The primary aim is to examine the feasibility of the MGSI-5 and the G3L-20 for use with this clinical population. Should enough patients be recruited, secondary aims are a) to assess whether there is an unmet need for additional clinical and support services and b) evaluate the psychometric properties of the scales for measuring quality of life.

#### Methods

A pen and paper cross-sectional non-experimental open audit design was used to administer the questionnaires and examine their feasibility.

# **Participants**

The aim of the sampling strategy was to recruit cisgender men diagnosed and treated for penile cancer at a single supra-regional network. To ensure data collection was in proportion to the aims of a feasibility study in a clinical population, no demographic information was collected. From the 55 study packs posted to patients, 22 were returned from patients treated as follows; i) sentinel node biopsy only (N=1),

ii) inguinal node dissection only (N=6), and iii) inguinal node dissection with postoperative pelvic radiotherapy with or without chemotherapy (N=15).

#### **Materials**

The following five PROMS were used and were presented in the following order;

# Male Genital Self-Image Scale

The MGSIS- $5^{17,18}$  has five items which are scored on a four point Likert scale where 1 = strongly disagree and 4 = strongly agree. A higher score represents a more positive response in relation to feelings and beliefs about their genitals. The overall score is the total of the responses with a possible range of four to 20.

# **Groin and Lower Limb Lymphedema**

The G3L- $20^{18}$  (which is a modified version of the Gynecologic Cancer Lymphedema Questionnaire<sup>19</sup>) provides a total score from zero to 20 that is the sum of dichotomized items (no = 0, yes = 1) and the last two items (never = 0, occasionally = 0, half of the time = 1, usually = 2, always = 3).

## Modified Lymphoedema Genitourinary Cancer Questionnaire (mLGUCQ)

The LGUCQ<sup>20,21</sup> provides partial information on scoring and this audit therefore used a modified version (mLGUCQ). The 18 Likert scale items are scored<sup>5</sup> from not at all (0) to very much (3). In this audit, item 4 (the swelling is reversible overnight) was reversed to align it with the other items) and the three dichotomized items about knowledge were scored as no (0) and yes (1). All scores were summed, giving a possible range from 0 to 57 where a higher score represents the greatest risk of lymphedema.

#### International Index of Erectile Function

The IIEF has five domains; erectile function (items 1-5 & 15), orgasmic function (9,10), sexual desire (11-12), intercourse satisfaction (6-8) and overall satisfaction (13-14). Each item is answered on a Likert scale with 6 options, scored from 0 to 5, and domains are then all summed so that lower scores represent poorer function; for example, item 1 is from 0 for 'no sexual activity' to 5 for 'almost always' for how often they can get an erection.

# European Organisation for Research and Treatment of Cancer - Quality of Life Group C-30

The EORTC QLC-C30 version  $3^{19,22}$  incorporates five functional scales (assessing physical, role, cognitive, emotional and social elements), three symptoms scales (fatigue, pain, nausea and vomiting), a global health status, singular items assessing additional symptoms that may be experienced by cancer patients and asks participants about the perceived financial impact of the disease; questions 1-28 are answered on a Likert scale of 1-4, where 1 = not at all and 4 = very much. Questions 29+30, which ask specifically about overall quality of life and health in the past week utilize a seven-point Likert scale where 1 = very poor and 7 = excellent. Total scores range from 0-100, where higher scores represent higher levels of function and higher levels of symptom burden. The average score from each sub scale was calculated and a linear transformation was applied to create a standardized raw score<sup>23</sup>.

# **Statistical Analysis**

Overall means, standard deviations and ranges are provided as well as reliability analyses to determine the appropriateness of items within each questionnaire. SPSS version 24 was used to complete the analysis and missing values were recoded to a value of '99'. To minimize the risk of bias in the statistical analysis, the proposal was

registered before data collection<sup>24</sup> and the study materials and data have been archived in a repository<sup>24</sup> to allow validation of these results, re-use and secondary analyses.

#### **Procedure**

A study pack was posted out to all potential participants with a stampaddressed envelope during 2018. All returned questionnaires were manually entered into an excel file. Data entry was duplicated and files compared to identify and correct human error.

