The evidence base for the SPINEDATA low back pain questionnaires

This document summarises the evidence for the selection of items in the low back pain questionnaires. There are many levels of evidence available, from clinical observation through to meta-analysis of the results of randomized controlled trials. There are also many types of validity, from face validity through to the demonstration of improved patient outcomes. This document draws on two types of high-quality published evidence, both of which are central to therapeutic decision-making in the care of low back pain (LBP): (1) evidence that the presence of a clinical finding indicates a better response to a particular treatment relative to a credible comparison treatment (therapeutic studies), and (2) evidence of the association between a clinical finding and an increased risk of chronicity/poor-outcome (prognostic studies). Some items were carried over from the previous baseline assessment procedure (COBRA) that had been used in this setting, as there was a clinical tradition of using these items based on their face validity.

Question	Evidence
Patient questionnaire	
Contextual (environmental and personal) factors	
What is your height? What is your weight?	Greater body mass index - associated with poor outcome in 3 prognostic studies ¹⁻³ .
Do you smoke cigarettes?	Smoking - associated with poor outcome in 2 prognostic studies ^{3,4} .
Is the hand that you use most often, your right or left hand?	Handedness is used to determine which elbow to access as a screening test for systemic hypermobility. In a study at the Spine Centre of Southern Denmark (n=4062 patients), this screening test had an overall accuracy of 94% when compared with the nine Beighton Hypermobility Criteria (unpublished data).
Have you ever had a back operation?	Previous low back surgery - carried over from COBRA.
Do you have or have you had any heart disease?	Screening for co-morbidities - associated with poor outcome in 2 prognostic
Do you have or have you had any serious lung disease?	studies ^{5,6} .
Do you have any allergies (including allergies to any medicines)?	
If you have any other important diseases or health conditions, please list:	
Please list any other medications that you are taking for any health condition:	
Do you have or have you had cancer?	History of lung, prostate or breast cancer - associated with an increased risk of cancer-related LBP ⁷ .
Have you experienced any unexpected weight loss?	Recent weight loss - associated with an increased risk of cancer-related LBP ⁸ .

Do you have morning stiffness in your back for more than 1 hour?	Morning stiffness - part of a symptom complex indicating increased probability of inflammatory spinal conditions ⁹ .
Have you taken corticosteroid medication for more than 3 months?	Use of corticosteroids - associated with an increased risk of fracture-related LBP ¹⁰ .
Was the onset of your low back pain associated with a recent or current pregnancy?	Pregnancy - LBP has a high prevalence during pregnancy and this may represent a subgroup with a different clinical course from other nonspecific LBP.
What is the intensity of the physical activity in your recreational activities?	Level of recreational physical activity - associated with poor outcome in 4 prognostic studies ¹¹⁻¹⁵ .
Do you take any type of pain-killer (analgesic)? If Yes, which pain killers are you taking? (name/dose)	Analgesic use - carried over from COBRA.
Have you applied for a pension either because of back pain or some other reason?	2 categories of having applied for pension LBP - carried over from COBRA.
Are you making a back pain-related insurance claim - employer or patient or compensation or complaint?	Compensable condition - associated with poor outcome in 7 prognostic studies ^{2,16-22} .
How do you get along with your workmates?	Workplace relationships - carried over from COBRA
Physical impairment	
Since the onset of this pain, have you experienced any pins and needles or numbness in your legs or feet?	Sensory loss - symptom associated with nerve root compression and used in the Fritz/Delitto subgrouping method (Traction category) ²³ .
Since the onset of this pain, have you experienced any weakness of your legs or feet?	Paraesthesia - symptom associated with nerve root compression and used in the Fritz/Delitto subgrouping method (Traction category) ²³ .
Since the onset of this pain, have you experienced any change in your	
bladder or bowel control?	Change of bladder or bowel control - symptom associated with cauda equina compression - identification of a specific LBP pathology.
bladder or bowel control?	Change of bladder or bowel control - symptom associated with cauda equina compression - identification of a specific LBP pathology.
bladder or bowel control? Performance of pain? Use when was the onset of pain?	Change of bladder or bowel control - symptom associated with cauda equina compression - identification of a specific LBP pathology. ain Longer pain duration associated with poor outcome in 8 prognostic studies ^{2,3,11,20,24-27} . Pain < 16 days duration a component in the Childs 2004 manipulation clinical prediction rule ^{24,28} . Duration > 3 months part of symptom complex indicating increased probability of ankylosing spondylitis ^{9,29} . Sudder exercise constrained with poor outcome in 2 prognostic

