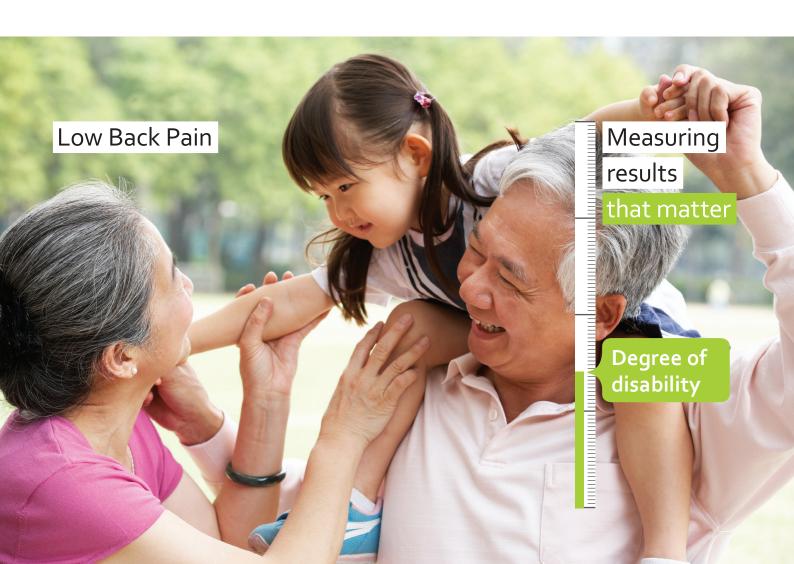


LOW **BACK PAIN DATA COLLECTION REFERENCE GUIDE**

Version 2.0 Revised: April 14th, 2015





We are thrilled that you are interested in measuring outcomes for your low back pain patients according to ICHOM standards. It is our hope that this Reference Guide will facilitate the process of implementing our Standard Set and ensure collection of comparable data for global benchmarking and learning.

© 2015 ICHOM. All rights reserved. When using this set of outcomes, or quoting therefrom, in any way, we solely require that you always make a reference to ICHOM as the source so that this organization can continue its work to define more standard outcome sets.

Introducing ICHOM and the Reference Guide

ICHOM brings together patient representatives, clinician leaders, and registry leaders from all over the world to develop Standard Sets, comprehensive yet parsimonious sets of outcomes and case-mix variables we recommend all providers track.

Each Standard Set focuses on patient-centered results, and provides an internationally-agreed upon method for measuring each of these outcomes. We do this because we believe that standardized outcomes measurement will open up new possibilities to compare performance globally, allow clinicians to learn from each other, and rapidly improve the care we provide our patients.

Our Standard Sets include initial conditions and risk factors to enable meaningful case-mix adjustment globally, ensuring that comparisons of outcomes will take into account the differences in patient populations across not just providers, but also countries and regions. We also include high-level treatment variables to allow stratification of outcomes by major treatment types. A comprehensive data dictionary is included in the appendix.

Working Group Members for Low Back Pain

The following individuals dedicated both time and expertise to develop the ICHOM Standard Set for Low Back Pain in partnership with ICHOM, under the leadership of Dr. Peter Fritzell, Registry Manager of SweSpine in Sweeden.

Australia	Netherlands	Singapore	United States
Beth Morrison	Miranda van Hooff	William Yeo	Isador Lieberman
Michelle Davies	Paul Willems	John Chen	Donna Ohnmeiss
Richard Kahler Denmark Martin Gehrchen	Wilco Jacobs Wilco Peul Norway Tore Solberg	Sweden Peter Fritzell Olle Hägg Björn Strömqvist United Kingdom	Matthew Smuck Thomas Cha Ajay Wasan Kevin Foley Neal Shonnard Safdar Khan
		Jeremy Fairbank	Carter Clement

Conditions and Treatment Approaches Covered for Low Back Pain

For Low Back Pain, the following conditions and treatment approaches (or interventions) are covered by our Standard Set.

Conditions	Lumbar Disc Herniation Lumbar Stenosis Lumbar Spondylolisthesis Degenerative Scoliosis Adult Idiopathic Scoliosis Degenerative Disc Disorder Other Degenerative Lumbar Disorders Mechanical, Acute, and Chronic Lumbar Back Pain and Back-Related Leg Pain
Conditions Not Covered	Individuals < 18 Years of Age Spinal Infection Spinal Tumor Spinal Fractures Traumatic Dislocation Congenital Scoliosis Documented as >20 Degrees, Moderate, Large, or Severe
Treatment Approaches	Conservative Therapy (e.g. physical therapy, chiropractic, drug therapy, injections, etc.) Surgical Therapy (e.g. spinal fusion, decompression, or discectomy)

ICHOM Standard Set for Low Back Pain

Case-Mix Variables

Patient Population	Measure	Supporting Information	Timing	Data Source
Demographic Factors				
All patients	Age	Date of birth	- . .	5
	Sex	Sex at birth	Baseline	Patient-reported
	Educational level	Level of schooling completed		
Baseline Functional	Status			
	Work status	N/A		·
	Duration of sick leave	N/A	-	
	Baseline patient- reported disability	Tracked via ODI	_	
All patients	Baseline patient- reported back and leg pain	Tracked via NPRS	Baseline Patient-re	Patient-reported
	Baseline patient- reported health- related quality of life	Tracked via the EQ-5D-3L		
Baseline Clinical Fact	tors			
	Smoking status	N/A	_	
All patients	Comorbidities	Modified Self-administered Comorbidity Questionnaire		Patient-reported
	Duration of back/leg	(SCQ) N/A	Baseline	
	Body mass index	Height and weight		
	Diagnostic classification	Glassman classification	Clinica	Clinical
Surgically treated	Morbidity state	ASA		
patients	Indication for surgery	Swespine classification	_	
Prior Treatment				
	Need for continuous	Use of narcotics or non-		Patient-reported
All patients	analgesic use	narcotics	Baseline Clinical	- atient-reported
	Prior interventions	Date and type of intervention		Clinical

Treatment Variables

Patient Population	Measure	Supporting Information	Timing	Data Source
Surgical and injection therapy patients	Type of procedural intervention	Discectomy, laminectomy, fusion, other, and injection therapy	During index visit or hospitalization for procedure	Clinical
	Level of procedural intervention	T12-S1 covered		