#### **Research Governance**

This study was approved as a service evaluation by Leeds Teaching Hospitals NHS Trust. Other than treatment group, no demographic information was collected or shared for this study. Consent was explicit at the start of the study pack, including sharing of the information reported.

## **Findings**

Completion of the questionnaires varied (see Table 1); all participants completed the sexual desire sub-scale of the IIEF and most completed the MGSIS and the G3L-20. The lowest completion rate was for the MLGCQu and the erectile function and overall satisfaction sub-scales of the IIEF.

Table 1: Means, range and standard deviation of the five questionnaires administered

Q	uestionnaire	n	Min	Max	Mean	±SD
	MGSIS-5	18	6.00	20.00	15.94	3.96
	G3L-20	20	0	15.00	6.15	5.36
	mLGUCQ	12	4	35.00	17.92	10.38
E	ORTC-QLC-30					
IIEF	Erectile	12	13	30.00	26.50	5.54
	function					
	Orgasmic	13	0	9.00	5.85	3.63
	function					
	Sexual desire	22	3.00	10.00	6.86	2.21
	Intercourse	15	3.00	15.00	13.13	3.74
	satisfaction					

Overall	12	2.00	10.00	7.08	2.87
satisfaction					

# Male Genital Self-Image Scale (MGSIS-5)

The first questionnaire was the MGSIS-5. The means for the individual questions and total score indicate a positive genital self-image (see Table 2), which are similar to those found in community samples of men aged 40 years and older<sup>15</sup>. Completion rates were high, with most participants completing most items.

Principal component analysis (PCA) was implemented to assess the separate components of the MGSIS-5. Correlation matrices confirmed that all entered variables had correlation coefficients greater than 0.3. The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy reported a value of 0.60, the suggested minimum to confirm an adequate sample <sup>25</sup>. Bartlett's test of sphericity was statistically significant (p<0.0001). These statistics confirm that PCA was an appropriate analysis to perform on the data. Cronbach's alpha analysis was performed to measure internal consistency and reliability and produced a value of 0.90, equating to very high internal consistency. Deletion of question four, 'I think my genitals work the way they are supposed to work' would increase the alpha value by 0.03 however this was deemed to be of limited benefit signifying that all questions were valuable within the questionnaire in this particular cohort.

Table 2: Descriptive values for the Male Genital Self-Image Scale (MGSIS-5)

N	%	%	%	%	Mean	±SD
	strongly	disagree	agree	strongly		
	disagree			agree		

I feel positively	18	5.6	5.6	38.9	50	3.33	0.84
about my genitals							
I am satisfied with	18	5.6	16.7	38.9	38.9	3.11	0.90
the appearance of							
my genitals							
I would feel	19	10.5	5.3	26.3	57.9	3.32	1.00
comfortable							
letting a sexual							
partner look at my							
genitals							
I think my	18	5.6	27.8	22.2	44.4	3.06	1.00
genitals work the							
way they are							
supposed to work							
I am not	20	5.0	15.0	30.0	50.0	3.25	0.91
embarrassed about							
my genitals							
<b>Total scores</b>	18					15.94	3.96

# Groin and Lower Limb Lymphedema (G3L-20)

The mean total score for the GL3-20 was 6.15 with a SD of 5.36 (see Table 3), which is higher than in a community population<sup>15</sup>. The plausible clinical cut-off scores<sup>19</sup> are in the range 3 to 6, which means it may identify some participants as

potentially having lymphedema. Completion rates were high, with most participants completing most items.

Principle component analysis was not able to generate a KMO value of Bartlett's test of sphericity, which means it failed to meet a statistical assumption and caution should be taken in interpreting these findings. Six components had an eigenvalue of greater than one which was able to explain 84.98% of the variance, the scree plot suggested that all six components should be retained. Cronbach's alpha was performed to assess internal consistency with a value of 0.90, indicating a very high level of internal consistency that is similar to a feasibility study in a community sample 15. The data did suggest the removal of questions relating to movement of the ankle, foot, toes and the incidence of blistering occurring however these had a negligible effect on the overall reliability coefficient hence they cannot be recommended for definitive removal in this sample.

