MN Community Measurement

Spine Surgery PRO Tools Appendix

Appendix: Patient Reported Outcome (PRO) Tools

The most important step in measuring the change in functional status and quality of life for patients is to implement the administration of the PRO tools into your clinic's processes and work flows. PRO tools need to be integrated into the preoperative evaluation and postoperative follow-up at one year. There are three PRO tools used to calculate the outcomes for the patient:

- Oswestry Disability Index (ODI), a low back pain specific assessment tool.
- PROMIS Global Health 10, a quality of life assessment tool.
- Visual Analog Pain scale (VAS).

Additional Information about PRO Tools

- Ideally, tools are completed by the patient at the time of the preoperative and postoperative visits; however, office visits are not required for tool completion. Any provider or office staff may administer the pre and postoperative assessment tools.
- Regardless of mode of administration, the content of all tools must be kept intact including question text, order and scoring. Altering the tool from its original form affects its psychometric properties as tested and invalidates the tool. **Do not submit scores from invalid tools.**

PRO Patient Reported Outcome Tools- Modes of acceptable administration

Administration Mode	ODI	VAS Pain	PROMIS-10
In person/during visit	Acceptable	Acceptable	Acceptable
Via mail	Acceptable	Acceptable	Acceptable
Via telephone	Acceptable	Not Acceptable*	Acceptable
Administer electronically **	Acceptable	Acceptable	Acceptable

*Tools that have a visual analog component cannot be administered reliably by phone interview.

**When administering electronically, the tool must be kept intact including content, order and scoring. Electronic examples: Email, patient portal, iPad/tablet, patient kiosk.

MN Community MEASUREMENT

Spine Surgery PRO Tools Appendix

Other Activities	ODI	VAS Pain	PROMIS-10
Store results in EMR	Acceptable	Acceptable	Acceptable
Must seek approval for other uses*	Yes	No	Yes

* examples: research, publication, use of tool beyond measure population, etc.

NOTE: All patients who meet eligible population criteria must be included in the data submission file, whether or not they completed the Patient Reported Outcome tools.

MN Community Measurement

Spine Surgery PRO Tools Appendix

Oswestry Disability Index (ODI) version 2.1a

This is a patient completed survey consisting of 10 structured questions in which the patient is asked to describe the impact of their low back pain and function in the following areas: pain, personal care, lifting, walking, sitting, standing, sleeping, sex life (if applicable), social life, and ability to travel. More information can be found at http://www.proqolid.org/instruments/oswestry_disability_index_odi?fromSearch=yes&text=yes.

Submit the individual question responses. If only the summary ODI score is available in the patient record, the medical group must demonstrate during the pre-submission data certification process that they are able to calculate the score accurately.

Individual question responses:

- If a question was skipped, leave that field blank.
    - Do not enter a zero unless zero was the valid response on the tool. Entering zero when the patient did not respond to a question will calculate the summary score incorrectly.
- If a patient selected more than one response to a question, submit the worst response.

Summary ODI score:

- Only for those unable to submit individual question responses.
- The patient must complete at least eight out of 10 questions asked.
- Please refer to developer's scoring table in this appendix. The following is an example calculation:

1. Score each question of the ODI (0 to 5, 5 being the worst case).
2. Sum the scores of all questions (ex. 20).
3. Double the sum (ex. 40).
4. Follow the developer's scoring table to determine final summary score:
    a. If all 10 questions answered in this example, the patient's Summary ODI score would be 40.
    b. If 9 questions answered, patient's summary ODI score would be 44.
    c. If 8 questions answered, patient's summary ODI score would be 50.
        i. If less than 8 questions are answered the summary score is invalid. DO NOT submit the score.

Spine Surgery PRO Tools Appendix

References

ODI © Jeremy Fairbank, 1980. All Rights Reserved. ODI - United States/English - Version of 29 Jul 11 - Mapi Institute. ID6287/ODI_AU2.1a_eng-US.doc

Fairbank J, Pynsent PB. The Oswestry Disability Index. Spine 2000; 25(22):2940-2953

Baker DJ, Pynsent PB and Fairbank JCT (1989) The Oswestry Disability revisited. In Roland Jenner JR (eds) Back pain: New approaches to rehabilitation and education. Manchester University Press.pp174-186

Fairbank JCT, Couper J, Davies JB, O'Brien JP. The Oswestry Low Back Pain Disability Questionnaire. Physiotherapy. 1980; 66:271-273

Permissions

Permission was granted to MNCM for the use of ODI version 2.1a and to post this tool on the MNCM Data Portal for use by individual clinical practices for the purposes of participating in the state-wide quality reporting and improvement effort. This tool is available in the public domain and is free of charge for individual clinician use in clinical practice.

