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**Clinical decision rule for primary care patient with acute low back pain at risk of
developing chronic pain**

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1 **Clinical decision rule for primary care patient with acute low back pain at risk of**
2 **developing chronic pain**

3
4 **Abstract:**

5 Background Context: Primary care clinicians need to identify candidates for early interventions
6 to prevent patients with acute pain from developing chronic pain.

7 Purpose: We conducted a 2-year prospective cohort study of risk factors for the progression to
8 chronic pain and developed and internally validated a clinical decision rule (CDR) that stratifies
9 patients into low, medium and high-risk groups for chronic pain.

10 Study Design/Setting: Prospective cohort study in primary care.

11 Patient Sample: Patients with acute low back pain (LBP; ≤ 30 days duration)

12 Outcome measures: Self-reported perceived non-recovery and chronic pain.

13 Methods: Patients were surveyed at baseline, 6 months and 2 years. We conducted bivariate
14 and multivariate regression analyses of demographic, clinical and psychosocial variables for
15 chronic pain outcomes, developed a CDR and assessed its performance by calculating the
16 bootstrapped areas under the receiver operating characteristic curve (AUC) and likelihood
17 ratios. This study was supported by NIH/NCCAM grants K23 AT002298, R21 AT004467,
18 NIH/NCCAM K24 AT007827, the Research Evaluation and Allocation Committee (REAC) of the
19 University of California San Francisco, and the Mount Zion Health Fund, San Francisco. The
20 funding agencies played no role in design and conduct of the study; collection, management,
21 analysis, and interpretation of the data; and preparation, review, or approval of the manuscript.
22 The authors report no conflict of interests.

23 Results: 605 patients enrolled. 13% had chronic pain at 6 months, 19% at 2 years. An eight-item
24 CDR was most parsimonious for classifying patients into three risk levels. Bootstrapped AUC
25 was 0.76 (0.70-0.82) for the 6-month CDR. Each 10-point score increase (60-point range) was
26 associated with an odds ratio of 11.1 (10.8-11.4) for developing chronic pain. Using a $<5\%$

1 probability of chronic pain as the cutoff for low risk and a >40% probability for high risk,
2 likelihood ratios were 0.26 (0.14-0.48) and 4.4 (3.0-6.3) for these groups, respectively.

3 Conclusions: A CDR was developed that may help primary care clinicians classify patients with
4 strictly defined acute LBP into low, moderate and high-risk groups for developing chronic pain
5 and performed acceptably in 1,000 bootstrapped replications. Validation in a separate sample is
6 needed.

7

8

9 Keywords: Low back pain, chronic pain, acute pain, clinical decision rule, prediction, primary
10 care

1 INTRODUCTION

2 Although most patients presenting with an episode of acute low back pain (LBP) in primary care
3 will recover in six to eight weeks with or without medical intervention,^{1,2} those who subsequently
4 develop chronic pain suffer considerably,³ often are difficult to treat, and account for most LBP-
5 related health expenses.⁴ Primary care clinicians need decision support to identify candidates
6 for early interventions for secondary prevention of chronic pain. Previous studies have identified
7 risk factors for chronic pain, and have attempted to develop clinical decision rules for the
8 primary care setting.^{5,6} The most important are the STarT-Back developed in the UK^{7,8} and the
9 Chronic Pain Risk Screener (CPRS) developed in the US.⁹ The STarT-BACK and several
10 instruments developed in Europe (Örebro Musculoskeletal Pain Screening Questionnaire
11 (ÖMPSQ)^{10,11}, Kiel Pain Inventory and Avoidance-Endurance Questionnaire,^{12,13} and
12 Heidelberger Kurz-Fragebogen (HKF).¹⁴) have not been evaluated in the US. Other limitations
13 of the latter instruments are that they were not developed or validated in primary care patients
14 and used delayed return-to-work as chronic pain outcomes, which only captures a subset of
15 patients taking sick leave.

16 Both the STarT-BACK and CPRS have been well validated in patients shortly following an index
17 visit at a primary care office.¹⁵ However, these index visit patients included patients with a wide
18 range of LBP duration; less than half suffered from *acute* LBP. Because patients who suffer LBP
19 for more than 3 months already have a much worse prognosis, instruments that work for this
20 population may not perform as well in patients with acute LBP. Hence, clinicians need a tool that
21 only addresses the prognosis of patients with truly acute LBP.¹

22 We therefore conducted a prospective cohort study to investigate the prognosis of patients with
23 strictly defined acute LBP¹⁶, and whether we can identify early risk factors that can help primary
24 care clinicians determine a more accurate prognosis. If available such risk stratification would

1 be feasible for primary care clinics and could potentially support physicians in treatment
2 allocation decisions. We included questionnaire items representative of all risk factors known at
3 the time of the cohort's inception and set out to develop a novel clinical decision rule (CDR).