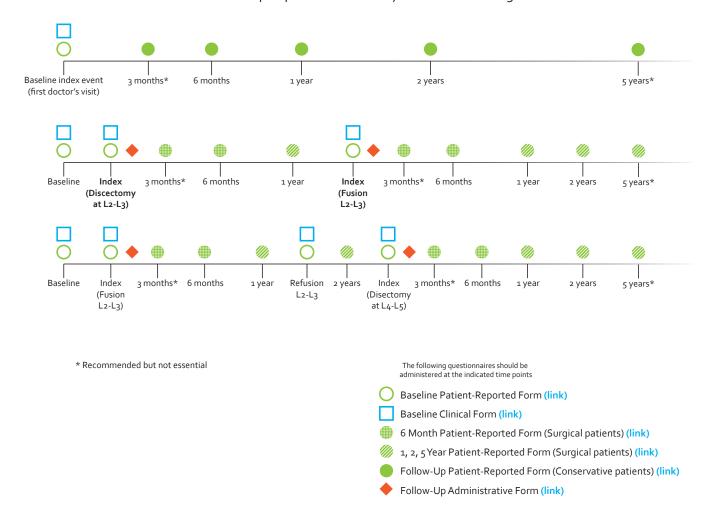
ODI: Oswestry Disability Index version 2.1a; NPRS: Numerical Pain Rating Scale; EQ-5D-3L: EuroQol-5D descriptive system (EQ-5D-3L) and visual analogue scale (EQ-VAS)

Outcomes

Patient Population	Measure	Supporting Information	Timing	Data Source
Acute Complications	of Treatment			
	Operative mortality	Date of death		
	Nerve root injury	N/A	— During the	Clinical
	Wrong site procedure	N/A	During theindex	
	Vascular injury	N/A	hospitalization	
	Dural tear	N/A	— nospitalization	
Surgically treated	Other complications	N/A		
patients	30 day mortality	Date of death	Within 30 days	Administrative (where available)
patients	Need for rehospitalization	Date of rehospitalization	of the index hospitalization	
	Deep wound infection	N/A	Within 6	Patient-reported
	Pulmonary embolus	N/A	months after	
	Need for	N/A	index	
	rehospitalization	N/A	hospitalization	
Disease Recurrence				
Surgically treated patients	Need for reoperation	Date of reoperation	3*, 6 months; 1, 2, 5* years after index event	Patient-reported (if lacking registry for tracking across institutions)
			When occurs	Clinical
Patient-Reported He	ealth Status			
All patients	Work status	Time to return to work and work demands		
	Need for continuous	Use of narcotics or non-	3*, 6 months;	Patient-reported
	analgesic use	narcotics	1, 2, 5* years	
	Disability	Tracked via ODI	_ after index	ratient-reported
	Back and leg pain	Tracked via NPRS	event	
	Health-related quality of life	Tracked via the EQ-5D-3L		

Follow-Up Timeline and Sample Questionnaires

The following timeline illustrates when Standard Set variables should be collected from patients, clinicians, and administrative sources. Links to the sample questionnaires may be found in the legend below.



Index Events and Reoperations

Index events to begin measurement of the Low Back Pain Standard Set include the initiation of non-surgical or surgical treatment of any of the diagnoses listed on page 3. Because the treatment of low back pain often leads to multiple therapies and sometimes multiple surgeries, it is important to be clear when the initiation of a new treatment constitutes a "reset" of the measurement timeline, called a new index event. In such cases, the follow-up of the prior event is discontinued.

There are three scenarios that constitute a new index event:

- 1) Spinal surgery after a period of non-surgical treatment
- 2) Second or following spinal surgery on a different level than the index surgery, regardless of diagnosis;
- 3) Second or following spinal surgery on the same level as index surgery, but for a different diagnosis.

Reoperations are <u>not</u> considered index events. Reoperations are defined as below. For reoperations, follow-up should continue as planned from the index surgery.

- 1) An operation on the same level as the prior index event due to a complication
- 2) An operation on another level but due to complication from prior index surgery
- 3) An operation on the same level for the same diagnosis as the prior index event

Collecting Patient-Reported Outcome Measures

Low Back Pain Survey Used	Licensing Information	Scoring Guides
Oswestry Disability Index version 2.1a (ODI)	The ODI is free for all health care organizations, but a license is needed for use. For more information, please visit http://www.proqolid.org/instruments/oswestry_disability_index_odi	See link at left
Numerical Pain Rating Scale (NPRS)	The NPRS is free for all health care organizations, and a license is not needed.	Not applicable
EuroQol-5D descriptive system (EQ-5D-3L) and visual analogue scale (EQ-VAS)	The EQ-5D-3L is free for non-profits and academic research, but a license is needed for use. For more information, please visit http://www.euroqol.org/eq-5d- products/how-to-obtain-eq-5d.html	See link at left

The Growing ICHOM Community

By implementing the ICHOM Standard Sets, you become part of an expanding, international community of innovative health care providers dedicated to improving value for patients. To learn more about how ICHOM can assist your organization in implementing outcome measurement, contact us at implement@ichom.org, or visit http://www.ichom.org/measure.

Appendix

Introduction to the Data Dictionary

This data dictionary is designed to help you measure the ICHOM Low Back Pain Standard Set as consistently as possible to the Working Group recommendation. ICHOM is actively preparing for benchmarking efforts based on this data, and all data submitted for comparisons will need to be transformed into the following data structure if not already structured as such. We are happy to provide an Excel version of this data dictionary for technical use.

Please timestamp all variables. Some Standard Set variables are collected at multiple timepoints, and we will ask you to submit these variables in a concatenated VARIABLEID_TIMESTAMP form for future analyses. For example, VARIABLEID_BASE (baseline); VARIABLEID_6MO (6 month follow-up); VARIABLEID_1YR (1 year follow-up), etc.

Case-Mix Variables

CASE-MIX VARIABLES

Variable ID: N/A
Variable: Patient ID

Definition: Indicate the patient's medical record number

Supporting Definition: This number will not be shared with ICHOM. In the case patient-level data is

submitted to ICHOM for benchmarking or research purposes, a separate ICHOM Patient Identifier will be created and cross-linking between the ICHOM Patient Identifier and the medical record number will only be known at the treating

institution

Inclusion Criteria: All patients
Timing: On all forms

Data Source: Administrative or clinical

Type: Numerical

Response Options: According to institution

Demographic Factors

Variable ID: AGE Variable: Age

Definition: What is your date of birth?

Supporting Definition: N/A

Inclusion Criteria: All patients

Timing: Baseline

Data Source: Patient-reported

Type: Date by DD/MM/YYYY

Response Options: DD/MM/YYYY

Variable ID: SEX Variable: Sex

Definition: Please indicate your sex at birth

Supporting Definition: N/A

Inclusion Criteria: All patients

Timing: Baseline

Data Source: Patient-reported

Type: Single answer

Response Options: 1 = Male

2 = Female

DATA COLLECTION REFERENCE GUIDE

999 = Undisclosed

Variable: EDUCATION
Variable: Educational level

Definition: Please indicate highest level of schooling completed

Supporting Definition: The level of schooling is defined in each country as per ISCED [International

Standard Classification]

Inclusion Criteria: All patients
Timing: Baseline

Data Source: Patient-reported

Type: Single answer

Response Options: o = None

1 = Primary 2 = Secondary 3 = Tertiary

Baseline Functional Status

Variable ID: WORK
Variable: Work status

Definition: What is your work status?