For medical groups who additionally intend to use the ODI for research, please refer to the MAPI Trust website for more direction:

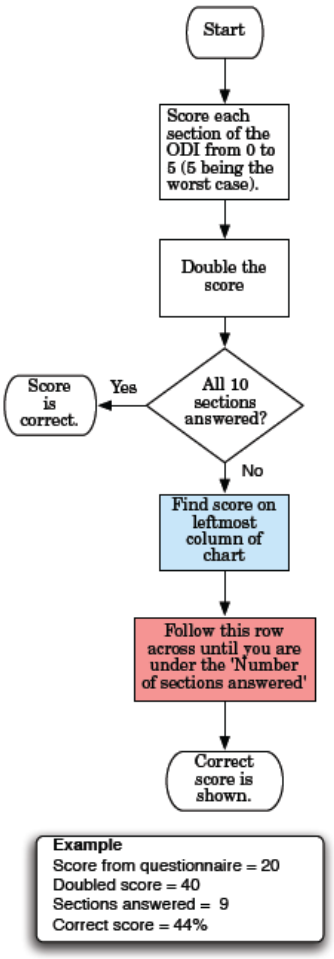
http://www.proqolid.org/instruments/oswestry_disability_index_odi?fromSearch=yes&text=yes

The tool developer, Dr. Jeremy Fairbank has stipulated that as a part of the user agreement that "For all new studies, version 2.1a of the ODI must be used." Version 2.1a is available for medical groups to use and can be accessed on the MNCM Data Portal RESOURCES tab by selecting "Spinal Surgery" from the drop-down menu.

MN Community Measurement

Spine Surgery PRO Tools Appendix

ODI made easy



	Number of sections answered								
	9	8	7	6	5	4	3	2	1
0	0	0	0	0	0	0	0	0	0
2	2	2	3	3	4	5	7	10	20
4	4	5	6	7	8	10	13	20	40
6	7	8	9	10	12	15	20	30	60
8	9	10	11	13	16	20	27	40	80
10	11	12	14	17	20	25	33	50	100
12	13	15	17	20	24	30	40	60	
14	16	18	20	23	28	35	47	70	
16	18	20	23	27	32	40	53	80	
18	20	22	26	30	36	45	60	90	
20	22	25	29	33	40	50	67	100	
22	24	28	31	37	44	55	73		
24	27	30	34	40	48	60	80		
26	29	32	37	43	52	65	87		
28	31	35	40	47	56	70	93		
30	33	38	43	50	60	75	100		
32	36	40	46	53	64	80			
34	38	42	49	57	68	85			
36	40	45	51	60	72	90			
38	42	48	54	63	76	95			
40	44	50	57	67	80	100			
42	47	52	60	70	84				
44	49	55	63	73	88				
46	51	58	66	77	92				
48	53	60	69	80	96				
50	56	62	71	83	100				
52	58	65	74	87					
54	60	68	77	90					
56	62	70	80	93					
58	64	72	83	97					
60	67	75	86	100					
62	69	78	89						
64	71	80	91						
66	73	82	94						
68	76	85	97						
70	78	88	100						
72	80	90							
74	82	92							
76	84	95							
78	87	98							
80	89	100							
82	91								
84	93								
86	96								
88	98								
90	100								

Interpreting the ODI Score

0 to 20%	minimal disability
21 to 40%	moderate disability
41 to 60%	severe disability
61 to 80%	crippled
81 to 100%	bed bound or exaggerative

MN Community MEASUREMENT

Spine Surgery PRO Tools Appendix

PROMIS Global Health - 10

PROMIS Global Health-10 is a patient completed assessment of health-related quality of life and consists of 10 structured questions reported on two subscales – general physical health and general mental health. The NIH – sponsored tool is publicly available, free of charge and has multiple modes of administration available.

In using the PROMIS-10 for reporting outcomes, it is strongly recommended by the developer of the tool that:

1) A summary score is not used and that the results are reported by its two subscales reflecting global physical health and global mental health and

2) The metric used for comparison is conversion to a T-score and reported as a change in T-score. T-Score distributions are standardized such that a 50 represents the average (mean) for the US general population, and the standard deviation around that mean is 10 points. A high score always represents more of the concept being measured. Thus, a person who has T-scores of 60 for the Global Physical Health or Global Mental Health scales is one standard deviation better (healthier) than the general population.

For more information, access the PROMIS website: http://www.nihpromis.org/default.

Given the need to correctly calculate outcomes for the subscale measures and convert the results to the appropriate T-score metric, medical groups must submit the corresponding number to each of the patient's response for all questions.

- If the patient selects more than one response for a PROMIS-10 question; submit a blank for the value for that question.

Versions of the PROMIS Global Health-10 (PROMIS-10)

MNCM has a license agreement with PROMIS Health Organization (PHO) to provide a PDF version of the tool to providers on the MNCM data portal. On an annual basis, MNCM reviews the PHO website to determine if there has been a version change. Version v1.1 is the version that has been in place since the 2013 transition to PROMIS-10. In August 2016, a minor version v1.2 was published. PHO indicates that a decimal change in a version reflects only a minor change, and this is the case for v1.2. The only changes in this version upgrade were related to the numeric scaling of questions 8 and 10. There were no changes in the context, wording of questions or order of questions. Granted, this changing of the numeric scale removes the need for conversion of responses for Q8 and Q10 to allow for scoring, but the MNCM Data Portal already does this conversion on file upload. It would be disruptive and burdensome to practices to implement a new tool based on this minor change that does not impact the psychometric properties of the tool. MNCM has decided to postpone upgrading to a new version of the tool until there are substantial changes (e.g. wording of questions or contextual instructions for the patient) that threaten comparability.