4 **METHODS**

5 Patient Selection: The Prognosis of Pain (POP) study was a 2-year longitudinal telephone
6 survey of 18-70 year old members of Kaiser Permanente, Northern California, the largest
7 integrated health plan in its region with 2.4 million adult members at the time. Acute LBP was
8 defined as back pain between the rib cage and buttocks of less than one month that was severe
9 enough to seek medical care and was not preceded by any other episodes of LBP in the past
10 year. The 1-month criterion for acuteness of pain was chosen in part for pragmatic reasons, as
11 we found that the time from scheduling a doctor's visit to being seen might be more than two
12 weeks from the date of first pain onset. Patients were included if they spoke English and had no
13 fever, history of cancer, chronic inflammatory disease, previous spine surgery, fibromyalgia,
14 chronic pain conditions, disabling psychiatric diseases, or ongoing prescriptions for narcotics
15 prior to the LBP episode. Patients with sciatica (i.e. LBP radiating below the knee), were not
16 excluded.

17 A computer program screened electronic medical records to identify patients seen the day
18 before for LBP, and a written invitation was sent by mail to join the study. This invitation offered
19 a \$20 gift certificate and did not reveal the inclusion criterion of pain duration; it therefore
20 prioritized minimization of false reporting over larger numbers of ineligible respondents.
21 Respondents were interviewed over the phone at baseline and 6 months. For the 2-year follow-
22 up, participants, when reached (maximum of 3 attempts), were given a choice between a phone
23 interview and an internet-based survey using SurveyGizmo (<http://www.surveygizmo.com>).¹⁷
24 The study was approved by the Institutional Review Boards of the University of California, San
25 Francisco and Kaiser Permanente. Two follow-up survey time points at 6 months and 2 years

1 allowed us to determine consistency of predictors over time. The surveys were conducted
2 between February 2008 and November 2010.

3 Baseline Measures: In addition to the typical demographic items (age, sex, ethnicity, foreign
4 born, education and income) we asked about marital status, employment status, heavy or
5 monotonous work, job satisfaction, and smoking. The following clinical parameters were
6 assessed at baseline: duration of current episode; history of prior episodes; pain-free interval
7 before current episode; pain location(s); sciatica; pain intensity by 11-point numeric rating scale
8 (NRS) as average, worst, and most tolerable pain or average bothersomeness; McGill Pain
9 Questionnaire;¹⁸ Roland-Morris Disability Questionnaire (RMDQ);¹⁹ and days on sick leave and
10 of reduced daily activities. The complete 24-item ÖMPSQ,¹¹ 10-item HKF¹⁴ and the 4-item
11 Perceived Stress Scale (PSS-4)²⁰ were included. Additional psychological predictor variables
12 were selected from validated instruments according to strong factor loadings and face validity
13 (Table 1).

14 To avoid overextensive participant burden from lengthy questionnaires we limited the survey to
15 selected items expected to perform reasonably well when a reduced item set was needed.²¹ In
16 addition to the psychological items in ÖMPSQ and HKF, we included another fear-avoidance
17 beliefs item from the Fear-Avoidance Beliefs Questionnaire (FABQ),²² another catastrophizing
18 item from the Coping Strategies Questionnaire (CSQ)²¹ and two from the Pain Catastrophizing
19 Scale (PCS)²³. As additional coping style items, we included ignoring and positive distracting
20 using single items from the CSQ, seeking instrumental and emotional support using four items
21 from CPCI²⁴⁻²⁶ and KPI²⁷⁻²⁹ and denial of stress using two items from Brief-COPE.³⁰ The 2-item
22 version of the self-efficacy for pain subscale²¹ from Arthritis Self-Efficacy Scale was also
23 included. Anxiety and depression were assessed by multiple ÖMPSQ and HKF items, and
24 positive affect by one item from the CES-D³¹ (Table 1).

1 Follow-Up Outcome Measures: No gold standard or international consensus exists regarding
2 the outcome definition for chronic LBP in cohort studies. Following recommendations from
3 expert LBP epidemiologists in the Netherlands,³² we applied a previously published primary
4 outcome measure that combines a lack of perceived recovery (less than “much improved” on a
5 6-point Likert Perceived Recovery Scale)³³ with current pain intensity of 3 or more on 0-10
6 Numeric Rating Scale.^{32,34} Its accuracy was assessed for this population sample in a prior
7 study.³⁴ In an exploratory fashion we also used a Grade 2 or higher chronic pain level
8 according to the validated Graded Chronic Pain Scale (GCPS) by von Korff (this instrument
9 yields a 4-grade-level chronic pain score as a function of pain intensity and pain-related
10 disability for the past 6 months), but only for 2-year follow-up analyses, as it includes recall of
11 the acute phase LBP at onset..⁹

12 Statistical Analyses: All analyses were conducted using Stata.³⁵ We proceeded in a series of
13 analytic steps from bivariate to multivariate analysis of predictor variables, data and consensus-
14 driven decisions for scoring and cut-off, and the calculation of areas under the receiver
15 operating characteristic curve (AUC) and likelihood ratios for the resulting CDR.

16 Step 1 was raw bivariate logistic regression analysis of predictor variables for our primary
17 outcome at 6 months and 2 years. We used individual items assessed at baseline as predictor
18 variables. In addition, we compared the odds ratios for predictors of the primary 2-year outcome
19 with those of the 2-year GCPS. We selected variables that were associated with our outcome at
20 $p < 0.1$ consistently at both time points for inclusion in Step 2.

