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## A clinical return-to-work rule for patients with back pain

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### Abstract

Since the 1950s, back pain has taken on the proportions of a veritable epidemic, counting now among the 5 most frequent reasons for visits to physicians' offices in North America<sup>1,2,3</sup> and ranking sixth among health problems generating the highest direct medical costs.<sup>4</sup> Because of its high incidence and associated expense, effective intervention for back pain has great potential for improving population health and for freeing up extensive societal resources.

So-called red flags to identify pain that is specific (i.e., pain in the back originating from tumours, fractures, infections, cauda equina syndrome, visceral pain and systemic disease)<sup>5</sup> account for about 3% of all cases of back pain.<sup>6</sup> The overwhelming majority of back-pain problems are thus nonspecific. One important feature of nonspecific back pain among workers is that a small proportion of cases (< 10%) accounts for most of the costs (> 70%).<sup>7,8,9,10,11,12,13,14</sup> This fact has led investigators to focus on the early identification of patients who are at higher risk of disability, so that specialized interventions can be provided earlier, whereas other patients can be expected to recover with conservative care.<sup>9,15,16,17,18,19,20,21,22,23,24,25</sup> Although this goal has become much sought-after in back-pain research, most available studies in this area have 3 methodological problems:

- Potential predictors are often limited to administrative or clinical data, whereas it is clear that back pain is a multidimensional health problem.
- The outcome variable is most often a 1-point dichotomous measure of return to work, time off work or duration of compensation, although some authors have warned against the use of first return to work as a measure of recovery. Baldwin and colleagues,<sup>26</sup> for instance, point out that first return to work is frequently followed by recurrences of work absence.

- Most published prediction rules developed for back pain have not been successfully validated on any additional samples of patients.

Our study aimed to build a simple predictive tool that could be used by primary care physicians to identify workers with nonspecific back pain who are at higher risk of long-term adverse occupational outcomes, and then to validate this tool on a fresh sample of subjects.

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## Methods

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From 1998 though 2002, we conducted a prospective cohort study called the RAMS-Prognosis Study (RAMS stands for *recherche sur les affections musculo-squelettiques*), which had a qualitative and a quantitative phase. The study was approved annually by the ethics committees of the participating hospitals.

In the first phase, 2 focus groups composed of people who have had severe back pain were held in November and December, 1998. The focus groups enriched the list of potential predictors ([Appendix 1](#))<sup>10,27</sup> to be investigated quantitatively in the interview-based second phase. The variables they identified were added to a list of those collected from the existing literature, to document as many potential predictors as possible.

Subjects for the second phase were recruited in 7 primary care settings of the Quebec City area: 4 emergency departments and 3 family medicine units, all having medical teaching responsibilities. Subjects of interest were adult workers aged 18–64 years who consulted for back pain, whatever its character or duration, between June 1999 and September 2000. Patients were eligible if the back pain was nonspecific and had caused them to be absent from their regular job for at least 1 day. Excluded were patients with any other condition that could affect their work capacity (pregnancy, for example, or a serious comorbidity) and those whose pain was located in the cervical spine only or had a specific cause.

Lists of potential subjects at each site were submitted weekly. A medical archivist telephoned these patients to request their participation in the study; those who agreed and were eligible were mailed an informed consent form to sign and return.

Participants were telephoned by trained interviewers for a baseline interview at around 3 weeks after their medical consultation, with repeated measurements at 6 and 12 weeks and 1 and 2 years. (Note that all timeframes are relative to each patient's index medical consultation.) The data collected described demographic, socioeconomic, behavioural, anthropometric, clinical, occupational and psychosocial variables, as well as information on the utilization of health services for back pain. Clinical information was drawn by a single individual from study participants' medical files. An online appendix (available at [www.cmaj.ca/cgi/content/full/172/12/1559/DC1](http://www.cmaj.ca/cgi/content/full/172/12/1559/DC1)) summarizes the standardized instruments used to measure key constructs.<sup>28,29,30,31,32,33,34,35,36,37,38,39,40,41,42,43,44,45,46,47,48,49,50,51,52,53,54,55,56,57,58,59,60</sup> When an instrument was unavailable in French, Vallerand's double-inverse translation method<sup>61</sup> was applied.

Return to work in good health (RWGH) is an index of back- pain outcome that takes into account work status, functional limitations and number of days of work-absence since the medical consultation. This variable has 4 categories based on the work of Baldwin's group<sup>26</sup> (presented in detail in [Table 1](#)): success, partial success, failure after attempt, and failure. Our work-absence data were self-reported; however, a validation study was conducted with data obtained from the employers of 40 volunteers. The type 1 intraclass coefficient correlating the 2 sets of data was 0.97 (95% confidence interval [CI] 0.93–0.98) for number of days of modified work, and 0.99 (95% CI 0.98–1.00) for number of days off any work.

