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Abstract

Objective

To examine the association between baseline patient-reported outcome measures (PROMs) and 5-year clinical pathway outcome in patients presenting with low back pain, and to explore whether a composite PROM burden score could support risk stratification.

Design

Retrospective observational study.

Setting

Spinal surgery, University Hospital of Wales.

Population

Patients presenting between 2012 and 2019 with low back pain only, excluding those aged over 65 years, those with previous spinal surgery, structural spinal abnormalities, or symptoms suggestive of alternative spinal diagnoses.

Results

A total of 173 patients with baseline PROMs were shortlisted; 159 had a complete set of PROMs data for composite-score analysis. Worse baseline PROMs were associated with more escalated 5-year pathways. The strongest individual associations were PHQ-9% and ODI. A composite score of VAS% + ODI + PHQ-9% showed the strongest overall association with outcome and the best performance for predicting pain clinic referral.

Conclusions

Baseline PROM burden was strongly associated with longer-term pathway outcome and may support triage-oriented risk stratification.

Introduction

Low back pain is the leading cause of disability worldwide, with more than 60% of the adult population experiencing it during their lifetime (1) (2). Apart from being debilitating, it is also reported as being highly recurrent and contributes significantly to individual morbidity and the wider public health burden (3). The understanding of low back pain has gradually shifted from being explained solely by anatomical or biomechanical factors, to include a complex combination of biological, psychological and social factors that interact to shape prognosis (4). Patients' cognitive appraisal of pain has been found to be an important predictor of symptom severity and chronicity (5). However, psychosocial risk factors are still under-recognised by clinicians in the onset of low back pain (6). This represents an avenue for clinical improvement, as a biopsychosocial model may support more comprehensive assessment, better risk stratification and more targeted interventions.

Patient reported outcome measures (PROMs) are defined as 'any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else" (7). Several validated PROMs are routinely collected within spinal clinics to quantify the different domains impacting patient health. Some examples, as used in this study, include: the Generalised Anxiety Disorder-7 (GAD-7), a measure of anxiety symptoms; the Patient Health Questionnaire-9 (PHQ-9), a measure of depressive symptoms; the Oswestry Disability Index (ODI), a measure of functional disability related to spinal symptoms; the Visual Analogue Scale (VAS), a measure of pain intensity; and the EQ-5D Visual Analogue Scale (EQ5D-VAS), a measure of self-rated overall health status. The questionnaires used for these scores are provided in Appendix 1.

Although PROMs are routinely used to assess individual domains of symptom burden, their potential value in predicting long term management within specialist spinal services remains less clear. Furthermore, there is a no clear standardized approach to PROM selection across practice (8). Exploring whether routinely collected PROMs, both individually and as a composite measure, are associated with subsequent clinical outcomes may help clarify their utility in early assessment and risk stratification. This study therefore aimed to examine the association between baseline PROM scores recorded at initial spinal surgical assessment and the predominant management pathway at five-year follow-up in patients presenting with low back pain.

Aims and Objectives

The overall aim of this study was to investigate whether baseline PROMs at first surgical assessment were associated with five-year clinical outcomes in patients with low back pain.

The specific objectives were:

6. To determine whether baseline disability, pain, psychological distress and health-related quality of life demonstrate an association with management pathways.
7. To develop an exploratory composite baseline burden score assuming equal weighting of all PROMs.
8. To compare composite burden scores between final outcome groups.
9. To explore the potential use of PROM-based stratification as a triage tool.

Methodology

This project was a retrospective observational analysis of a dataset of patients presenting to the spinal surgery service at University Hospital Wales from 2012 to 2019. The study population included only patients presenting with low back pain at their initial specialist appointment, including those with diagnoses of degenerative disc disease. Patients aged over 65 years, those with previous spinal surgery, those with structural spinal abnormalities, and those with symptoms suggestive of alternative spinal diagnoses were excluded to reduce confounding from more complex spinal pathology and prior surgical history.

Baseline PROMs were obtained from an existing dataset, including the following scores as variables: PHQ-9, GAD-7, VAS (neck/back), ODI and EQ5D-VAS. Patient age at baseline was also measured as a variable. Outcome data for each patient was collected from patients notes and referral letters on Welsh Clinical Portal. The outcome was defined as the patient's principal management pathway at five years following the patient's initial clinic visit. Final outcomes were classed into the following groups: (1) reassure and discharge, (2) conservative management, (3) spinal injections, (4) spinal surgery, and (5) referral to pain clinic.