21 Step 2 used the variables selected in Step 1 in multivariate logistic regression models and
22 proceeded to stepwise backward elimination of the least supported variables. In addition, we
23 analyzed the correlations between predictor variables and eliminated collinear redundant

1 variables ($r > .35$) to arrive at the most parsimonious sets, separately for the 6-month and the 2-
2 year predictions.

3 Step 3 used the beta-coefficients of each of the final multivariable regression models (one
4 predicting 6-month outcomes, one predicting 2-year outcomes), multiplied by 10 and rounded to
5 the closest half integer, to create two scoring rules. The performance of each scoring rule was
6 assessed by bootstrapped analysis with 1,000 replications and calculation of the AUROC and
7 associated 95% confidence intervals (CIs).

8 Step 4 determined the number of patients who were positive or negative on our outcome
9 measures for each point score. We then empirically identified reasonable cutoffs for low,
10 moderate and high-risk groups based on discussion with content experts. A minimal risk group
11 was defined as patients that have a less than 5% chance of developing chronic pain at 6
12 months and less than 10% at 2 years. Conversely, if a patient has a risk of 40% or more of
13 developing chronic pain at either 6 months or 2 years, a clinician likely would consider closer
14 follow-up office appointments and potentially more intensive early interventions to prevent
15 chronic pain, and these were defined as a high-risk group. In the middle range, less intensive
16 interventions may suffice until further follow-up assessments. By simple inspection of the table
17 with the two patient groups being either positive or negative on the outcome for each score
18 point, we determined the cut-off for the summary score and assessed the proportion of patients
19 in each risk group.

20 Step 5: We calculated likelihood ratios with 95% confidence intervals (CI's) for the classification
21 into these three risk groups by our CDR, according to the formula by Simel and colleagues.³⁶

22

23

1 RESULTS

2 The Prognosis of Pain (POP) study enrolled 605 eligible members of Kaiser Permanente,
3 Northern California (KPNC) from February 2008 to March 2009 (Figure 1). This represents 25%
4 of the 2,454 respondents to invitations mailed to 42,650 patients who were seen for any kind of
5 LBP in clinics of the health plan during the twelve months of recruitment. Overall, 521
6 participants (86%) responded at 6 months and 443 (73%) at the 2-year follow-up. The average
7 age was 50.5 (± 12.6) years, 56% were female, 65% Caucasian-American, 18% foreign born,
8 61% had a college degree, and 59% were employed full-time (for further details, see ¹⁶) The
9 sample represented the socioeconomic and ethnic diversity of primary care patients in the San
10 Francisco Bay Area.³⁷ These patients sought medical care for pain of considerable intensity
11 (average in past week 5.6 ± 1.8 ; 2.6 ± 1.8 when most tolerable; 8.6 ± 1.4 when worst; 11-point
12 NRS), bothersomeness (6.5 ± 2.3) and disability (mean Roland-Morris score 15.8 ± 4.7). The
13 median duration of pain at baseline interview was 14 days; 8% had been on sick leave; and
14 27% had some sciatic pain to below the knee during this episode, 10% at the time of the
15 interview. The final sample included 510 patients with complete 6-month follow-up data and 443
16 patients with complete 2-year data. Using our primary combined outcome criterion,³⁴ 13% of the
17 patients (95% confidence interval [CI], 10%–16%) experienced persistent or recurrent pain at 6
18 months and 19% (CI, 15%–22%) at 2 years after pain onset.¹⁶ Numerous patients who self-
19 reported as much improved at 6 months felt worse at 2 years (details in ¹⁶). Participants lost to
20 follow-up were slightly younger and included slightly more females but did not differ in those
21 variables that were included in the CDR.

22 Bivariate analyses (analysis Step 1)

23 All variable had <2% missing responses and were used without substitution. The following 12
24 variables had odds ratios at significance levels of $p < 0.1$ for our primary outcome at both time

1 points, five were protective and seven were predictive of chronic pain. Protective were:
2 completed college, ability to walk for 1 hour, ability to sleep tonight, coping by TV or music, and
3 self-efficacy in ability to decrease pain; predictive were additional pain in upper back, higher
4 level of least pain since onset, smoking, catastrophizing (2 items), expectancy of chronicity and
5 the need to holding onto something when getting off the sofa. Additional variables that satisfied
6 at least one of our outcome criteria and the GCPS were perceived stress, coping by ignoring,
7 coping by prayer, belief that activity worsens pain, anxiety or tension, RMDQ items 2, 5, 18, 22,
8 yoga at baseline, McGill overall pain intensity, worst pain since onset, sciatica since onset,
9 African-American ethnicity, and being separated or widowed. No significant bivariate
10 associations consistent across at least 2 outcome measures were found for age, sex, income
11 level, born outside the US, duration of pain, sciatica at time of interview, average pain intensity
12 since onset, pain level willing to tolerate, cut-down activity days, days in bed, days lost from
13 work, retirement, job satisfaction, other RMDQ items, positive affect, enjoyment, positive
14 thinking, depression, ability to do light work or household chores for 1 hour, heavy or
15 monotonous work, multiple other pain-avoidance and catastrophizing items, coping by seeking a
16 friend or talking with family member, staying active, detachment, reinterpretation, challenge
17 appraisal, asking for instrumental or emotional support, other perceived stress or stress denial
18 items.