Table 1

Table 1: Definitions of "return to work in good health" outcome categories

Category	Definition
Success	At regular work (i.e., the that performed before the index medical consultation for back pain) as of day of interview and functional limitations < 30% and no more than 3 days of absence from regular work since last interview (i.e., 7 d, for the interviews at 1 and 2 yr)
Partial success	Other situation unrelated to back pain (e.g., became homebound by choice)
Failure	Attending regular work, as of day of interview and functional limitations < 30% and more than 3 days of absence from regular work since last interview (i.e., 7 d, for the interviews at 1 and 2 yr)
Failure after attempt	Attending regular work and functional limitations < 30%

Table 1

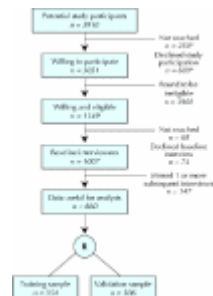
Subsequent to descriptive analysis, participants were randomly assigned (by means of a randomization function in SAS software) into 2 subgroups: about 40% into a “training sample” and the rest into a “validation sample.” Predictive analyses were conducted to identify, not causal relationships, but only prognostic indicators that could be clinically useful.<sup>62</sup> Recursive partitioning with KnowledgeSeeker software (version 3.0, Angoss Software International Ltd., Toronto, Ont.) was used to build a predictive model of 2- year RWGH in the training sample.<sup>63</sup> Because the distinction between the “failure after attempt” and “failure” groups has no clinical pertinence, data for these 2 categories of outcome were lumped together. The threshold for statistical significance was fixed first at 0.01, to favour the selection of the strongest predictors and simplicity in the model built. Afterward, it was relaxed to  $p \leq 0.05$  to permit us to identify complementary and alternative associations.

Classification error rate, sensitivity, specificity, and positive and negative predictive values (the probability, respectively, of having and not having an actual adverse occupational outcome when so predicted by the model) were computed for each model by comparing the predicted classification of subjects to their actual status at 2 years. In these analyses, the subjects were dichotomized along different groupings of the outcome categories. The “success” category was always considered among the “non-diseased” group. Area under the receiver operating characteristic curve<sup>64</sup> was used as the main criterion to select one model over another, followed by the number of variables. Each selected model was then applied to the validation sample. We “pruned” the final model to try to keep it as simple as possible. All baseline, 6-week and 12-week variables were candidate predictors, including individual items or questions of specific measurement tools ([Appendix 1](#)).

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## Results

Numbers of eligible subjects, refusals and participants are shown in [Fig. 1](#). The proportion of eligibility among subjects who were reached (37.6%) was applied to those not reached, to estimate a total number of eligible subjects. A total of 1007 subjects (68.4% of the 1471 expected to have been eligible) participated in the baseline interview, conducted an average of 25 days after the index consultation (standard deviation [SD] 10.2 d). Of those who participated in the baseline interview, 923 (91.7%) completed the interview at 6 weeks of follow-up, 907 (90.1%) at 12 weeks, 913 (90.7%) at 1 year, and 864 (85.8%) at 2 years. Three patients died during the follow-up period. Completed records of all 5 interviews were available for 860 participants, whose data were used for the recursive partitioning analysis.



**Fig. 1: Eligible subjects, refusals and participants in the study.**\*Eligibility unknown. R = randomization.

The mean age of the participants was just under 39 years; a majority (58.5%) were male ([Table 2](#)). Almost half (47.8%) had earned a postsecondary diploma, from either a community college or a university.

Table 2

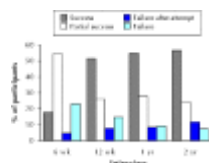
Table 2: Selected sociodemographic variables of study participants (workers with back pain) at the baseline interview

Characteristic*	No.	Pct.	Mean (SD)	Data missing
n = 1007				
Age, or median (range) (18–44)			38.7 (10.4)	0
Female	418 (41.5)			0
Graduated from primary school	186 (18.6)			24
Secondary school	327 (32.3)			
Community college	305 (30.3)			
University	189 (18.8)			
Body mass index < 27 kg/m <sup>2</sup>	662 (65.4)			27
≥ 27 kg/m <sup>2</sup>	298 (29.4)			
Currently smokes cigarettes	588 (58.3)			17
Former smoker	282 (28.1)			
Never smoked	136 (13.5)			
Duration of current back pain, if specified, in years (range 1–40/40+)			70.8 (40.4)	3
Time of back pain onset	233 (23.2)			5

Table 2

At baseline, a majority of subjects reported their back pain to be recurrent (“it comes and goes”) or persistent (“the pain is always there, to different degrees”); fewer than one-quarter reported that theirs was a one-time problem (“never had back pain before”). The median time since the beginning of patients' first episode was nevertheless 6 years. Pain was mostly situated in the lumbar and lumbosacral areas. Over half of our study subjects reported pain radiating to the arms or legs.

The 2-year evolution of RWGH among study subjects is illustrated in [Fig. 2](#). The most important changes in RWGH occurred at about 12 weeks, at which time about 50% of subjects were in the RWGH success category (compared with 18% at 6 weeks). At 2 years, close to 20% were still in the “failure after attempt(s)” and “failure” groups.



**Fig. 2: Progress among study participants toward return to work in good health.** Note that subjects could not go back into the “failure” group; this category could thus only diminish over time.