Variables	Meaning
Age	Age at baseline
VAS	Pain Intensity score for back
EQ5D-VAS	Self-reported health status
ODI	Functional Disability score for low back pain
PHQ-9	Depression score
GAD-7	Anxiety score
Outcome Group	5-year outcome category

Table 1: Variables collected for this study

Several derived variables were created for analysis. VAS back score was converted to VAS% by multiplying by 1 and PHQ-9 and GAD-7 were converted into PHQ-9% and GAD-7% by expressing each as a percentage of its maximum possible score. ODI and EQ5D-VAS were not converted as they are already represented as percentages. This was done to improve comparability between PROMs measured on different scales. Two composite burden scores were then created: Total VAS% + ODI + PHQ-9% and Total VAS% + ODI + PHQ9% + GAD7%. EQ5D-VAS was not included in the composite scores because of many missing values.

The dataset was anonymised and then analysed using Microsoft Excel and SPSS. Descriptive statistics were used to summarise baseline PROM values across outcome groups. Because PROM data were variably distributed and outcome groups were unequal in size, Kruskal-Wallis testing was used as the principal non-parametric comparison across outcome categories. Receiver operating characteristic (ROC) analysis was used to assess the discriminatory performance of individual and composite PROM variables for clinically relevant higher-intensity outcomes. As this study used pre-existing anonymised data for service evaluation purposes, research ethics committee approval was not required.

Results

A total of 173 patients with baseline PROMs and a 5-year final outcome were recorded. Mean baseline scores across outcome groups were as follows:

Outcome Group (n)	VAS Mean (n, sd)	EQ5D-VAS Mean (n, sd)	ODI Mean (n, sd)	PHQ-9 Mean (n, sd)	GAD-7 Mean (n, sd)
1 – Discharge (17)	5.9 (17, 3.0)	70.3 (8, 24.7)	36.0 (16, 23.6)	7.8 (16, 6.8)	5.8 (16, 6.3)
2 – Conservative (81)	7.0 (78, 1.9)	54.0 (45, 22.1)	46.5 (79, 17.9)	12.0 (76, 7.2)	9.5 (76, 6.3)
3 – Injection (29)	7.2 (29, 1.7)	52.3 (18, 27.2)	47.1 (29, 18.6)	12.9 (28, 7.8)	8.7 (28, 7.4)
4 – Surgery (22)	8.1 (22, 1.5)	37.5 (10, 26.3)	57.9 (22, 19.0)	15.5 (20, 7.7)	11.3 (20, 7.1)
5 – Pain Clinic (21)	8.3 (20, 1.7)	24.8 (14, 22.2)	68.6 (21, 14.4)	22.0 (19, 4.2)	16.6 (19, 4.7)

Table 2: PROMs means by outcome group

Mean VAS Back, ODI, PHQ-9 and GAD-7 scores increased progressively from patients who were discharged to those referred to pain clinic, while mean EQ5D-VAS scores decreased across the same groups, indicating poorer self-reported health. While there is a clear mean trend across outcomes, the standard deviations show that there is also meaningful variation within each outcome group. Outcome group 5 (pain clinic) not only showed the highest mean VAS, ODI, PHQ-9 and GAD-7 scores and the lowest EQ5D-VAS scores, but also had the lowest standard deviation across these PROMs. Across all PROMs, VAS Back scores showed relatively low variability (SD 1.7-1.9) between outcome groups 2-5.

For analysis with composite burden scores, patients without PHQ-9, GAD-7, ODI or VAS scores were excluded, resulting in a refined dataset of 159 patients. To allow comparison between PROMs of differing score ranges, the percentage values of PROMs variables were used in further analysis.

Outcome	n	Mean Total VAS+ODI+PHQ9 (sd)	95% CI	Mean Total VAS+ODI+PHQ9+ GAD7 (sd)	95% CI
1	16	123.1 (70.6)	85.5-160.7	150.7 (97.1)	99.0-202.5
2	74	161.3 (51.3)	149.4-173.2	206.3 (74.8)	189.0-223.6
3	29	165.9 (51.7)	146.3-185.6	207.5 (80.8)	176.8-238.2
4	20	198.6 (47.4)	176.4-220.8	252.2 (76.5)	216.4-288.0
5	20	236.3 (30.1)	222.2-250.4	315.1 (44.9)	294.1-336.1

Table 3: Mean Composite Scores and their Confidence Intervals

The confidence intervals for the composite scores also suggest increasing separation between lower and higher outcome groups, particularly between Outcomes 1-2 and the pain clinic group. The pain clinic group demonstrated the highest mean composite burden scores and the narrowest spread relative to the other outcome categories, consistent with a more distinct high-burden baseline phenotype.