*Table 3: Descriptive statistics for the Groin and Lower Limb Lymphedema questionnaire* (G3L-20)

	N	% Yes	% No
Do you have limited movement of	21	19.0	81.0
your hip?			
Do you have limited movement of	20	25.0	75.0
your knee?			
Do you have limited movement of	20	10.0	90.0
your ankle?			
Do you have limited movement of	20	15.0	85.0
your foot?			

Do you have limited movement of	20	10.0	90.0
your toes?			
Does your leg or foot feel weak?	21	47.6	52.4
Have you experienced tenderness?	22	36.4	63.6
Have you experienced swelling?	20	55.0	45.0
Have you experienced swelling with	22	36.4	63.6
pitting?			
Have you experienced redness?	20	35.0	65.0
Have you experienced blistering?	21	9.5	90.5
Have you experienced	21	52.4	47.6
firmness/tightness?			
Have you experienced increased	22	22.7	77.3
temperature in your leg			
Have you experienced heaviness?	21	42.9	57.1
Have you experienced numbness?	22	36.4	63.6
Have you experienced stiffness?	21	47.6	52.4
Have you experienced aching?	22	45.5	54.5
Have you experienced hip swelling?	22	9.1	90.9
Have you experienced groin swelling?	22	31.8	68.2
Have you experienced pockets of	22	38.1	61.9
fluid?			
Total	N	Mean	±SD
	20	6.15	5.36

## Modified Lymphoedema Genitourinary Cancer Questionnaire (mLGUCQ)

The mean total score for the mLGUCQ was 17.92 with a SD of 10.38 (see Table 4). As far as we are aware, there is no data to provide a comparison.

Principle component analysis was not able to generate a KMO value of Bartlett's test of sphericity, which means it failed to meet a statistical assumption and caution should be taken in interpreting these findings. Five components had an eigenvalue of greater than one which was able to explain 86.97% of the variance. Cronbach's alpha was performed to assess internal consistency with a value of 0.87 indicating a high level of internal consistency. The data did suggest the removal of some questions relating to understanding of what lymphedema and its treatments were, reversible swelling overnight, whether the swelling was affected getting in and out of bed, antibiotic use and pain killer reliance, however the overall reliability coefficient was not significantly improved with their removal. The small sample size is also likely to have impacted the analysis.

Table 4: Descriptive statistics for the modified Lymphoedema Genitourinary Cancer Questionnaire (mLGUCQ)

	N	% Not at	% A little	% Quite	% Very
		all	bit	a bit	much
Have you noticed any	21	61.9	14.3	14.3	9.5
swelling in your genitals?					
Have you noticed any	20	35.0	25.0	20.0	20.0
swelling in your legs?					
The swelling is	16	12.5	31.3	31.3	25.0
noticeably more by the					
end of the day?					

The swelling is reversible	16	56.3	25.0	18.8	
overnight					
The swelling is affecting	17	64.7	5.9	11.8	17.6
the clothes and shoes I					
can wear					
The swelling is affecting	17	64.7	23.5	11.8	
my sitting					
The swelling is affecting	17	76.5	11.8	5.9	5.9
getting in and out of bed					
The swelling is affecting	17	35.3	35.3	5.9	23.5
my walking					
The swelling is affecting	17	88.2	11.8		
my passing urine					
The swelling is affecting	15	46.7	20.0	6.7	26.7
my sexual function					
The skin around the	15	33.3	26.7	13.3	26.7
swollen area feels tight					
The skin around the	17	58.8	17.6	11.8	11.8
swollen area has changed					
colour					
The skin around the	16	37.5	31.3	31.3	
swollen area feels					
different					

The skin around the	18	83.3	11.1		5.6
swollen area feels					
wet/cold					
The swelling gives me	17	41.2	35.3		23.5
discomfort in my legs					
The swelling gives me	18	61.1	22.2	11.1	5.6
discomfort in my genitals					
I need to take pain killers	16	81.3	12.5	6.3	
for the discomfort					
During this period have	17	58.8	11.8	11.8	17.6
you needed antibiotics					
for infections					
	N	% Yes	% No		
I have a clear	17	82.4	17.6		
understanding about what					
causes lymphedema					
I am aware of the	16	87.5	12.5		
treatment methods and					
therapy options for					
lymphedema					
I feel confident in my	16	87.5	12.5		
knowledge regarding he					
symptoms, prevention					
and care of lymphedema					
Total	N	Mean	SD		