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: Baseline

Data Source: Patient-reported

Type: Single answer

Response Options: o = Unable to work due to a condition other than back or leg pain

1 = Unable to work due to back or leg pain

2 = Not working by choice (student, retired, homemaker)

3 = Seeking employment (I consider myself able to work but cannot find a job)

4 = Working part-time 5 = Working full-time

Variable ID: SICKLEAVE
Variable: Sick leave

Definition: Are you currently on sick leave from work?

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: Baseline

Data Source: Patient-reported **Type:** Single answer

Response Options: o = No

1 = Yes, full time for my back problems2 = Yes, part time for my back problems

3 = Yes, due to another disease

Variable ID: SICKLEAVEDUR
Variable: Duration of sick leave

Definition: Since when?

Supporting Definition: N/A

Inclusion Criteria: All patients

If answered 'yes' to currently being on sick leave (SICKLEAVE)

Timing: Baseline

Data Source: Patient-reported

Type: Single answer

Response Options: 1 = 1 week or less

2 = 1-4 weeks 3 = 1-3 months 4 = 3-6 months 5 = 6-9 months 6 = 9-12 months 7 = 1-2 years

8 = More than 2 years

Variable ID: ODI_Qo1

Variable: Question 1 of ODI

Definition: This guestionnaire is designed to give us information as to how your back (or leg)

trouble affects your ability to manage in everyday life.

Please answer every section. Select only one option in each section that most

closely describes you today.

Section 1 - Pain intensity

Supporting Definition: N/A

> Inclusion Criteria: All patients Timing: Baseline

> > Data Source: Patient-reported Type: Single answer

Response Options: 1 = I have no pain at the moment

> 2 = The pain is very mild at the moment 3 = The pain is moderate at the moment 4 = The pain is fairly severe at the moment 5 = The pain is very severe at the moment

6 = The pain is the worst imaginable at the moment

ODI Qo2 Variable ID:

> Variable: Question 2 of ODI

Definition: Section 2 - Personal care (washing, dressing, etc.)

Supporting Definition: N/A

> Inclusion Criteria: All patients Timing: Baseline

> > Data Source: Patient-reported Type: Single answer

Response Options: 1 = I can look after myself normally without causing extra pain

2 = I can look after myself normally but it is very painful 3 = It is painful to look after myself and I am slow and careful 4 = I need some help but manage most of my personal care

5 = I need help every day in most aspects of self care

6 = I do not get dressed, wash with difficulty and stay in bed

Variable ID: ODI Qoa

Variable: Question 3 of ODI **Definition:** Section 3 - Lifting

Supporting Definition: N/A

> **Inclusion Criteria:** All patients Timing: Baseline

> > **Data Source:** Patient-reported Single answer Type:

Response Options: 1 = I can lift heavy weights without extra pain

2 = I can lift heavy weights but it gives extra pain

3 = Pain prevents me from lifting heavy weights off the floor but I can manage if

they are conveniently positioned, e.g. on a table

4 = Pain prevents me from lifting heavy weights but I can manage light to medium

weights if they are conveniently positioned

5 = I can lift only very light weights 6 = I cannot lift or carry anything at all

Variable ID: ODI_Qo4

Variable: Question 4 of ODI **Definition:** Section 4 - Walking

Supporting Definition: N/A

> Inclusion Criteria: All patients

Timing: Baseline

Data Source: Patient-reported

Type: Single answer

Response Options: 1 = Pain does not prevent me walking any distance

2 = Pain prevents me walking more than one mile

3 = Pain prevents me walking more than a quarter of a mile

4 = Pain prevents me walking more than 100 yards

5 = I can only walk using a stick or crutches

6 = I am in bed most of the time and have to crawl to the toilet

Variable ID: ODI_Qo5

Variable: Question 5 of ODI **Definition:** Section 5 - Sitting

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: Baseline

Data Source: Patient-reported **Type:** Single answer

Response Options: 1 = I can sit in any chair as long as I like

2 = I can sit in my favorite chair as long as I like
3 = Pain prevents me from sitting for more than 1 hour
4 = Pain prevents me from sitting for more than half an hour
5 = Pain prevents me from sitting for more than 10 minutes

6 = Pain prevents me from sitting at all

Variable ID: ODI_Qo6

Variable: Question 6 of ODI **Definition:** Section 6 - Standing

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: Baseline

Data Source: Patient-reported

Type: Single answer

Response Options: 1 = I can stand as long as I want without extra pain

2 = I can stand as long as I want but it gives me extra pain
3 = Pain prevents me from standing for more than 1 hour
4 = Pain prevents me from standing for more than half an hour
5 = Pain prevents me from standing for more than 10 minutes

6 = Pain prevents me from standing at all

Variable ID: ODI_Qo7

Variable: Question 7 of ODI **Definition:** Section 7 - Sleeping

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: Baseline

Data Source: Patient-reported **Type:** Single answer

Response Options: 1 = My sleep is never disturbed by pain

2 = My sleep is occasionally disturbed by pain
3 = Because of pain I have less than 6 hours sleep
4 = Because of pain I have less than 4 hours sleep
5 = Because of pain I have less than 2 hours sleep

6 = Pain prevents me from sleeping at all

Variable ID: ODI_Qo8

Variable: Question 8 of ODI

Definition: Section 8 - Sex life (if applicable)

Supporting Definition: N/A

Inclusion Criteria: All patients

Timing: Baseline

Data Source: Patient-reported

Type: Single answer

Response Options: 1 = My sex life is normal and causes no extra pain

2 = My sex life is normal but causes some extra pain
3 = My sex life is nearly normal but is very painful
4 = My sex life is severely restricted by pain
5 = My sex life is nearly absent because of pain

6 = Pain prevents any sex life at all

Variable ID: ODI_Qo9

Variable: Question 9 of ODI **Definition:** Section 9 - Social life

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: Baseline

Data Source: Patient-reported **Type:** Single answer

Response Options: 1 = My social life is normal and causes me no extra pain

2 = My social life is normal but increases the degree of pain

3 = Pain has no significant effect on my social life apart from limiting my more

energetic interests, e.g. sport, etc

4 = Pain has restricted my social life and I do not go out as often

5 = Pain has restricted social life to my home 6 = I have no social life because of pain

Variable ID: ODI_Q10

Variable: Question 10 of ODI **Definition:** Section 10 - Traveling

Supporting Definition: N/A

Inclusion Criteria: All patients

Timing: Baseline

Data Source: Patient-reported **Type:** Single answer

Response Options: 1 = I can travel anywhere without pain

2 = I can travel anywhere but it gives extra pain
 3 = Pain is bad but I manage journeys over two hours
 4 = Pain restricts me to journeys of less than one hour

5 = Pain restricts me to short necessary journeys under 30 minutes 6 = Pain prevents me from travelling except to receive treatment

Variable ID: NPRS_Qo1

Variable: Question 1 of NPRS

Definition: On a scale of o to 10, with o being no pain at all and 10 being the worst pain

imaginable, please indicate your average back pain over the last 7 days

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: Baseline

Carrier Datient

Data Source: Patient-reported **Type:** Numerical value

Response Options: Ordinal values from 0 to 10, with 'No pain' marked at '0' and 'Worst pain

imaginable' marked at '10'

Variable ID: NPRS Q02

Variable: Question 2 of NPRS

Definition: On a scale of o to 10, with o being no pain at all and 10 being the worst pain

imaginable, please indicate your average leg pain over the last 7 days

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: Baseline

Data Source: Patient-reported

Type: Numerical value

Response Options: Ordinal values from 0 to 10, with 'No pain' marked at '0' and 'Worst pain

imaginable' marked at '10'

Variable ID: EQ5D_Q01

Variable: Question 1 of EQ₅D

Definition: By selection an option in each group below, please indicate which statements best

describe your own health state today.