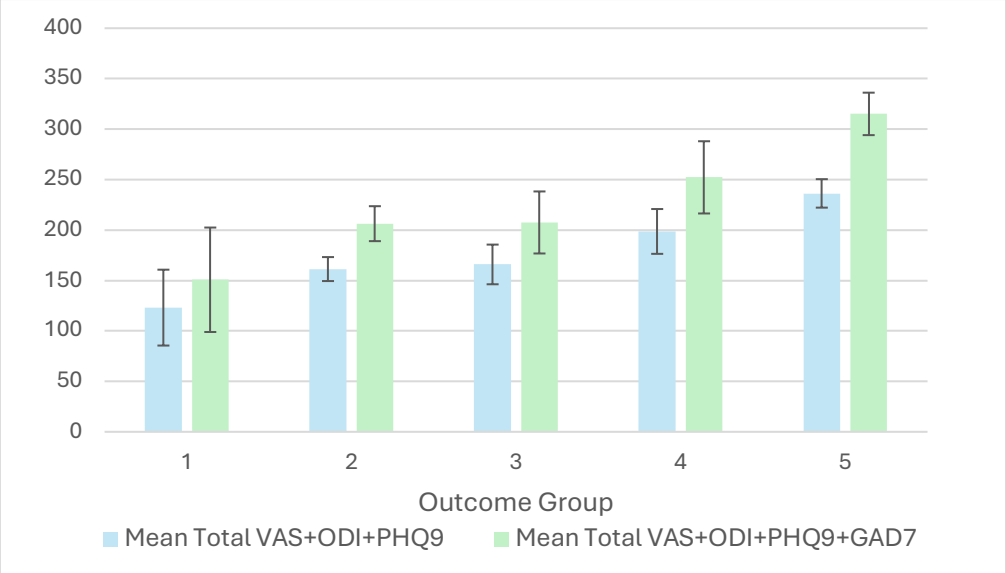


Figure 1: Mean Composite Scores (95% Ci)

Statistical Testing

One-way ANOVA and non-parametric Kruskal-Wallis tests were ran on the refined dataset. Due to unequal outcome group sizes and skewed PROMs values, the Kruskal-Wallis trend was deemed most appropriate for this dataset.

Variable	Kruskal-Wallis p value	Spearman trend with outcome	Interpretation
Age	0.175	$\rho = 0.034$, $p = 0.643$	No association
VAS%	0.00072	$\rho = 0.314$, $p = 0.000055$	Significant trend
ODI	0.00000063	$\rho = 0.415$, $p < 0.000001$	Strong trend
PHQ-9%	0.00000044	$\rho = 0.416$, $p < 0.000001$	Strong trend
GAD-7%	0.000043	$\rho = 0.319$, $p = 0.000041$	Significant trend
Total VAS+ODI+PHQ9	0.000000026	$\rho = 0.456$, $p < 0.00000001$	Strongest trend
Total VAS+ODI+PHQ9+GAD7	0.000000084	$\rho = 0.428$, $p < 0.0000001$	Very strong trend

Table 4: Statistical Tests for the variables

The dataset shows a statistically significant gradient across 5-year outcomes for pain, disability, depression and anxiety. There is no statistically significant association between age and final outcome for this dataset. The strongest trend was seen with the composite score Total VAS+ODI+PHQ9, and the trend decreased when GAD7% was added to the composite.

Predicting outcome

Receiver operating characteristic (ROC) analysis was performed to evaluate whether baseline PROM could identify patients who ultimately had higher outcome values.

Predictor	AUC
VAS%	0.731
ODI	0.830
PHQ9%	0.858
GAD7%	0.805
Total VAS+ODI+PHQ9	0.878
Total VAS+ODI+PHQ9+GAD7	0.875

Table 5: ROC analysis for predicting outcome 5 compared with outcomes 1-4

Amongst independent PROM baselines, PHQ9% was the best at predicting outcome 5. However, the three-component composite score was the best amongst all predictors. A practical threshold value for Total VAS+ODI+PHQ9 was identified at 203.5. At this threshold:

Predictor	AUC
VAS%	0.714
ODI	0.782
PHQ9%	0.755
GAD7%	0.711
Total VAS+ODI+PHQ9	0.801
Total VAS+ODI+PHQ9+GAD7	0.783

Table 6: ROC analysis for predicting outcomes 4-5 compared with outcomes 1-3

ROC analysis was repeated for a broader definition of higher outcome (outcome 4 and 5). Here, ODI was the strongest independent predictor of outcomes 4-5, but the three-component composite score was still the best predictor overall. A practical threshold of approximately 197 was identified. Table x shows the performance characteristics of the three component composite score based on the threshold scores.