12	17.92	10.38	

# International Index of Erectile Function (IIEF)

The mean overall score was 58.73 with a SD of 12.54 (see Table 5), which was showed the best satisfaction compared to all other scores. The worst score was for orgasmic function (5.85, SD = 3.63). Comparison with IIEF scores in other studies is challenging because it is unclear if they have applied a linear transformation to create a standardized raw score. For example, neither a systematic review of quality of life research on penile cancer<sup>26</sup> nor a more recent multi-institutional study<sup>27</sup> with 25 patients that report IIEF scores clarify if they are standardized. Nevertheless, completion of this questionnaire was the lowest (see the varied 'N' in the **Error! Not a valid bookmark self-reference.**), which raises questions about the feasibility of the IIEF for this clinical population.

PCA analysis was not able to generate a KMO value of Bartlett's test of sphericity, which means caution should be applied when interpreting any data. Five components had an eigenvalue of greater than one which was able to explain 90.61% of the variance. Cronbach's alpha was performed to assess internal consistency with a value of 0.85 indicating a high level of internal consistency. The data did suggest the removal of two questions relating to sexual desire and overall sex life satisfaction, however the overall reliability coefficient was not significantly improved with their removal.

Table 5: Descriptive statistics for the IIEF, including individual question means, and category means

	N	Mean	±SD

			1.71
sexual activity			
When you had erections with sexual stimulation, how	15	4.40	1.24
often were your erections hard enough for penetration?			
When you attempted intercourse, how often were you	14	4.79	0.80
able to penetrate (enter) your partner?			
During sexual intercourse, how often were you able to	14	4.71	0.83
maintain your erection after you had penetrated			
(entered) your partner?			
During sexual intercourse, how difficult was it to	14	4.64	0.92
maintain your erection to completion of intercourse?			
How many times have you attempted sexual	15	4.13	1.81
intercourse?			
When you attempted sexual intercourse, how often	15	4.53	1.13
was it satisfactory for you?			
How much have you enjoyed sexual intercourse?	15	4.47	1.19
When you had sexual stimulation or intercourse, how	15	3.53	2.00
often did you ejaculate?			
When you had sexual stimulation or intercourse, how	13	2.54	1.81
often did you have the feeling of orgasm or climax?			
How often have you felt sexual desire?	14	3.07	1.44
How would you rate your level of sexual desire?	15	3.87	1.19
How satisfied have you been with your overall sex	12	3.92	1.44
life?			
How satisfied have you been with your sexual	12	3.17	1.74

relationship with your partner?				
How do you rate your confidence that you could get		12	4.42	0.90
and keep an erection?				
Overall total mean		11	58.73	12.54
	<b>Erectile function</b>	12	26.50	5.54
	Orgasmic function	13	5.85	3.63
	Sexual desire	14	6.86	2.21
	Intercourse satisfaction	15	13.13	3.74

# European Organisation for Research and Treatment of Cancer - Quality of Life Group C-30 version 3 (EORTIC QLQ-C30)

The findings show an overall picture of high functionality and low symptoms (see Table 6). For the symptomology scales, where the higher the mean the more symptoms the patient presents with, no category mean was greater than 29.29, signifying an overall low number of presenting symptoms on average in this cohort. Some participants did report higher incidences of symptomology, for example despite the mean for nausea and vomiting being 3.79, signifying very low, the maximum score recorded in that category was 33.3%. Similarly, appetite loss on average was recorded as 13.64, yet the maximum recorded value within this symptoms category was 66.67% which would equate to fairly high levels of appetite loss. As an established and general measure (rather than specific to penile cancer), PCA analysis was unnecessary.