19 Multivariate Analyses (analysis Step 2)

20 After backward elimination, eight variables remained for the 6-month prediction model and eight
21 slightly different variables for the 2-year model. They are listed in Table 2 and discussed below.
22 When using only these eight variables for each model, the regression models explained 16% (6-
23 month) and 10% (2-year) of the respective outcome variance. Using Grade 2 or higher of the
24 GCPS as outcome (instead of our primary outcome combining perceived recovery with pain

1 intensity) at 2 years provided similar results (not shown) for included parameters, AUC, and
2 explained variance.

3 Point Score Creation (analysis Step 3)

4 Table 3 shows the beta-coefficients and odds ratios for each model. Multiplying the beta
5 coefficients by 10 and rounding to the closest half integer created the 6-month and 2-year
6 scoring rules. This method gives differential weights to individual predictors according to their
7 beta-coefficients in the multivariate model. Note that multipliers for dichotomous items are
8 based on values of 0 or 1, whereas continuous variables are multiplied by values between 0 and
9 10. The 6-month scoring rule ranged from -25 to 34 points. Applied to our sample, the AUC was
10 0.78 (95% CI 0.72-0.84; Figure 1). Applying the bootstrap procedure for 1,000 replications, a
11 10-point increase in the 60-point score was associated with a 11.1 odds ratio (95% CI 10.8-
12 11.4; $p < 0.001$) for having chronic pain 6 months after baseline. After bootstrapping, the AUC
13 was slightly lower: 0.76 (95% CI 0.70-0.82).

14 Using the same process for creating a scoring rule for the eight strongest predictor variables at
15 the 2-year outcome, we obtained summary scores between -18 and 28.5. Applied to our sample
16 at the 2-year follow-up, the AUC was 0.70 (95% CI 0.64-0.76; bootstrapped 0.69; 0.62-0.75).

17 Applying the bootstrap procedure for 1,000 replications, a 10-point increase in the score was
18 associated with a 11.1 odds ratio (95% CI 10.7-11.5; $p < 0.001$) for having chronic pain 2 years
19 after baseline.

20 Selection of Cutpoints (analysis Step 4)

21 After inspection of the outcomes table for each rule, we identified optimal score cut-offs for
22 creating the three clinically-useful risk groups at 6 months and 2 years and assessed the
23 proportion of patients in each risk group. The results are shown in Table 4.

1 Following a discussion among clinical colleagues, we assumed that a score with a predictive
2 value of or near 5% would be a good cut-off for the lowest risk group, and that a 40% predictive
3 value would be an appropriate cut-off for recommending further assessment and therapeutic
4 measures. Applying these criteria to the 6-month prediction, score cutoffs were less than -4 for
5 low-risk and above +7 for high-risk groups. The low risk group included 47% of all patients, the
6 mid-range risk group 38%, and the high-risk group 15%. The resulting proportions of chronic
7 pain patients in the three risk groups were 3.8%, 14.1% and 39.7%, respectively.

8 Applying the 2-year decision rule in the 2-year follow-up dataset, we obtained scores between -
9 18 and 28.5 and found that relatively low scores had a higher than 5% risk of developing chronic
10 pain. We, therefore, chose a 10% cutoff for the low-risk group, maintained the 40% cutoff for the
11 high-risk classification, and thus classified 49% as low risk at a score of ≤ 1 , 36% as mid-level
12 risk at scores of >1 and <9 , and 15% as high risk with scores of ≥ 9 .

13 Likelihood ratios (Analysis Step 5)

14 Likelihood ratios for correctly classifying patient into low, medium, and high-risk categories were
15 0.26 (95% CI 0.14-0.48), 1.08 (0.79-1.5), and 4.35 (3.0-6.3) at six months and 0.50 (0.34-0.72),
16 1.12 (0.82-1.52), and 3.14 (2.06-4.78), respectively, at 2 years (Table 4).

17

18 **DISCUSSION**

19 To the best of our knowledge, this is the first attempt to develop a clinical decision rule (CDR)
20 for the prediction of chronic LBP among patients with strictly defined *acute* LBP of less than four
21 weeks duration in the US. A variety of methods exists for developing such rules.^{38,39} This CDR
22 was developed using multivariable logistic regression to help primary care clinicians decide
23 whether a patient who presents with a new episode of non-specific LBP with or without sciatica

1 is at risk of developing chronic pain and may warrant closer follow-up and potentially a more
2 intensive therapeutic intervention. The CDR is limited to patients who had no LBP in the
3 previous year and never had spine surgery. Prior CDRs were developed and validated in
4 patients with LBP of *any* duration; a majority of these had pain for more than 3 months and
5 already had a higher pre-test probability for persistent pain. When a CDR constructed of items
6 that were identical or highly similar to the 9-item STarT-Back from the UK was applied in our
7 sample, its performance was found unsatisfactory in patients with truly *acute* LBP.⁴⁰