Outcome comparison	Outcome 5 vs 1-4	Outcome 4-5 vs 1-3
Threshold	203.5	197
Sensitivity (%)	90	72
Specificity (%)	76	75
Positive predictive value (%)	35	49
Negative predictive value (%)	98	89

Table 7: Performance characteristics of Total VAS+ODI+PHQ

This indicates that the composite score performed particularly well for identifying patients who did not progress to the pain-clinic pathway, functioning better as a rule-out tool than a rule-in tool. Patients with scores below the threshold were unlikely to require later pain-clinic management, whereas higher scores identified increased probability of this pathway but did not reliably confirm it.

Discussion

This study found that baseline disability, depression, anxiety, pain severity and reduced perceived health-related quality of life were significantly associated with five-year clinical pathway outcomes in patients with low back pain, while age was not. The strongest predictors of poorer long-term outcome were PHQ-9 and ODI, suggesting that psychosocial and functional burden at initial assessment may help identify patients at risk of poor long-term outcome. These findings are consistent with the broader biopsychosocial understanding of low back pain described in the literature. Moreover, patients in the pain-clinic outcome group had more consistently severe baseline PROMs and poorer self-perceived health than other outcome groups. This signifies that patients referred to pain clinic are often those with complex symptoms characterised by high functional limitation and psychological distress that requires multi-disciplinary pain management.

Secondly, the data suggests that a simple composite score may be more clinically useful than considering individual PROMs in isolation. The three-component score combining VAS%, ODI and PHQ-9% out-performed each single measure as well as the composite score that included the GAD-7 score. This represents a pragmatic area of improvement for patient risk stratification that is easy to calculate and captures a multi-dimensional burden of illness.

The score appears more useful as a triage-support tool rather than a tool to help make treatment decisions. It performed well in identifying patients unlikely to receive pain-clinic or surgery/pain clinic pathways as shown by the negative predictive values. However, it was less able to distinguish between other outcome groups such as distinguishing patients requiring surgery or injections. Additionally, the ability for baseline PROMs or composite scores to predict the exact management category was limited. These are likely because treatment decisions within a specialist service are dependent on multifarious factors – imaging results, previous interventions, frailty and co-morbidity, disc prolapses and overall specialist assessment- that were not captured in this dataset.

An important consideration is that the outcome categories represent different clinical management decisions rather than a direct measure of patient recovery or treatment success. Another limitation of this study is that incomplete PROM data reduce the sample size for analysis of EQ5DVAS and composite scores, and may have introduced selection bias. This study is also limited to a single hospital, and the findings of such a study might differ in different populations and healthcare settings. Despite these limitations, the findings remain clinically meaningful and highlight potential for further study.

Conclusion

Baseline PROM burden at first surgical assessment was strongly associated with five-year clinical pathway outcome in patients with low back pain. Pain, disability, and depression were the most informative baseline domains, while age was not associated with outcome. A simple composite score combining VAS% + ODI + PHQ9% showed the strongest overall relationship with five-year pathway. However, PROMs alone were insufficient to accurately predict all outcome categories and hence, a more feasible conclusion is that baseline PROMs burden may help identify patients at risk of a more escalated pathway and may justify earlier multi-disciplinary input or psychosocial optimisation.