*Table 6: Descriptive statistics for the functional and symptom scales of the EORTC QLC-C30 version 3* 

Functional Scales

	n	Min	Max	Mean	±SD
Physical function	21	26.67	100.00	75.56	25.24
Role Function	22	0	100.00	70.45	37.07
Emotion Function	21	0	100.00	78.97	31.03
Cognitive Function	21	16.67	100.00	85.54	22.65
Social Function	21	0	100.00	64.29	37.37
	Sym	tom Scal	es		
	n	Min	Max	Mean	±SD
Fatigue	22	0	88.89	29.29	27.97
Nausea and Vomiting	22	0	33.33	3.79	8.81
Pain	20	0	100.00	26.67	33.07
Dyspnoea	22	0	66.67	18.18	19.86
Insomnia	21	0	66.67	23.81	26.13
Appetite Loss	22	0	66.67	13.64	22.20
Constipation	22	0	100.00	21.21	31.78
Diarrhoea	22	0	100.00	18.18	26.68
Financial Difficulties	20	0	100.00	18.33	36.63

# **Conclusions**

The aim of this audit was to conduct the first ever study examining the feasibility of the MGSI-5 and the G3L-20 for use in the treatment and management of penile cancer. This was achieved through a psychometric design, in which male genital body image and groin and lower limb lymphedema quality-of-life measures were posted to patients.

## Male Genital Self-Image Scale (MGSIS-5)

The MGSIS-5 was developed in a young male community sample with one feasibility study in men aged 40 years and older<sup>15</sup>. In the framing of the items, the time-frame is unclear and responses may therefore be subject to the participants particular mood at the time. We would recommend clarifying the time-frame; for example, 'within the last month'. One of the items asks about functionality whereas the other items explore their feelings towards particular elements of their genitals. While this may lack face validity, this analysis confirms the one component solution, lending support to the validity of the MGSIS-5 in this clinical population.

The findings for the participants in this audit are similar to the community sample of men aged 40 years and older. This may mean that this measure will fail to differentiate between clinical and community samples (and therefore be unable to provide plausible clinical cutoffs). Nevertheless, we did not collect information on time since treatment, so it is possible that these participants' genital body image may have adapted over time. Also, clinical cutoffs may be unnecessary if completing the measure before meeting a health professional primes participants to discuss their sexual and urological health. Last, responses are along a 4-point Likert scale and we considered whether there would be need for greater differentiation if these were to have clinical utility; in-terms of reliability, the optional number of Likert scales is between 4 and 7<sup>28</sup>.

Completion was higher for the MGSIS-5 than for the IIEF. The analysis indicated that the sexual desire and overall satisfaction components of the IIEF failed to add anything useful, which may reflect the unique features of penile cancer compared to other urological clinical populations. Nevertheless, as all participants completed the sexual desire items, we would caution against abandoning

consideration of this issue for patients; instead, it may be worth testing the feasibility of sexual desire psychometric measures<sup>29</sup> for this population or adding sexual desire items to the MGSIS.

# Groin and Lower Limb Lymphedema (G3L-20 and the mLGUCQ)

Originally a gynecologic lymphedema measure<sup>19</sup>, the G3L-20 has been tested in a community sample of men aged 40 years and older<sup>15</sup>. The mean total score for the G3L-20 in this study (5.36) was 1) similar to the gynecologic sample with lymphedema (8.89) and 2) higher than the G3L-20 community sample (1.97) and for the gynecologic sample with no lymphedema (1.63). As a feasibility study, we did not collect information on lymphedema status; nevertheless, the high completion rates and initial findings suggest it would be justified.

As far as we are aware, there is no data to compare with the mLGUCQ findings in this study. Consequently, we cannot make any comparisons between the G3L-20 and the mLGUCQ; instead, the initial completion rates justify further study with larger samples.

#### Limitations

Feasibility studies are important stepping stones in the development of psychometric measures. Rare conditions, such as penile cancer, face a double challenge; first, the robustness of the statistics employed increases with sample size<sup>30</sup> but, second, there are few potential participants. The findings in this study therefore need treating with caution. A conservative conclusion given these limitations would be to recommend the resources for a larger feasibility study, either conducted over time or at multiple specialist supra-regional networks, to increase potential recruitment of participants and the robustness of the findings.

#### **Conclusion**

This study shows that we can conclude that the resources would be justified to test these measures out in larger samples, such as multi-site studies, and to collect demographic information. We would recommend adding 1) more Likert responses and 2) the time-frame to the MGIS and 3) exploring either the use of sexual desire psychometric measures or the addition of sexual desire items to the MGSIS for this patient group.

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