Mobility

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: Baseline

Data Source: Patient-reported **Type:** Single answer

Response Options: 1 = I have no problems in walking about

2 = I have some problems in walking about

3 = I am confined to bed

Variable ID: EQ5D_Q02

Variable: Question 2 of EQ5D

Definition: Self-care
Supporting Definition: N/A
Inclusion Criteria: All patients

Timing: Baseline

Data Source: Patient-reported **Type:** Single answer

Response Options: 1 = I have no problems with self-care

2 = I have some problems washing or dressing myself

3 = I am unable to wash or dress myself

Variable ID: EQ5D_Q03

Variable: Question 3 of EQ5D

Definition: Usual activities (For example work, study, housework, family, or leisure activities)

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: Baseline

Data Source: Patient-reported **Type:** Single answer

Response Options: 1 = I have no problems with performing my usual activities

2 = I have some problems with performing my usual activities

3 = I am unable to perform my usual activities

Variable ID: EQ5D_Q04

Variable: Question 4 of EQ5D **Definition:** Pain/discomfort

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: Baseline

Data Source: Patient-reported **Type:** Single answer

Response Options: 1 = I have no pain or discomfort

2 = I have moderate pain or discomfort3 = I have extreme pain or discomfort

Variable ID: EQ5D_Q05

Variable: Question 5 of EQ5D **Definition:** Anxiety/depression

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: Baseline

Data Source: Patient-reported **Type:** Single answer

Response Options: 1 = I am not anxious or depressed

2 = I am moderately anxious or depressed 3 = I am extremely anxious or depressed

Variable ID: EQ5D_Q06

Variable: Question 6 of EQ5D

Definition: To help people say how good or bad a health state is, we have drawn a scale (rather

like a thermometer) on which the best state you can imagine is marked 100 and

the worst state you can imagine is marked o.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: Baseline

Data Source: Patient-reported

Type: Visual scale

Response Options: Refer to visual analogue scale in sample questionnaire

Baseline Clinical Factors

Variable ID: SMOKE

Variable: Smoking status **Definition:** Do you smoke?

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: Baseline

Data Source: Patient-reported **Type:** Single answer

Type: Single ans

Response Options: o = No

1 = Yes

Variable ID: COMORB
Variable: Comorbidities

Definition: Have you been told by a doctor that you have any of the following?

Supporting Definition: Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003)

Inclusion Criteria: All patients
Timing: Baseline

Data Source: Patient-reported **Type:** Multiple answer

Separate multiple entries with ";"

Response Options: o = I have no other diseases

1 = Heart disease (For example angina, heart attack, or heart failure)

2 = High blood pressure

3 = Leg pain when walking due to poor circulation

4 = Lung disease (For example asthma, chronic bronchitis, or emphysema)

5 = Diabetes 6 = Kidney disease 7 = Liver disease

8 = Problems caused by stroke

9 = Disease of the nervous system (For example Parkinson's disease or Multiple

Sclerosis)

10 = Cancer (within the last 5 years)

11 = Depression12 = Arthritis

Variable ID: BACKPAINDUR
Variable: Duration of back pain

Definition: How long have you had your current back pain?

Supporting Definition: N/A

Inclusion Criteria: All patients

Timing: Baseline

Data Source: Patient-reported

Type: Single answer

Response Options: o = I don't have back pain

1 = Less than 3 months

2 = 3-12 months 3 = 1-2 years

4 = More than 2 years

Variable: LEGPAINDUR
Variable: Duration of leg pain

Definition: How long have you had pain radiating to your leg(s)?

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: Baseline

Data Source: Patient-reported

Type: Single answer

Response Options: o = I don't have pain radiating to my leg(s)

1 = Less than 3 months 2 = 3-12 months

3 = 1-2 years

4 = More than 2 years

Variable: HEIGHT Variable: Height

Definition: Indicate the patient's height

Supporting Definition: Height and weight are used to calculate BMI

Inclusion Criteria: All patients
Timing: Baseline

Data Source: Clinical

Type: Numerical value

Response Options: Numerical value of height in cm or in

Variable ID: HEIGHTUNIT Variable: Height units

Definition: Indicate units of height

Supporting Definition: N/A

Inclusion Criteria: All patients

Timing: Baseline

Data Source: Clinical

Type: Single answer **Response Options:** 1 = centimeters

2 = inches

Variable ID: WEIGHT Variable: Weight

Definition: Indicate the patient's weight

Supporting Definition: Height and weight are used to calculate BMI

Inclusion Criteria: All patients
Timing: Baseline

Data Source: Clinical

Type: Numerical value

Response Options: Numerical value of weight in kg or lbs

Variable ID: WEIGHTUNIT Variable: Weight units

Definition: Indicate units of weight

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: Baseline

Data Source: Clinical

Type: Single answer

Response Options: 1 = kilograms

2 = pounds

Variable ID: GLASSSYM

Variable: Diagnostic classification (according to Glassman criteria): Symptoms

Definition: Select one

Supporting Definition: Back pain dominant, acute: Primary complaint is LBP. Symptoms ≤3 months

Leg pain dominant, acute: Primary complaint is leg pain. Symptoms ≤ 3 months Back pain = Leg pain, acute: Patient reports 50 + 10% of each. Symptoms ≤ 3

months

Back pain dominant, chronic: Primary complaint is LBP. Symptoms >3 months Leg pain dominant, chronic: Primary complaint is leg pain. Symptoms >3 months Back pain = leg pain, chronic: Patient reports 50 +/- 10% of each. Symptoms >3

months

Neurogenic claudication: Numbness, weakness, or pain to the buttocks or legs,

exacerbated by walking or standing, relieved by sitting

Cauda equina syndrome: Dominant complaint is motor weakness, incontinence or

Cauda equina syndrome, with or without associated complaints of pain

Inclusion Criteria: All patients

Timing: Baseline **Data Source:** Clinical

Type: Single answer

Response Options: 1 = Back pain dominant, acute

2 = Leg pain dominant, acute 3 = Back pain = Leg pain, acute 4 = Back pain dominant, chronic 5 = Leg pain dominant, chronic 6 = Back pain = leg pain, chronic 7 = Neurogenic claudication

8 = Cauda equina syndrome

Variable ID: GLASSSP

Variable: Diagnostic classification (according to Glassman criteria): Structural pathology