8 The variables included in the new CDRs reflect risk factors that have been found in prior
9 studies: College education was protective and the only significant demographic predictor.⁴¹
10 Pain spreading to the upper back was a consistent clinical risk factor. Sciatica⁴² and difficulty
11 sleeping¹⁰ predicted poor outcomes at 6 months, the inability to walk for 1 hour¹⁰ poor outcomes
12 at 2 years. At both follow-ups, a coping style of watching TV or listening to music⁴³ was
13 protective, whereas catastrophizing⁴⁴ and coping with pain by ignoring¹³ were psychological risk
14 factors. Five of eight predictor variables were identical for outcomes at our 2 follow-up time
15 points, three were different. The expectancy of pain to persist was maladaptive at 6 months,^{45,46}
16 while a low willingness to tolerate pain¹⁴ and perceived stress^{41,42} increased risk at 2 years. We
17 do not have an explanation for the difference.

18 The observed likelihood ratios for the 6-month CDR of 0.26 (95% CI 0.14-0.48) for the low-risk
19 and 4.4 (95% CI 3.0-6.3) for the high-risk classifications are moderately accurate.⁴⁷ The rule is
20 likely to be clinically useful, as almost half of all patients fell into a low-risk group that was
21 unlikely to develop chronic pain at 6 months. Approximately 15% of patients were classified as
22 high-risk and may warrant more intensive interventions. The remaining 38% of mid-level risk
23 patients, assessed at an average of 2 weeks (range 2-30 days) after pain onset, had a mean
24 risk of 14% for developing chronic pain. They may warrant closer oversight by their primary care

1 clinician than the low-risk group, but it may be justified to suggest waiting a bit longer before
2 prescribing more intense and costly interventions.

3 We previously reported for this cohort that due to the recurring course of cLBP, individuals with
4 persistent pain at 6 months were not identical to those at 2 years, and that the proportion of
5 persistent pain patients had increased between the two follow-up time points.¹⁶ Creating a 2-
6 year decision rule with the 2-year follow-up made it impossible to use the 5% criterion as cutoff
7 for low risk classification. We therefore used a 10% criterion but maintained the 40% risk for the
8 high-risk classification cutoff. The results show that the prediction of the longer-term outcome is
9 challenging in patients with strictly defined acute LBP. Longer-term predictions over years
10 appear to be less precise than the prediction for 6 months, which is not surprising as the
11 outcome is much further into the future than for the 6-month CDR.

12 A scoring method that assigns weights to individual predictor variables may best be used by a
13 programmed risk classification calculator rather than by hand but it increases the precision of
14 the prediction.³⁸ Whereas the 6-month CDR maybe most useful for the primary care clinical
15 practice, the 2-year CDR maybe useful for long-term clinical research. Five of the predictive
16 items for the 6-month rule are identical with those for the 2-year rule. For validation of the rules
17 in a separate sample and in particular for clinical application we would recommend assessing all
18 eleven items, and then applying the relevant 8 items for 6-month predictions and the slightly
19 different set of 8 items for a 2-year prediction.

20 The main limitation of our study is that we have not assessed the decision rules' performance in
21 a separate validation sample. The observed variance in these predictor item scores among
22 study participants with acute LBP early into their episode is rather large and reduces their
23 predictive power. Moreover, as shown for this cohort, a high recurrence rate leads to different
24 individuals having persistent pain at different time points.¹⁶ This variance creates a challenge for

1 creating a rule that performs strongly with patients where it is most needed, early in the course
2 of a new episode of LBP.

3 A second limitation is that we included only questionnaire items that were known to be
4 potentially predictive at the time of the study's implementation. Somatization,⁴⁸ reduced levels of
5 body awareness,⁴⁹ and potentially many others may be further parameters of predictive value
6 and were not included in our questionnaire. However, we included a wide range of
7 demographic, clinical and psychological predictor variables carefully chosen according to the
8 best knowledge of the time.

9 A third limitation is that we relied on diagnostic codes from electronic medical records created by
10 primary care providers and patient self-report. It is possible that clinical findings that indicate a more
11 severe baseline condition, such as positive signs for spinal nerve compression or spinal claudication from
12 spinal stenosis, can be identified as important risk factors for chronic pain at the very first onset of LBP
13 by clinical exam and imaging studies. However, current clinical guidelines do not recommend imaging in
14 the first weeks after new-onset LBP in patients who most likely would not need an immediate referral to
15 a spine surgeon. Future studies would benefit from clinical exams at study entrance.

16 A fourth potential limitation is that the study population did not include uninsured patients; only
17 3% reported annual household incomes below \$25,000. However, income level was not
18 predictive of the outcome.