Was there a reason or cause for the onset?	Mechanism of injury - associated with poor outcome in 2 prognostic studies ^{30,31} .
Did the onset of your low back pain follow physical trauma?	Onset post trauma - symptom used in the Fritz/Delitto subgrouping method ^{23,32} .
On average, how many days of the week do you have this pain?	Pain frequency - associated with poor outcome in 1 prognostic study ¹¹ .
At what time of the day is the pain worst?	Diurnal variation - carried over from COBRA.
Your back pain now? (0-10)	Greater pain intensity associated with poor outcome in 14 prognostic studies ^{12,21,22,27,31,33-42} .
The most severe back pain that you have had in the last 14 days? (0-10)	
Your average back pain in the last 14 days? (0-10)	
Your leg pain now? (0-10)	Leg pain associated with poor outcome in 12 prognostic
The most severe leg pain that you have had in the last 14 days? (0-10)	studies ^{1,2,11,12,15,22,24,39,43-46} . Leg pain > LBP associated with nerve root
Your average leg pain in the last 14 days? (0-10)	compression (sensitivity 82%, specificity 54%).
Do some movements of your back increase the pain?	Movement-related pain - associated with poor outcome in 1 prognostic study ¹⁶ .
Have you had previous episodes of low back pain?	Prior episodes - associated with poor outcome in 10 prognostic studies ^{11,20,21,27,31,33,41,44,46,47} .
Do you experience episodes of low back pain that are triggered by very	Recurrences with minor activity- symptom used in the Fritz/Delitto
minor activity?	subgrouping method ^{23,32} .
Pain chart	Pain distribution: Leg pain associated with poor outcome in 12 prognostic
	studies ^{2,2,2,2,2,2,2,3,5,5,5} . Widespread pain associated with poor outcome in
Pain drawing regions	46 body regions coded to indicate areas of pain
Activity limitation	
Activity initiation	
(sciatica) (RMDO1) I change positions frequently to try and get my back or	prognostic studies ^{12,17,18,36,37,40,47} RMDO = Roland Morris Disability
leg comfortable (RMDO2). I walk more slowly than usual because of my back	Questionnaire. Item 15 (night pain) is also a red flag.
problem or leg pain (sciatica) (RMDQ3). Because of my back problem or leg	
pain (sciatica), I am not doing any of the jobs that I usually do around the	
house (RMDQ4),Because of my back problem or leg pain (sciatica), I use a	
handrail to get upstairs (RMDQ5), Because of my back problem or leg pain	

(sciatica), I have to hold on to something to get out of an easy chair (RMDQ6), I get dressed more slowly than usual because of my back problem or leg pain (sciatica) (RMDQ7), I only stand for short periods of time because of my back problem or leg pain (sciatica) (RMDQ8), Because of my back problem or leg pain (sciatica), I try not to bend or kneel down (RMDQ9), I find it difficult to get out of a chair because of my back problem or leg pain (sciatica) (RMDQ10), My back or leg is painful almost all the time (RMDQ11), I find it difficult to turn over in bed because of my back problem or leg pain (sciatica) (RMDQ12), I have trouble putting on my socks or stockings because of the pain in my back or leg (RMDQ13), I only walk short distances because of the pain in my back or leg (RMDQ13), I only walk short distances because of my back problem or leg pain (sciatica) (RMDQ14), I sleep less well because of my back problem or leg pain (sciatica) (RMDQ15), I avoid heavy jobs around the house because of my back problem or leg pain (sciatica) (RMDQ16), Because of my back problem or leg pain (sciatica), I am more irritable and bad tempered with people than usual (RMDQ17), Because of my back problem or leg pain (sciatica), I go upstairs more slowly than usual (RMDQ18), I stay in bed most of the time because of my back problem or leg pain (sciatica) (RMDQ19), Because of my back problem or leg pain (sciatica), my sexual activity is decreased (RMDQ20), I keep rubbing or holding areas of my body that hurt or are uncomfortable (RMDQ21), Because of my back problem or leg pain (sciatica), I am doing less of the daily work around the house than I would usually do (RMDQ22), I often express concern to other people over what might be bappening to my health (RMDQ23)	
Participation restriction	
Are you either currently employed or currently studying?	Assists in differentiation of people who have taken time off paid work from those performing unpaid work. Component of the Orebro screening questions ⁴⁸ .
What job or type of study?	Employment type - carried over from COBRA.
Are you unemployed?	Unemployed - carried over from COBRA.
Have you taken sick leave for back pain in the last 3 months?	Sick leave assessment - carried over from COBRA.
If you have taken sick leave for back pain in the last 3 months - how many days sick leave?	Longer time off work - associated with poor outcome in 6 prognostic studies ^{4,11,15,20,38,49} .