Appendix

Mr M J H McCarthy
Consultant Spinal Surgeon

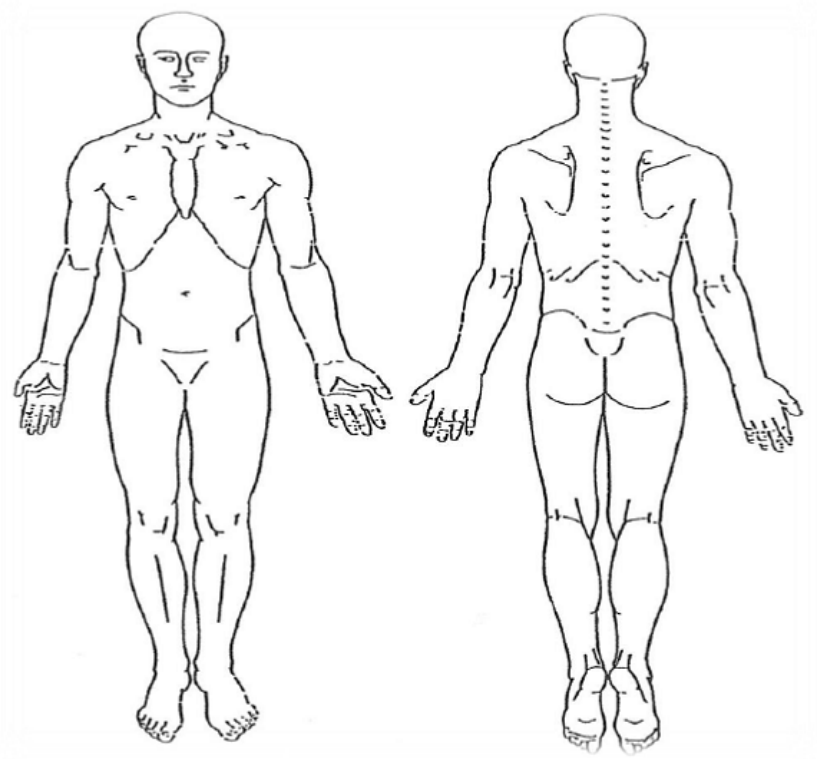
Affix Patient Label

Spinal Patient Reported Outcome Measures

This document contains a series of standard assessments that are very useful in helping us assess your spinal problem. The questions also help to determine whether or not there has been any benefit from the treatments you have received.

Todays Date:

Where is your pain / problem located? Please shade the pain / problem areas on the diagram and mark the worst affected area.



On a scale of 0 to 10, how much neck / back pain have you felt over the last month?

No pain 0 1 2 3 4 5 6 7 8 9 10 Worst Pain

On a scale of 0 to 10, how much arm / leg pain have you felt over the last month?

No pain 0 1 2 3 4 5 6 7 8 9 10 Worst Pain

EQ5D

Under each heading, please tick the ONE box that best describes your health **TODAY**:

MOBILITY
- I have no problems in walking about ❑
- I have slight problems in walking about ❑
- I have moderate problems in walking about ❑
- I have severe problems in walking about ❑
- I am unable to walk about ❑

SELF-CARE
- I have no problems washing or dressing myself ❑
- I have slight problems washing or dressing myself ❑
- I have moderate problems washing or dressing myself ❑
- I have severe problems washing or dressing myself ❑
- I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*
- I have no problems doing my usual activities ❑
- I have slight problems doing my usual activities ❑
- I have moderate problems doing my usual activities ❑
- I have severe problems doing my usual activities ❑
- I am unable to do my usual activities ❑

PAIN / DISCOMFORT
- I have no pain or discomfort ❑
- I have slight pain or discomfort ❑
- I have moderate pain or discomfort ❑
- I have severe pain or discomfort ❑
- I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION
- I am not anxious or depressed ❑
- I am slightly anxious or depressed ❑
- I am moderately anxious or depressed ❑
- I am severely anxious or depressed ❑
- I am extremely anxious or depressed ❑

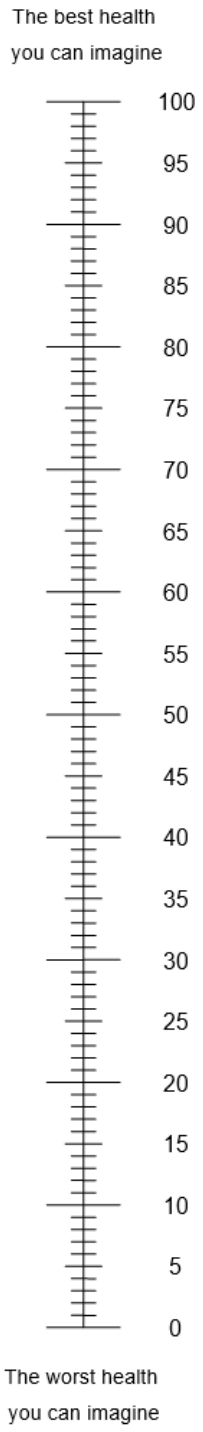
We would like to know how good or bad your health is **TODAY**.