Spine Surgery PRO Tools Appendix

Note: Review of PROMIS Global Health instruments in August 2018 demonstrate no additional version and therefore no needed change related to version.

Therefore, medical groups should continue to utilize PROMIS-10 v1.1, available on the MNCM Data Portal Resources Tab, until further notice.

In the future, with a substantive change in tool that necessitates a new version, medical groups will receive advanced notice of a version change and the tool will be provided on the MNCM Data Portal.

References

Hays, R. D., Bjorner, J. B., Revicki, D. A., Spritzer, K. L., & Cella, D. (2009). Development of physical and mental health summary scores from the patient-reported outcomes measurement information system (PROMIS) global items. Quality of Life Research, 18(7), 873-880.

http://www.nihpromis.org/

Permissions

Permission was granted to MNCM for the use of the PROMIS Global Health- 10 in individual clinical practice for the purposes of participating in the state-wide quality reporting and improvement effort. If any medical group or practice plan to use results from the PROMIS-10 tool for other purposes or other populations (i.e., research study and publication), it is recommended that an additional user agreement with PROMIS Health Organization be obtained by the medical group that outlines its planned use. Request form for instruments can be obtained at www.nihpromis.org/measures/instrumentdetails

MN Community MEASUREMENT

Spine Surgery PRO Tools Appendix

Visual Analog Pain Scale

Visual Analog Pain scales are a method for assessing the patient's pain level using a line to assess where the patient is on the continuum of pain. There are numerous pain rating scales in use (public domain).

Principles that the work group felt were important:

1. Do not display the numeric values of the scale on the line that the patient is using to indicate their pain; however, the selection needs to translate (behind the scenes) to a numeric value for measurement.
2. Use the scale wording, "No Pain" on the left-hand (zero) side to "Intolerable" on the right-hand (ten) side aligning with pain descriptions cited in research by Million et al.
3. Have two separate questions – one that asks about back pain and another that asks about leg pain.

This tool was created by MNCM based on the measure development workgroup's principles. This tool is available for groups to download and use from the MNCM Data Portal under the Resources Tab by selecting "Spinal Surgery" from the drop-down menu. Groups are welcome to replicate this tool for use including electronic administration, but must do so exactly.

Because this is a visual analog scale, the tool cannot be administered over the telephone.

- If a patient selects more than one response to a question, submit the worst (higher numeric value) response.
- If the patient selects a line between boxes, submit the value associated with the next highest box.
    - For example, if the patient marks the line between 5.0 and 5.5, submit 5.5.

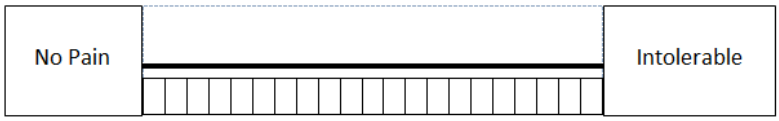
Spine Surgery PRO Tools Appendix

Visual Analog Pain Scale

Back Pain:

How severe is your **back** pain today?

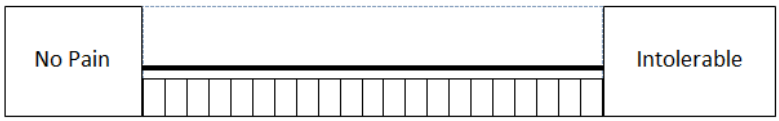
Please place an "X" in a box below the line to indicate how bad you feel your back pain is today.



Leg Pain:

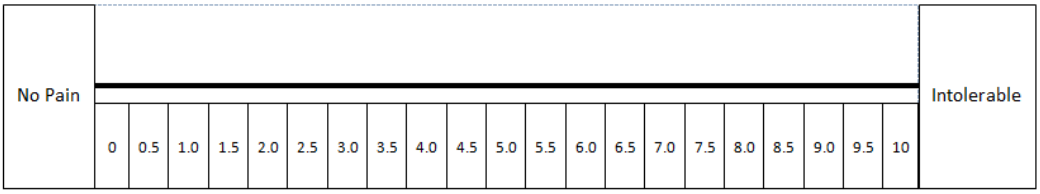
How severe is your **leg** pain today?

Please place an "X" in a box below the line to indicate how bad you feel your leg pain is today.



Key for Numeric Translation

Do not include this in the portion of the tool for the patient to complete



References

Million R, Hall W, Nilsen KH, Baker RD, Jayson MI. Assessment of the progress of the back-pain patient 1981 Volvo Award in Clinical Science. Spine. 1982 May-Jun; 7(3):204-12.

MN Community MEASUREMENT

Spine Surgery PRO Tools Appendix