Are you still on sick leave for back pain or for another reason?	2 categories of sick leave. Longer time off work - associated with poor outcome in 6 prognostic studies ^{4,11,15,20,38,49} .
Are you on restricted work hours because of back pain or because of another health problem?	2 categories of restricted hours- carried over from COBRA.
Do you have a flexjob?	Flexjob - carried over from COBRA.
Are you undertaking rehabilitation?	Undertaking rehabilitation - carried over from COBRA.
Psychological	
Age	Older age associated with poor outcome in 12 prognostic studies ^{11-14,30,38-} ^{41,44,46,50,51} . Age >65 associated with spinal stenosis (sensitivity 77%, specificity 69%) ⁹ , age >50 associated with increased risk of fractures ⁵² .
Gender	Gender - associated with poor outcome in 8 prognostic studies ^{3,17,18,25,26,30,39,45,46,50} .
Are you receiving a pension either because of back pain or some other reason?	2 categories of receiving pension- carried over from COBRA.
In your job, are you or were you exposed to vibration for more than 2 hours a day (for example: (a) driving a bus or truck or similar, or (b) not simply using light hand tools but also using large shaking machinery)?	Exposure to vibration - carried over from COBRA.
Is your work/domestic activity monotonous?	Job variety – a component of the Orebro screening questions ⁴⁸ .
How physically strenuous do you consider your work to be?	Physically demanding activity - associated with poor outcome in 7 prognostic studies ^{1,4,11,12,30,44,47} .
In 6 weeks time, how difficult do you think it will be to sit or stand long enough to perform your usual work?	Self-perceived risk of poor outcome - component of the Orebro screening questions ⁴⁸ .
If you are in paid employment and you take into consideration your work routines, management, salary, promotion possibilities and work mates, how satisfied are you with your job?	Job satisfaction - associated with poor outcome in 7 prognostic studies ^{2,12,16,38,39,42,46} .
If you are in paid employment, in your estimation what are the chances that you will be working in 6 months?	Expectations of recovery - associated with poor outcome in 2 prognostic studies ^{37,47} .
Health-related quality of life	From the EQ-5D ⁵³ , as poor general health was associated with poor outcome in 7 prognostic studies ^{1-3,12,37,39,46} .
Do your feel socially isolated?	Social isolation - associated with poor outcome in 3 prognostic studies ^{1,12,46} . In a study at the Spine Center of 179 patients, this screening question had an

	overall accuracy of 86% when compared to the Friendship Scale ⁵⁴ .
"When I feel pain, it's terrible and I feel it's never going to get any better"	Catastrophization - associated with poor outcome in 3 prognostic
"When I feel pain, I feel I can't stand it anymore"	studies ^{12/21,43} . In a study at the Spine Center of 353 patients, this screening
	catastrophization subscale of the Coning Strategies Questionnaire ⁵⁴
In your view, how large is the risk that your current pain may become	Expectations of recovery - associated with poor outcome in 2 prognostic
nersistent?	studies ^{37,47} A component of the Orebro screening questions ⁴⁸
Do vou feel anxious?	Anxiety - associated with noor outcome in 4 prognostic studies 1,15,37,39 In a
	study at the Spine Center of 179 patients, this screening question had an
	overall accuracy of 78% when compared to the Friendship Scale ⁵⁴ .
During the past month, have you often been bothered by feeling down,	Depression - associated with poor outcome in 6 prognostic
depressed or hopeless?	studies ^{1,4,20,37,39,55} . These two screening questions were devised in the
During the past month, have you often been bothered by little interest or	PRIME-1000 study ⁵⁶ and in a study at the Spine Center of 382 patients, had
pleasure in doing things?	an overall accuracy of 86% when compared to the Beck Depression
	Inventory".
"Physical activity might harm my back"	Items from the Fear-Avoidance Beliefs Questionnaire (physical activity sub-
"I should not do physical activities which (might) make my pain worse"	the Delitto subgrouping method (stabilization exercises group) ⁵⁸ High EABO
	scores associated with poor outcome in 5 prognostic studies ^{22,24,35,50,59} . In a
	study at the Spine Center of 353 patients, these two fear-avoidance beliefs
	screening questions had an overall accuracy of 88% when compared to the
	whole Fear-Avoidance Beliefs Questionnaire (physical subscale) ⁵⁴ .
Quality of life and health utility outcome measure	
Mobility, Self-care, Usual activities (e.g. work, study, housework, family or	EuroQOL ⁵³ = 6 question quality of life and health utility outcome measure
leisure activities), Pain/discomfort, Anxiety/depression, EUROQOL Quality of	
life thermometer	
Clinician questionnaire	
Physical impairment	
Pain caused by active movement in particular directions (flexion, extension,	The notion that pain in particular movement directions has diagnostic and
lateral flexion, rotation) and the areas of the body in which pain is	therapeutic implications remains a lively debate, but the scientific evidence
	is inconclusive ^{10,00,00} . The research literature contains contradictory findings