The scale on the right is numbered from 0 to 100.

100 means the best health you can imagine.

0 means the worst health you can imagine.

Please mark an X on the scale to indicate how your health is **TODAY**.



Oswestry Disability Index (ODI) v2

These questions are designed to give us information about your **low back or leg problem**. **Please move on to the next page if you do not have a low back or leg problem.** Mark **ONE** box only in each section that **most closely describes you over the last month**. Please answer as much as possible.

Section 1 – Pain Intensity
- ☐ I have no pain at the moment.
- ☐ The pain is very mild at the moment.
- ☐ The pain is moderate at the moment.
- ☐ The pain is fairly severe at the moment.
- ☐ The pain is very severe at the moment.
- ☐ The pain is the worst imaginable at the moment.

Section 2 – Personal Care (washing, dressing, etc.)
- ☐ I can look after myself without causing extra pain.
- ☐ I can look after myself normally but it is very painful.
- ☐ It is painful to look after myself and I am slow and careful.
- ☐ I need some help but manage most of my personal care.
- ☐ I need help everyday in most aspects of self-care.
- ☐ I do not get dressed, wash with difficulty and stay in bed.

Section 3 – Lifting
- ☐ I can lift heavy weights without extra pain.
- ☐ I can lift heavy weights but it gives extra pain.
- ☐ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, e.g. on a table.
- ☐ Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
- ☐ I can lift only very light weights.
- ☐ I cannot lift or carry anything at all.

Section 4 – Walking
- ☐ Pain does not prevent me from walking any distance.
- ☐ Pain prevents me walking more than 1 mile.
- ☐ Pain prevents me walking more than ½ mile.
- ☐ Pain prevents me walking more than 100 yards.
- ☐ I can walk only with a stick or crutches.
- ☐ I am in bed most of the time and have to crawl to the toilet.

Section 5 – Sitting
- ☐ I can sit in any chair as long as I like.
- ☐ I can sit in my favourite chair as long as I like.
- ☐ Pain prevents me from sitting for more than 1 hour.
- ☐ Pain prevents me from sitting for more than ½ hour.
- ☐ Pain prevents me from sitting for more than 10 minutes.
- ☐ Pain prevents me from sitting at all.

Section 6 – Standing
- ☐ I can stand as long as I want without extra pain.
- ☐ I can stand as long as I want but it gives me extra pain.
- ☐ Pain prevents me from standing for more than 1 hour.
- ☐ Pain prevents me from standing for more than ½ hour.
- ☐ Pain prevents me from standing for more than 10 minutes.
- ☐ Pain prevents me from standing at all.

Section 7 – Sleeping
- ☐ My sleep is never disturbed by pain.
- ☐ My sleep is occasionally disturbed by pain.
- ☐ Because of pain I have less than 6 hours of sleep.
- ☐ Because of pain I have less than 4 hours of sleep.
- ☐ Because of pain I have less than 2 hours of sleep.
- ☐ Pain prevents me from sleeping at all.

Section 8 – Sex Life (if applicable)
- ☐ My sex life is normal and causes no extra pain.
- ☐ My sex life is normal but causes some extra pain.
- ☐ My sex life is nearly normal but is very painful.
- ☐ My sex life is severely restricted by pain.
- ☐ My sex life is nearly absent because of pain.
- ☐ Pain prevents any sex life at all.

Section 9 – Social Life
- ☐ My social life is normal and gives me no extra pain.
- ☐ My social life is normal but increases the degree of pain.
- ☐ Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g. sports, etc.
- ☐ Pain has restricted my social life and I do not go out as often.
- ☐ Pain has restricted my social life to my home.
- ☐ I have no social life because of pain.

Section 10 – Traveling
- ☐ I can travel anywhere without pain.
- ☐ I can travel anywhere but it gives extra pain.
- ☐ Pain is bad but I manage journeys over two hours.
- ☐ Pain restricts me to journeys of less than one hour.
- ☐ Pain restricts me to short necessary journeys less than 30 minutes.
- ☐ Pain prevents me from traveling except to receive treatment.

PHQ-9

Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Use "✔" to indicate your answer)*	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

(For office coding: Total Score _____ = ___ + ___ + ___)

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	**Somewhat difficult**	**Very difficult**	**Extremely difficult**
☐	☐	☐	☐

GAD-7

Over the last 2 weeks, how often have you been bothered by the following problems? *(Use "✔" to indicate your answer)*	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

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