19

20 **CONCLUSION:**

21 Despite these limitations, we conclude that our study provides a clinical decision rule that is
22 urgently needed for one of the most frequent and most costly conditions in primary care.⁵⁰ It
23 contains 8 items for the 6-month and 8 items for the 2-year risk classification (5 are common to

- 1 both) into 3 levels of risk for developing chronic pain in patients presenting in primary care with
- 2 a new-onset episode of strictly defined acute low back pain. The next step is to prospectively
- 3 validate this tool in an independent population.

ACCEPTED MANUSCRIPT

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27

28

1 Table 1: Prediction Items

2

3 Numbers in parenthesis refer to item numbers in instruments. L: Linton's ÖMPSQ¹¹; H: Heidelberger Kurzfragebogen^{14,51}

4

5 Clinical questions related to LBP

6	When did your pain start? (L7)	Days
7	Did it ever go below the knee?	y/n
8	Does it today go below the knee most of the time?	y/n
9	How would you rate the <i>average</i> (H5) pain you have had during the past week? (L8)	0-10
10	How would you rate the pain you have had during the past week when it was	
11	most tolerable? (H6) ("...the pain you had since it began?" if answer to L7 is <1 week)	0-10
12	How much pain would you be willing to tolerate and still consider the therapy successful? (H7)	0-10
13	Are you on sick leave because of pain?	y/n
14	If yes: How many days? (L5)	Days
15	Have you been on sick leave before for back pain?	y/n
16	On how many days during the past week did back or leg pain (sciatica) cause you to	
17	cut down for more than half of the day on things you usually do?	Days
18	On how many days during the past week did back or leg pain (sciatica) cause you to	
19	stay in bed for more than half the day?	Days
20	On how many days during the past week did back or leg pain (sciatica) cause you to	
21	lose days from work or school for more than half the day?	Days
22	Do you have pain in other parts of your body in addition to your back pain? (H4)	y/n
23	Do you have pain in the <input type="checkbox"/> neck <input type="checkbox"/> shoulders <input type="checkbox"/> upper back	
24		
25	<u>McGill Pain Questionnaire</u> ¹⁸	
26	<u>Roland Morris Disability Questionnaire (RMDQ)</u> ⁵² for function or disability	0-24
27		
28	Do you smoke?	y/n
29	If yes: More than 10 cigarettes per day?	y/n
30		
31	<u>ÖMPSQ and HKF-R10 items</u> ^{11,51,53}	
32	Is your work heavy or monotonous? (L4)	0-10
33	Based on all the things you do to cope or deal with your pain, on an average day,	
34	how much are you able to decrease it? (L11)	0-10
35	I can do light work for an hour. (L12)	0-10
36	I can walk for an hour (L13)	0-10
37	I can do ordinary household chores (L14)	0-10
38	I can do the weekly shopping (L15)	0-10
39	I can sleep at night (L16)	0-10
40	How tense or anxious have you felt in the past week? (L17)	0-10
41	How much have you been bothered by feeling down or depressed in the past week? (L18/H10a)	0-10
42	Did you cry a lot or feel like crying in the past week? (H10b)	0-10
43	I still enjoy doing things I liked before (H10e)	0-10
44	In your view, how large is the risk that your current pain may become persistent	
45	(may not go away)? (L19)	0-10
46	In your estimation, what are the chances that you will be working in 6 months? (L20)	0-10
47	If you take into consideration your work routines, management, salary, promotion	
48	possibilities, and work mates, how satisfied are you with your job? (L21)	0-10
49	Physical activities make my pain worse (L22)	0-10
50	In your view from past experience, does massage bring pain relief? (H8)	y/n/dk
51	An increase in pain is an indication that I should stop what I am doing until the pain is decreasing (L23)	0-10
52	I should not do my normal work with my present pain (L24)	0-10
53		