Definition: Select one

Supporting Definition: Not defined: No study ordered, or no study interpretation available for

determination of structural pathology

Age appropriate: Structural changes are consistent with normal aging and not a

clinically relevant source of symptoms

Disc pathology with normal disc height: Disc pathology without significant loss of disc height, includes disc herniation, internal disc desiccation and annual tear Disc space collapse: Disc pathology with mechanical disc space collapse with or with part and disc space pathology.

without associated disc space pathology

Spondylolisthesis/Spondylolysis: Any listhesis, including degenerative and isthmic

spondylolisthesis

Scoliosis/Kyphosis: Lumbar spine deformity including localized scoliosis or

kyphosis

Facet pathology: Significant face arthrosis or degeneration, including synovial

cysts

Inclusion Criteria: All patients

Timing: Baseline **Data Source:** Clinical

Type: Single answer

Response Options: 1 = Not defined

2 = Age appropriate

3 = Disc pathology with normal disc height

4 = Disc space collapse

5 = Spondylolisthesis/ Spondylolysis

6 = Scoliosis/Kyphosis 7 = Facet pathology

Variable ID: GLASSCP

Variable: Diagnostic classification (according to Glassman criteria): Compressive pathology

Definition: Select one

Supporting Definition: Not defined: No study ordered, or no study interpretation available for

determination of compressive pathology

None: No clinically relevant compressive pathology

Central: Compression in the central canala region (between the lateral margins of

the dura) from any etiology

Lateral: Compression in the lateral recess or foraminal regions (lateral to the lateral

margins of the dura) from any etiology

Combined: Compression in the central canal and latera recess/foraminal regions

from any etiology

Recurrent: Recurrent compression following previous surgical treatment at the

same level, either in a central canala and/or recess/foraminal regions

Inclusion Criteria: All patients

Timing: Baseline

Data Source: Clinical

Type: Single answer

Response Options: 1 = Not defined

2 = None 3 = Central 4 = Lateral 5 = Combined 6 = Recurrent

Variable ID: ASA
Variable: ASA rating

Definition: Answer the following questions only if the patient is receiving spinal procedures

(surgery or injections)

Indicate the morbidity state of the patient

Supporting Definition: ASA1: no disturbance

ASA2:mild/moderate

ASA3: severe

ASA4: life-threatening ASA5: moribund

Inclusion Criteria: Surgically treated patients

Timing: Baseline **Data Source:** Clinical

Type: Single answer

Response Options: 1 = 1

999 = Unknown

Variable ID: SURGIND

Variable: Surgical indication

Definition: Indicate the reason for surgery

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

Timing: Baseline

Data Source: Clinical

Type: Single answer

Response Options: 1 = Paramedian disc herniation

2 = Central disc herniation

3 = Central spinal stenosis with degen. listhesis 4 = Central spinal stenosis without degen. listhesis

5 = Lateral spinal stenosis

6 = Spondylolysis/Spondylolisthesis, isthmic

7 = Segmental pain (with or without degen. listhesis)

8 = Postoperative instability

9 = Degen. scoliosis

999 = Other

Prior Treatment

Variable ID: PAINMEDPR

Variable: Need for continuous analgesic use (non-narcotics)

Definition: Do you take any of the following?

Over the counter or non-prescription pain medication

Supporting Definition: N/A

Inclusion Criteria: All patients

Timing: Baseline

Data Source: Patient-reported

Type: Single answer

Response Options: o = No

1 = Yes, regularly 2 = Yes, sometimes

Variable ID: PAINMEDO

Variable: Need for continuous analgesic use (narcotics)

Definition: Prescription pain medication (opioid or narcotic medications)

Supporting Definition: N/A

Inclusion Criteria: All patients

Timing: Baseline

Data Source: Patient-reported

Type: Single answer

Response Options: o = No

1 = Yes, regularly 2 = Yes, sometimes

Variable ID: PRIORINTER
Variable: Prior back surgery

Definition: Indicate if the patient has had previous procedural back interventions

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

Timing: Baseline **Data Source:** Clinical

Type: Single answer

Response Options: o = No

1 = Yes

Variable ID: PRIORINTER1DATE

Variable: Prior interventions dates*

Definition: Indicate when the patient had previous procedural back interventions

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

If patient has had previous procedural back interventions (INTERVENT)

Timing: Baseline

Data Source: Clinical

Type: Date by MM/YYYY

Response Options: MM/YYYY

Variable ID: PRIORINTER1TYPE

Variable: Prior interventions types*

Indicate the type of the previous procedural back interventions Definition:

Supporting Definition: N/A

> Inclusion Criteria: Surgically treated patients

> > If patient has had previous procedural back interventions (INTERVENT)

Timing: Baseline Data Source: Clinical Type: Single answer

Response Options: 1 = Discectomy

2 = Decompression

3 = Fusion

PRIORINTER1LEVEL Variable ID: Variable: Prior interventions levels*

Definition: Indicate the levels of the previous procedural back interventions

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

If patient has had previous procedural back interventions (INTERVENT)

Timing: Baseline Data Source: Clinical **Type:** Single answer

Response Options: $1 = T_{12}-L_1$

2 = L1-L2 3 = L2-L3 $4 = L_3 - L_4$ 5 = L4 - L56 = L5-S1

PRIORINTER₂DATE Variable ID: Variable: Prior interventions dates*

Definition: Indicate when the patient had previous procedural back interventions

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

If patient has had previous procedural back interventions (INTERVENT)

Timing: Baseline Data Source: Clinical

Type: Date by MM/YYYY

Response Options: MM/YYYY

> Variable ID: PRIORINTER2TYPE Variable: Prior interventions types*

Definition: Indicate the type of the previous procedural back interventions

Supporting Definition: N/A

> Inclusion Criteria: Surgically treated patients

> > If patient has had previous procedural back interventions (INTERVENT)

Timing: Baseline Data Source: Clinical

Single answer Type: Response Options: 1 = Discectomy

2 = Decompression

3 = Fusion

Variable ID: PRIORINTER2LEVEL Variable: Prior interventions levels*

Indicate the levels of the previous procedural back interventions Definition:

Supporting Definition: N/A

> Inclusion Criteria: Surgically treated patients

> > If patient has had previous procedural back interventions (INTERVENT)

Timing: Baseline Clinical Data Source:

Type: Single answer

Response Options: $1 = T_{12}-L_1$

2 = L1-L2 3 = L2-L3 4 = L3-L4 5 = L4-L5 6 = L5-S1

Variable ID: PRIORINTER3DATE

Variable: Prior interventions dates*

Definition: Indicate when the patient had previous procedural back interventions

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

If patient has had previous procedural back interventions (INTERVENT)

Timing: Baseline **Data Source:** Clinical

Type: Date by MM/YYYY

Response Options: MM/YYYY

Variable: PRIORINTER3TYPE
Variable: Prior interventions types*

Definition: Indicate the type of the previous procedural back interventions

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

If patient has had previous procedural back interventions (INTERVENT)