experienced during these movements.	regarding which directions of pain are associated with a positive response to diagnostic injections and the use of diagnostic injections as a reference standard also remains controversial. However, pain on movement is commonly used by clinicians to subgroup patients, to assess severity and to monitor progress.
	The directions of movement that are affected by pain are easier to assess than the amount of associated movement limitation. It is difficult to measure movement limitation accurately without the use of goniometry apparatus and this is often not practical in routine care.
Directional preference (McKenzie) in the most clinically-relevant direction. Which movement direction displayed this directional preference?	Centralization and peripheralization - signs used in the McKenzie subgrouping method ⁶⁵⁻⁶⁷ and the Fritz/Delitto subgrouping method (specific exercise category) ²³ . Non-centralization associated with poor outcome in 2 prognostic studies ^{22,59} .
Lateral shift	Lateral shift - sign used in the Fritz/Delitto subgrouping method ²³ .
Aberrant movement	Aberrant movement - sign used in the Fritz/Delitto subgrouping method (stabilization exercise category) ⁵⁸ . Mid-ROM catch pain - symptom used in the Fritz/Delitto subgrouping method ^{23,32} .
Left and right Straight Leg Raise Test - degrees of range of motion	Straight leg raise (SLR) - sign associated with nerve root compression (sensitivity 80%, specificity 40%), associated with poor outcome in 5 prognostic studies ^{4,11,25,26,43,49} .
Left and right Straight Leg Raise Test - dorsiflexion of ankle	SLR ankle dorsiflexion - carried over from COBRA.
Left and right Straight Leg Raise Test - hamstring tightness	SLR hamstring tightness only - carried over from COBRA.
Crossed Straight Leg Raise Test - degrees of range of motion	Crossed SLR - sign associated with nerve root compression (sensitivity 25%, specificity 90%) ⁹ .
Muscle strength: left and right hip flexion, knee extension, knee flexion, ankle dorsiflexion, ankle eversion, ankle inversion, Extensor Hallicus Longus, Extensor Digitorum Longus, Flexor Hallicus Longus, Flexor Digitorum Longus	22 areas of potential muscle weakness. Muscle weakness can be a sign of nerve root compression. ^{9,68} .
Sensation - (left and right) lumbar dermotomes, L4 dermotome, L5 dermotome, S1 dermotome, altered sensation but non-dermatomal	10 areas of altered sensation. Altered sensation can be a sign of nerve root compression ⁶⁸ .
Deep tendon reflex testing: (left and right) patella, hamstring, archilles	Hyporeflexia can be a sign of nerve root compression, hyperflexia a sign of

	upper motor neuron lesions ⁶⁸ .
Muscle atrophy (left or right) quadriceps, calf, Ext. Dig Brevis, Gluteals	Muscle atrophy can be a sign of nerve root compression ⁶⁸ .
Is there paraspinal tenderness on only one side (unilateral)?	Localised unilateral LBP - symptom used in the Fritz/Delitto subgrouping method ^{23,32} .
If there is tenderness with the Springing Test – is there pain referral?	Pain referral during the Springing Test - carried over from COBRA
SIJ pain with maximum flexion of hip - thigh and knee (left and right)	SIJ pain assessment - carried over from COBRA.
Tenderness with direct palpation of SIJ ligaments (left and right)	
SIJ pain with maximum flexion of hip - "P4" Posterior Pelvic Pain Provocation (left and right)	
Prone Knee Bend Test (left and right)	Prone Knee Bend Test - sign used in the Fritz/Delitto subgrouping method (extension/mobilisation category) ^{23,32} .
Were peri-anal sensation or tone or reflex tested? If peri-anal sensation or tone or reflex were tested, was any abnormality detected?	Anal sphincter testing - carried over from COBRA.
Hyperextension elbow joint (dominant side) > 10 degrees	In a study at the Spine Center of 4062 patients, this test had an overall accuracy of 93.9% when compared with the 9 Beighton Hypermobility Criteria (unpublished data). Ligamentous laxity - sign used in the Fritz/Delitto subgrouping method (immobilisation category) ^{23,32} .
Straight Leg Raise Test - regions of pain radiation (left and right leg)	22 low back and lower limb regions coded to indicate areas of pain referral during SLR.
Tenderness: Springing Test T10, T11, T12, L1, L2, L3, L4, L5, S1	9 level Springing Test - Localised tenderness – the sign most believed by clinicians (25%) to differentiate subgroups ⁶⁹ .
Were there any other clinical findings that you consider to be important in this case? (optional)	Capacity for clinicians to add any other clinical findings that are relevant to this patient.
Pathoanatomy	
MRI imaging findings	The MRI images from sub-set of patients have been quantitatively coded using a detailed research protocol ⁷⁰ .
MRI imaging findings - Narrative report (from radiologist)	These are not routinely entered into the database but a complete narrative report from a radiologist can be obtained for each patient who underwent an MRI.

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