1	If you were aware of pain during the last week, how often did you have the following thoughts and feelings?(H9)	
2	g I cannot stand it any longer!	0-10
3	h I wonder whether I have the same bad disease as...	0-10
4	m How much longer do I have to endure this pain?	0-10
5	n I wonder whether there is a bad disease behind all of this pain?	0-10
6		
7	<u>2-item Version of Coping Strategies Questionnaire (CSQ-2i)</u> ²¹	
8	Parameters: diverting attention (1 mental positive thinking); reinterpreting pain sensations + detachment (2, 9);	
9	catastrophizing (3 magnification); ignoring sensations (4, 11); praying (5); coping self-statements (6, 13 challenge	
10	appraisal, endurance); increased behavioral activity (7, 14 active/passive distraction).	
11	“People who experience pain have developed a number of ways to deal with their pain. When you feel pain, how	
12	much do you do the following:	
13	1. I think of things I enjoy doing	0-10
14	2. I just think of it as some other sensation, such as numbness	0-10
15	3. It is terrible and I feel it is never going to get any better	0-10
16	4. I don’t pay any attention to it	0-10
17	5. I pray for the pain to stop	0-10
18	6. I tell myself I can’t let the pain stand in the way of what I have to do	0-10
19	7. I do something active, like household chores or projects	0-10
20	9. I pretend it is not a part of me	0-10
21	11. I ignore it	0-10
22	13. I see it as a challenge and don’t let it bother me	0-10
23	14. I do something I enjoy, such as watching TV or listening to music	0-10
24		
25	<u>More coping items from CPCi</u> ²⁵ on “asking for assistance” (42); “seeking social support” (6); CRSS/KPI ^{28,54} (68)	
26	(introduction as in CSQ)	
27	CPCi 42. I ask for help in carrying, lifting or pushing something	0-10
28	CPCi 6. I make arrangements to see a friend or family member	0-10
29	KPI 68. I have somebody console me	0-10
30	KPI 26+66. I talk with my partner or family	0-10
31		
32	<u>Selected PCS-items</u> ²³ for catastrophizing: magnification (13), rumination (9), and helplessness (2)	
33	“If you were aware of pain during the last week, how often did you have the following thoughts and feelings?”	
34	13) I wonder whether something serious may happen	0-10
35	9) I can’t seem to keep the pain out of my mind	0-10
36	2) I feel I can’t go on	0-10
37		
38	<u>Two work-related fear avoidance items from FABQ</u> ²² :	
39	3) Physical activity such as bending, lifting, walking or driving might harm my back	0-10
40	11) My normal work might harm my back	0-10
41		
42	<u>2-item version of self-efficacy for pain subscale</u> ²¹ from Arthritis Self-Efficacy Scale (ASES)	
43	As of now, how certain are you that you can decrease your pain quite a bit?	0-10
44	As of now, how certain are you that you can continue most of your daily activities?	0-10
45		
46	<u>Perceived Stress Scale</u> (4-item version PSS-4) ²⁰	
47		
48		
49		

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1 Table 2: Items used in the 6 month and 2 year risk scores

2

Item	Response	6-month model	2-year model
Did your pain ever go below the knee during this episode of back pain?	Y/N	X	
Do you have additional pain in the upper back?	Y/N	X	X
How would you rate the pain you have had during the past week when it was most tolerable? ¹	0-10		X
Can you sleep at night? ^{*2}	0-10	X	
Can you walk for an hour? ^{*2}	0-10		X
In your view, how large is the risk that your current pain may become persistent (may not go away)? ²	0-10	X	
You think it is terrible and you feel it is never going to get any better ^{**3}	0-10	X	X
When you feel pain you ignore it ^{**3}	0-10	X	X
You do something you enjoy, such as watching TV or listening to music ^{**3}	0-10	X	X
In the last month, how often have you felt confident about your ability to handle your personal problems? ^{****4}	0-10		X
Did you complete college education (BS, BA)?	Y/N	X	X

3

4 Item Stems:

5 * "Could you please answer with a number on a scale from 0 - 10? The 0 means "I can NEVER do this
6 because of pain" and the 10 means "I can ALWAYS do this without pain being a problem."

7 ** "When you feel back pain, how much do you do the following, where a 0 indicates you never do that
8 and a 10 indicates you always do it when you feel back pain:"

9 *** "The next question asks about your life in general, and about stress you have, not only from your back
10 pain, but also stress from other aspects of your life including family, relationships, work, health etc. We
11 would like for you to tell us about your feelings and thoughts during the last month. Again, use the scale
12 from 0 to 10, where 0 is never, and 10 is always, and tell us how often you felt or thought a certain way."

13

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1 Table 3. Odds Ratios and β -Coefficients for Multivariate Regression Model for Predicting Chronic Pain at 6 Months and 2 Years and
 2 Corresponding Point Score.

3

Parameter	6-month prediction model			2-year prediction model		
	β -Coefficient	OR 6-mo (95% CI)	Point Multiplier	β -Coefficient	OR 2-y (95% CI)	Point Multiplier
College Education [y/n]	-.47 (-1.05-.10)	.62 (.35-1.10)	-5	-.29 (-.83-.24)	.75 (.44-1.27)	-3
Coping with TV and Music [0-10]	-.11 (-.20--.02)	.90 (.82-.98)	-1	-.11 (-.20--.03)	.89 (.82-.97)	-1
Ability to Sleep [0-10]	-.09 (-.18-.01)	.92 (.84-1.01)	-1			
Ability to Walk 1 hour [y/n]				-.05 (-.11-.02)	.95 (.89-1.02)	-5
Pain in Upper Back [y/n]	1.80 (1.09-2.51)	6.06 (2.98-12.31)	18	.65 (-.12-1.42)	1.92 (.89-4.13)	6.5
Pain Below Knee [y/n]	.59 (-.01-1.19)	1.80 (.99-3.27)	6			
Pain Willing to Tolerate [0-10]				.16 (.00-.31)	1.17 (1.00-1.36)	1.5
Expectancy of Chronic Pain [0-10]	.12 (.01-.24)	1.13 (1.01-1.27)	1			
Catastrophizing [0-10]	.11 (-.01-.22)	1.12 (1.01-1.24)	1	.08 (-.01-.17)	1.08 (.99-1.19)	1
Coping by Ignoring Pain [0-10]	.10 (.01-.19)	1.11 (1.01-1.21)	1	.15 (.06-.23)	1.16 (1.06-1.26)	1.5
Perceived Stress 4 [0-10]				.12 (.02-.21)	1.12 (1.02-1.24)	1

4

1 Table 4: Proportion of Patients with Chronic Pain in Each Risk Group and Likelihood Ratios for Correct Risk Classification.