Timing: Baseline

Data Source: Clinical

Type: Single answer

Response Options: 1 = Discectomy

2 = Decompression

3 = Fusion

Variable ID: PRIORINTER3LEVEL
Variable: Prior interventions levels*

Definition: Indicate the levels of the previous procedural back interventions

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

If patient has had previous procedural back interventions (INTERVENT)

Timing: Baseline

Data Source: Clinical

Type: Single answer

· · · · · · · ·

Response Options: 1 = T12-L1

2 = L1-L2 3 = L2-L3 4 = L3-L4 5 = L4-L5 6 = L5-S1

Variable ID: PRIORINTER4DATE

Variable: Prior interventions dates*

Definition: Indicate when the patient had previous procedural back interventions

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

If patient has had previous procedural back interventions (INTERVENT)

Timing: Baseline **Data Source:** Clinical

Type: Date by MM/YYYY

Response Options: MM/YYYY

Variable ID: PRIORINTER4TYPE

Variable: Prior interventions types*

Definition: Indicate the type of the previous procedural back interventions

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

If patient has had previous procedural back interventions (INTERVENT)

Timing: Baseline **Data Source:** Clinical

Type: Single answer **Response Options:** 1 = Discectomy

2 = Decompression

3 = Fusion

Variable ID: PRIORINTER4LEVEL
Variable: Prior interventions levels*

Definition: Indicate the levels of the previous procedural back interventions

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

If patient has had previous procedural back interventions (INTERVENT)

Timing: Baseline **Data Source:** Clinical

Type: Single answer

Response Options: 1 = T12-L1

2 = L1-L2 3 = L2-L3 4 = L3-L4 5 = L4-L5 6 = L5-S1

Variable ID: PRIORINTER5DATE

Variable: Prior interventions dates*

Definition: Indicate when the patient had previous procedural back interventions

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

If patient has had previous procedural back interventions (INTERVENT)

Timing: Baseline **Data Source:** Clinical

Type: Date by MM/YYYY

Response Options: MM/YYYY

Variable ID: PRIORINTER5TYPE
Variable: Prior interventions types*

Definition: Indicate the type of the previous procedural back interventions

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

If patient has had previous procedural back interventions (INTERVENT)

Timing: Baseline

Data Source: Clinical

Type: Single answer **Response Options:** 1 = Discectomy

2 = Decompression

3 = Fusion

Variable ID: PRIORINTER5LEVEL
Variable: Prior interventions levels*

Definition: Indicate the levels of the previous procedural back interventions

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

If patient has had previous procedural back interventions (INTERVENT)

Timing: Baseline

Data Source: Clinical

Type: Single answer

Response Options: 1 = T12-L1 2 = L1-L2 3 = L2-L3 4 = L3-L4 5 = L4-L56 = L5-S1

^{*} Create functionality that allows user to add additional prior interventions as needed, up to 10

Variable ID: PROCEDURETYPE

Variable: Current procedural intervention: Type

Definition: Indicate type of current procedural intervention

Supporting Definition: Decompression: e.g. laminectomy **Inclusion Criteria:** Surgical and injection therapy patients

Timing: During index visit or hospitalization for procedure

Data Source: Clinical

Type: Single answer **Response Options:** 1 = Discectomy

- December

2 = Decompression (laminectomy)

3 = Fusion

4 = Other back surgery 5 = Injection therapy

Variable ID: PROCEDURELEVEL

Variable: Current procedural intervention: Level

Definition: Indicate the level of the current procedural intervention

Supporting Definition: N/A

Inclusion Criteria: All patients

Timing: During index visit or hospitalization for procedure

Data Source: Clinical

Type: Multiple answer

Response Options: $1 = T_{12}-L_1$

2 = L1-L2 3 = L2-L3 4 = L3-L4 5 = L4-L5

 $6 = L_5 - S_1$

DATA COLLECTION REFERENCE GUIDE

Acute Complications of Treatment

ns of Treatment OUTCOMES

Variable ID: DEATH

Variable: Death in hospital (all cause)

Definition: Indicate if patient died in-hospital following procedure (all-cause mortality)

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

Timing: During the index hospitalization

Data Source: Clinical

Type: Single answer

Response Options: o = No

1 = Yes

Variable ID: DEATHDATE Variable: Date of death

Definition: Indicate date of death

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

Timing: During the index hospitalization

Data Source: Clinical

Type: Date by DD/MM/YYYY

Response Options: DD/MM/YYYY

Variable ID: NERROOINJ

Variable: latrogenic nerve root damage (incl. cauda equina)

Definition: Indicate if there was iatrogenic nerve root damage (including cauda equina) due to

the intervention

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

Timing: During the index hospitalization

Data Source: Clinical

Type: Single answer

Response Options: o = No

1 = Yes

Variable ID: WRONGSP

Variable: Unintentional surgery on wrong site/level

Definition: Indicate if there was unintentional surgery on the wrong level/site, not on level of

main pathology

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

Timing: During the index hospitalization

Data Source: Clinical

Type: Single answer

Response Options: o = No

1 = Yes

Variable ID: VASINJ

Variable: latrogenous damage to a vessel

Definition: Indicate if there was relevant iatrogenous damage to a vessel

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

Timing: During the index hospitalization

Data Source: Clinical

Type: Single answer

Response Options: o = No

1 = Yes

Variable ID: DURTEAR

Variable: latrogenous damage of dura with liquor emission

Definition: Indicate if there was iatrogenous damage of a dura with liquor emission

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

Timing: During the index hospitalization

Data Source: Clinical

Type: Single answer

Response Options: o = No

1 = Yes

Variable ID: OTHERCOMPL
Variable: Other complications

Definition: Indicate if there were other complications (e.g. superficial hematoma,

malpositioned implant, donor-site pain, DVT without PE, and/or device failure)

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients
Timing: During the index hospitalization

Data Source: Clinical

Type: Single answer

Response Options: o = No

1 = Yes

Variable ID: 30DAYMORTADMIN

Variable: Death within 30 days of procedure

Definition: Indicate if patient died within 30 days following procedure (all-cause mortality)

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

Timing: Within 30 days of the index hospitalization

Data Source: Administrative (where available)

Type: Single answer

Response Options: o = No

ı = Yes

Variable ID: 30DAYMORTADMINDATE

Variable: Date of death

Definition: Indicate date of death

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

Timing: Within 30 days of the index hospitalization

Data Source: Administrative (where available)

Type: Date by DD/MM/YYYY

Response Options: DD/MM/YYYY

Variable ID: REHOSPADMIN

Variable: Readmission to acute care facility within 30 days

Definition: Indicate if the patient was admitted to an acute care facility as an inpatient within

30 days from the date of index intervention for ANY reason

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

Timing: Within 30 days of the index hospitalization

Data Source: Administrative (where available)

Type: Single answer

Response Options: o = No

1 = Yes

Variable ID: REHOSPADMINDATE
Variable: Date of rehospitalization

Definition: Indicate date of rehospitalization(s)

Supporting Definition: Do not include admissions to rehabilitation hospital or nursing home

Inclusion Criteria: Surgically treated patients

Timing: Within 30 days of the index hospitalization

Data Source: Administrative (where available)

Type: Date by DD/MM/YYYY

Response Options: DD/MM/YYYY

Variable ID: WOUINF

Variable: Deep wound infection

Definition: The following questions refer to your low back surgery that occurred roughly 6

months ago:

Were you treated with antibiotics (penicillins or similar) for 6 weeks or longer for a

deep infection in the surgical site within 3 months after surgery?

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

Timing: 6 months after index hospitalization

Data Source: Patient-reported **Type:** Single answer

Response Options: o = No

1 = Yes

Variable ID: PULMEMB

Variable: Pulmonary embolus

Definition: Were you diagnosed with and treated for pulmonary emboli (blood clot in the lung)

within 3 months after surgery?

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

Timing: 6 months after index hospitalization

Data Source: Patient-reported

Type: Single answer

Response Options: o = No

1 = Yes

Variable ID: REHOSPPATIENT

Variable: Need for rehospitalization

Definition: Were you admitted overnight in the hospital (excluding emergency room visits) for

ANY reason during the 30 days after you underwent your back surgery?

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

Timing: 6 months after index hospitalization

Data Source: Patient-reported

Type: Single answer

Response Options: o = No

1 = Yes

Disease Recurrence

Variable ID: REOPPATIENT

Variable: Need for reoperation

Definition: Have you had any additional low back surgery at the same level?

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported (if lacking registry for tracking across institutions)

Type: Single answer

Response Options: o = No

1 = Yes

Variable ID: REOPDATE

Variable: Date of reoperation

Definition: If yes, when did you have you surgery?

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

If answered 'yes' to having a reoperation (REOP)

Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported (if lacking registry for tracking across institutions)

Type: Date by DD/MM/YYYY

Response Options: DD/MM/YYYY

Variable ID: REOP

Variable: Current procedure a reoperation at same level?

Definition: Indicate if the current surgery is a reoperation at the same level because the prior

surgery at the same level did not reach its technical or clinical goals

Supporting Definition: N/A

Inclusion Criteria: Surgically treated patients

Timing: When occurs **Data Source:** Clinical

Type: Single answer

Response Options: o = No

1 = Yes

Variable ID: REOPREAS

Variable: Tyope of reoperation (if applicable) **Definition:** Indicate the type of reoperation

Supporting Definition: Hardware removal: removal of implants (For example, screws, rods)

Non-union: failure of bony consolidation of bridge/union at minimum 12 months

after surgery

Neuro-compression: compression of neural structures with or without neurological

deficits (select recurrent disc herniation or other neuro-compression)

Post-op infection: superficial or deep (subfascial) wound/tissue infection after

surgery

Implant malposition: incorrect position of the implant

Implant failure: problem due to an implant (For example, loosening, breakage)

Wrong level: procedure mistakenly performed at wrong vertebral level

Sagittal imbalance: sagittal malalignment of the spine (select lumbar flatback

deformity or junctional kyphosis)

Cerebrospinal fluid leakage: includes CSF fistula, seudomeningocele, etc. Epidural hematoma: collection of blood adjacent to dura, potentially creating

compression

Inclusion Criteria: Surgically treated patients

If answered 'yes' to having a reoperation (REOP)

Timing: When occurs

Data Source: Clinical

Type: Single answer

ype. Single answer

Response Options: 1 = Hardware removal

2 = Non-union

3 = Neuro-compression
4 = Post-op infection
5 = Implant malposition
6 = Implant failure
7 = Wrong level
8 = Sagittal imbalance

9 = Cerebrospinal fluid leakage

10 = Epidural hematoma

Patient-Reported Health Status

Variable ID: WORK
Variable: Work status

Definition: What is your work status?

Supporting Definition: N/A

Inclusion Criteria: All patients

Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported

Type: Single answer

Response Options: o = Unable to work due to a condition other than back or leg pain

1 = Unable to work due to back or leg pain

2 = Not working by choice (student, retired, homemaker)

3 = Seeking employment (I consider myself able to work but cannot find a job)

4 = Working part-time 5 = Working full-time

Variable ID: WORKDUR

Variable: Time to return to work

Definition: How long after you received treatment for Low Back Pain did you return to work

(where applicable)?

Supporting Definition: N/A

Inclusion Criteria: All patients

If patient is working (WORK)

Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported

Type: Single answer

Response Options: 1 = Less than 3 months

2 = 3-6 months 3 = 6-9 months 4 = 9-12 months 5 = 1-2 years

6 = More than 2 years

Variable ID: WORKDEM
Variable: Work demands

Definition: Are you working at a physically less demanding job now because of your leg or

back pain?

Supporting Definition: N/A

Inclusion Criteria: All patients

If patient is working (WORK)

Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported

Type: Single answer

Response Options: o = No 1 = Yes

Variable ID: PAINMEDPR

Variable: Need for continuous analgesic use (non-narcotics)

Definition: Do you take non-narcotic pain relievers (For example NSAIDs, acetaminophen)?

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported **Type:** Single answer

Response Options: 0 = No

1 = Yes, regularly 2 = Yes, sometimes

Variable ID: PAINMEDO

Variable: Need for continuous analgesic use (narcotics)

Definition: Do you take narcotics, also known as opioids (For example morphine, codeine,

dextropropoxyphene)?

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported

Type: Single answer

Response Options: o = No

1 = Yes, regularly 2 = Yes, sometimes

Variable ID: ODI_Qo1

Variable: Question 1 of ODI

Definition: This questionnaire is designed to give us information as to how your back (or leg)

trouble affects your ability to manage in everyday life.

Please answer every section. Select only one option in each section that most

closely describes you today. Section 1 - Pain intensity

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported

Type: Single answer

Response Options: 1 = I have no pain at the moment

2 = The pain is very mild at the moment
3 = The pain is moderate at the moment
4 = The pain is fairly severe at the moment
5 = The pain is very severe at the moment

6 = The pain is the worst imaginable at the moment

Variable ID: ODI_Q02

Variable: Question 2 of ODI

Definition: Section 2 - Personal care (washing, dressing, etc.)