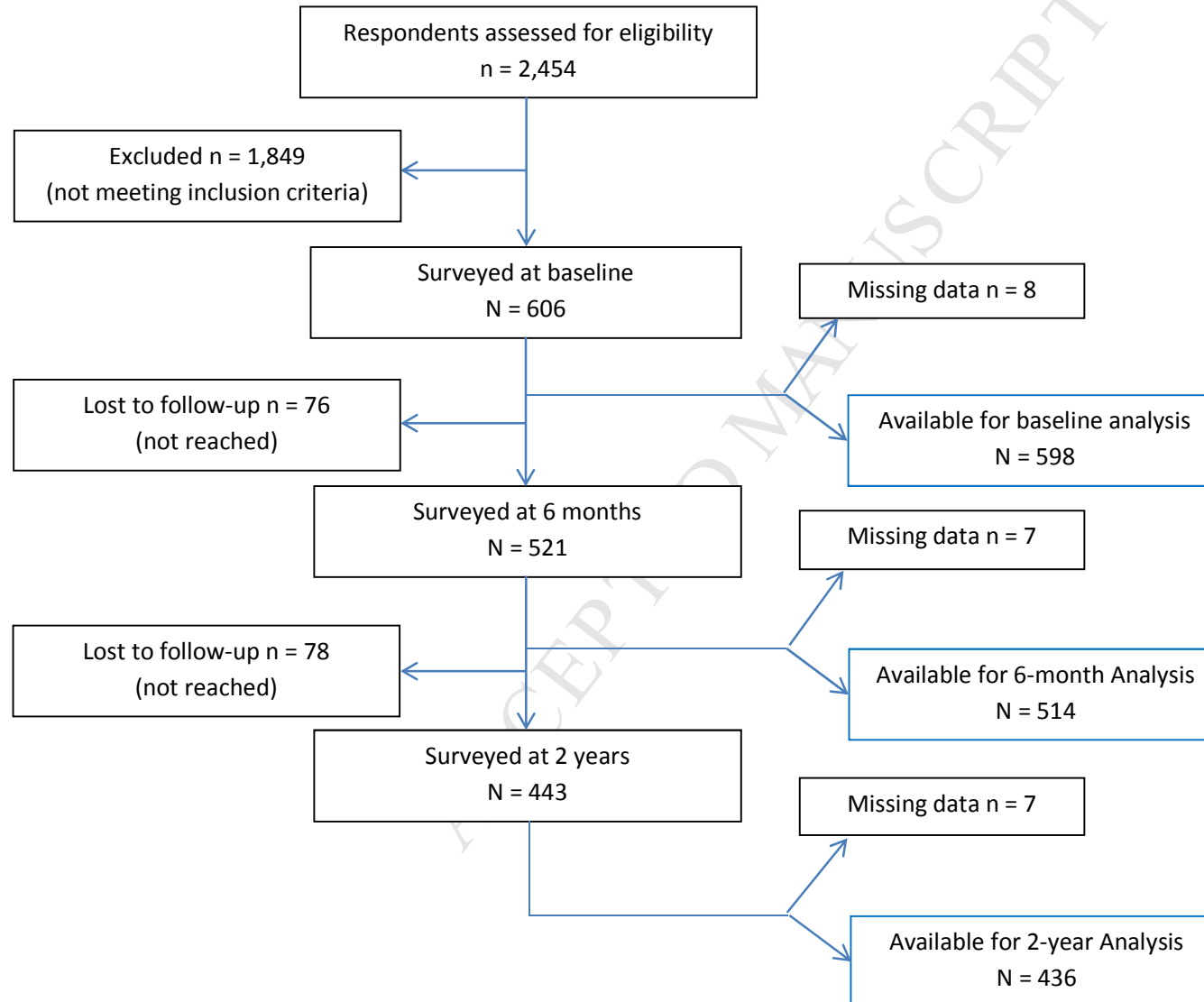
Risk group (total <i>N</i>)	Number of Patients		Percentage with chronic back pain (95% CI)	Likelihood ratio (95% CI)
	with chronic back pain	without chronic back pain		
6 month model (509)	67	442		
Low risk (score < - 4)	9	230	3.8 (1.7 – 7.0)	0.26 (0.14 – 0.48)
Moderate risk (score -4 to 7)	27	165	14.1 (9.5 – 19.8)	1.1 (0.79 – 1.5)
High risk (score ≥8)	31	47	39.7 (28.8 – 51.5)	4.4 (3.0 – 6.3)
2 year model (440)	82	358		
Low risk (score < - 4)	22	194	10.1% (6.49-15.0)	0.50 (0.34-0.72)
Moderate risk (score -4 to 7)	32	125	20.4% (14.4-27.5)	1.12 (0.82-1.52)
High risk (score ≥8)	28	39	41.8% (29.8-54.5)	3.14 (2.06-4.78)

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1 Figure 1: Flow Diagram

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