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported

Type: Single answer

Response Options: 1 = I can look after myself normally without causing extra pain

2 = I can look after myself normally but it is very painful
 3 = It is painful to look after myself and I am slow and careful
 4 = I need some help but manage most of my personal care
 5 = I need help every day in most aspects of self care

6 = I do not get dressed, wash with difficulty and stay in bed

Variable ID: ODI_Qo3

Variable: Question 3 of ODI **Definition:** Section 3 - Lifting

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported **Type:** Single answer

Response Options: 1 = I can lift heavy weights without extra pain

2 = I can lift heavy weights but it gives extra pain

3 = Pain prevents me from lifting heavy weights off the floor but I can manage if

they are conveniently positioned, e.g. on a table

4 = Pain prevents me from lifting heavy weights but I can manage light to medium

weights if they are conveniently positioned

5 = I can lift only very light weights 6 = I cannot lift or carry anything at all

Variable ID: ODI_Qo4

Variable: Question 4 of ODI Definition: Section 4 - Walking

Supporting Definition: N/A

> Inclusion Criteria: All patients

Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported

Type: Single answer

Response Options: 1 = Pain does not prevent me walking any distance

2 = Pain prevents me walking more than one mile

3 = Pain prevents me walking more than a quarter of a mile

4 = Pain prevents me walking more than 100 yards

5 = I can only walk using a stick or crutches

6 = I am in bed most of the time and have to crawl to the toilet

Variable ID: ODI Qos

Variable: Question 5 of ODI **Definition:** Section 5 - Sitting

Supporting Definition: N/A

Inclusion Criteria: All patients Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported

Type: Single answer

Response Options: 1 = I can sit in any chair as long as I like

2 = I can sit in my favorite chair as long as I like

3 = Pain prevents me from sitting for more than 1 hour 4 = Pain prevents me from sitting for more than half an hour 5 = Pain prevents me from sitting for more than 10 minutes

6 = Pain prevents me from sitting at all

Variable ID: ODI_Qo6

Variable: Question 6 of ODI **Definition:** Section 6 - Standing

Supporting Definition: N/A

Inclusion Criteria: All patients Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported

Type: Single answer

Response Options: 1 = I can stand as long as I want without extra pain

> 2 = I can stand as long as I want but it gives me extra pain 3 = Pain prevents me from standing for more than 1 hour 4 = Pain prevents me from standing for more than half an hour 5 = Pain prevents me from standing for more than 10 minutes

6 = Pain prevents me from standing at all

Variable ID: ODI_Qo7

Variable: Question 7 of ODI **Definition:** Section 7 - Sleeping

Supporting Definition:

Inclusion Criteria: All patients 3*, 6 months Timing:

1, 2, 5* year after index event

Data Source: Patient-reported

Type: Single answer

Response Options: 1 = My sleep is never disturbed by pain

2 = My sleep is occasionally disturbed by pain
3 = Because of pain I have less than 6 hours sleep
4 = Because of pain I have less than 4 hours sleep
5 = Because of pain I have less than 2 hours sleep

6 = Pain prevents me from sleeping at all

Variable ID: ODI_Qo8

Variable: Question 8 of ODI

Definition: Section 8 - Sex life (if applicable)

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported

Type: Single answer

Response Options: 1 = My sex life is normal and causes no extra pain

2 = My sex life is normal but causes some extra pain
3 = My sex life is nearly normal but is very painful
4 = My sex life is severely restricted by pain
5 = My sex life is nearly absent because of pain

6 = Pain prevents any sex life at all

Variable ID: ODI_Qo9

Variable: Question 9 of ODI **Definition:** Section 9 - Social life

Supporting Definition: N/A

Inclusion Criteria: All patients

Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported

Type: Single answer

Response Options: 1 = My social life is normal and causes me no extra pain

2 = My social life is normal but increases the degree of pain

3 = Pain has no significant effect on my social life apart from limiting my more

energetic interests, e.g. sport, etc

4 = Pain has restricted my social life and I do not go out as often

5 = Pain has restricted social life to my home 6 = I have no social life because of pain

Variable ID: ODI Q10

Variable: Question 10 of ODI **Definition:** Section 10 - Traveling

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported

Type: Single answer

Response Options: 1 = I can travel anywhere without pain

2 = I can travel anywhere but it gives extra pain
 3 = Pain is bad but I manage journeys over two hours
 4 = Pain restricts me to journeys of less than one hour

5 = Pain restricts me to short necessary journeys under 30 minutes 6 = Pain prevents me from travelling except to receive treatment

Variable ID: NPRS_Qo1

Variable: Question 1 of NPRS

Definition: On a scale of o to 10, with o being no pain at all and 10 being the worst pain

imaginable, please indicate your average back pain over the last 7 days

Supporting Definition: N/A

Inclusion Criteria: All patients

Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported **Type:** Numerical value

Response Options: Ordinal values from 0 to 10, with 'No pain' marked at '0' and 'Worst pain

imaginable' marked at '10'

Variable ID: NPRS_Q02

Variable: Question 2 of NPRS

Definition: On a scale of o to 10, with o being no pain at all and 10 being the worst pain

imaginable, please indicate your average leg pain over the last 7 days

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported **Type:** Numerical value

Response Options: Ordinal values from 0 to 10, with 'No pain' marked at '0' and 'Worst pain

imaginable' marked at '10'

Variable ID: EQ5D_Q01

Variable: Question 1 of EQ5D

Definition: By selection an option in each group below, please indicate which statements best

describe your own health state today.

Mobility

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported **Type:** Single answer

Response Options: 1 = I have no problems in walking about

2 = I have some problems in walking about

3 = I am confined to bed

Variable ID: EQ5D_Q02

Variable: Question 2 of EQ5D

Definition: Self-care **Supporting Definition**: N/A

Inclusion Criteria: All patients

Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported

Type: Single answer

Response Options: 1 = I have no problems with self-care

2 = I have some problems washing or dressing myself

3 = I am unable to wash or dress myself

Variable ID: EQ5D_Q03

Variable: Question 3 of EQ5D

Definition: Usual activities (For example work, study, housework, family, or leisure activities)

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported

Type: Single answer

Response Options: 1 = I have no problems with performing my usual activities

2 = I have some problems with performing my usual activities

3 = I am unable to perform my usual activities

Variable ID: EQ5D_Q04

Variable: Question 4 of EQ5D **Definition:** Pain/discomfort

Supporting Definition: N/A

Inclusion Criteria: All patients

Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported

Type: Single answer

Response Options: 1 = I have no pain or discomfort

2 = I have moderate pain or discomfort3 = I have extreme pain or discomfort

Variable ID: EQ5D_Q05

Variable: Question 5 of EQ5D **Definition:** Anxiety/depression

Supporting Definition: N/A

Inclusion Criteria: All patients
Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported

Type: Single answer

Response Options: 1 = I am not anxious or depressed

2 = I am moderately anxious or depressed 3 = I am extremely anxious or depressed

Variable ID: EQ5D_Q06

Variable: Question 6 of EQ5D

Definition: To help people say how good or bad a health state is, we have drawn a scale (rather

like a thermometer) on which the best state you can imagine is marked 100 and

the worst state you can imagine is marked o.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Supporting Definition: N/A

Inclusion Criteria: All patients

Timing: 3*, 6 months

1, 2, 5* year after index event

Data Source: Patient-reported

Type: Visual scale

Response Options: Refer to visual analogue scale in sample questionnaire

* 3 month and 5 year time points are recommended but not essential

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Reference Guide Revisions

Reference Guide Version	Location within Reference Guide	Content Change
2.1	Introduction to the Data Dictionary	Modifications to introductory paragraph
2.1	The Growing ICHOM Community	Removed map and updated information

www.ichom.org ichomteam@ichom.org