[Fig. 3](#) presents the final predictive model as a clinical algorithm that allows estimation of the probability, for a given individual, of RWGH success, partial success and failure (which includes failure after attempt). The classification error rate was 37.0% in the training sample and 40.5% in the validation sample. Measures of validity to detect RWGH failure, partial success or both outcomes taken together for this model are presented for both samples in [Table 3](#), with a set of example calculations shown in [Fig. 4](#). All validity measures were quite stable when applied to the validation sample. In all cases, findings for negative predictive value were high (74%–91%). It was highest for predicting “failure after attempt/failure” (91%), whereas the highest positive predictive value was for detecting the combined outcome of “failure after attempt/failure” or “partial success” simultaneously (57%).

Table 3

Table 3: Measures of validity\* for the final predictive model of the 2-year *c* in good health\* in the 2 samples of study participants

Validity measure	% of training sample, n = 334			% of valid
	Failure or failure after attempt	Partial success	Partial success + failure or failure after attempt	Failure or failure after attempt
Classification error†	37.0			
Sensitivity	75	64	73	74
Specificity	64	68	71	63
Positive predictive value	33	32	66	33
Negative predictive value	94	85	78	91

\* Calculated from 2 × 2 tables comparing each definition of outcome to the heading of the “observed” group or categories of the “non-disease” group, which always includes at least the “success” category. An example is provided in Fig. 4.

† Classification error = 1 - (sensitivity + specificity) / 2. In this case, error rate = (75 + 64) / 2 = 69.5%.

Table 3

Predicted 2-year outcome	Actual 2-year outcome		Total
	Failure or failure after attempt	Success or partial success	
Failure or failure after attempt	8 (41)	5 (10)	13 (41)
Success or partial success	5 (15)	4 (10)	9 (15)
Total	13 (41)	9 (15)	22 (36)

Sensitivity:  $a/(a+c) = 8/(8+5) = 75.0\%$   
 Specificity:  $d/(b+d) = 4/(5+4) = 44.4\%$   
 Positive predictive value:  $a/(a+b) = 8/(8+5) = 61.5\%$   
 Negative predictive value:  $d/(c+d) = 4/(10+4) = 28.6\%$   
 Prevalence of adverse outcome:  $(a+c)/(a+b+c+d) = 13/(13+9) = 59.1\%$

**Fig. 4: Example of calculations of the measures of validity presented in [Table 3](#).**



**Fig. 3: Clinical algorithm to predict an outcome at 2 years of return to work in good health (RWGH) among workers consulting in primary care settings for back pain.** All values shown are percentages. High-probability categories in each group, as were used ...

## Interpretation

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This study corroborates the complex nature of back pain and the inherent difficulty in developing clinical prediction tools for such conditions. With a large coverage of potential predictors measured at baseline and at 6 and 12 weeks, the best model we obtained contains 7 predictors measured at baseline (patient's recovery expectations, radiating pain, previous back surgery, intense pain, frequent change of position because of back pain, irritability and bad temper, and difficulty sleeping). It is far from perfect; nonetheless, its high negative predictive value may constitute a strong advantage.

Most previous studies on the prediction of the long-term outcome of back pain used a dichotomous measure of return to work, duration of work absence or compensation data. Because of methodological differences and the nature of predictive analyses (which are not intended to identify causal relationships, and should not be interpreted as doing so),<sup>64</sup> it is not relevant to directly compare the predictors. In fact, 2 studies could end up with different sets of predictors; but the nature of the predictors is not very important, as long as they constitute an efficient and reproducible prognostic tool. The comparison must be made on the predictive validity of the models, that is, on their capacity to classify subjects correctly with respect to their outcome and on demonstration of the reproducibility of this validity. The few existing previously determined models explained some 25%–30% of the variance of continuous outcomes,<sup>25,65</sup> similar to what we observed when we applied our final predictive model to long-term absence (data not shown). With regard to other measures of predictive validity, it is quite often negative predictive values that are highest,<sup>65,66,67</sup> as in our study.

This study had several strengths: the inclusion of all workers consulting for back pain, whatever the source of pain (i.e., not only workers' compensation cases); the large sample; the prospective design, with repeated measures taken at key points in the natural history of the disease; a high participation rate; coverage of numerous variables that were considered; the use of a more specific and eventually more valid measure of occupational outcome; and the use of recursive partitioning.

Classically in prospective cohort studies, subjects must be free of the disease at the beginning of observation, so that only new (incident) cases are observed and the directionality of associations is non-equivocal. Since only about 1 in 5 back-pain patients consulting in primary care settings have never had back pain before, a so-called inception cohort study of incident cases would require great resources and include only subjects with homogeneous characteristics, which would limit its external validity. Primary care physicians meet with a heterogeneous population of back-pain patients (most with recurrent or persistent pain) for whom they must give a prognosis. A prediction tool that works for a subgroup of patients only is unlikely to be useful to clinicians, especially if the subgroup includes only a minority of their clients.

In this study, several measures of the type and severity of pain were used as potential predictors. If these variables had been important to the prognosis, they would have been retained. Our model is thus applicable to all sorts of back-pain problems, as seen in day-to-

day primary care practice. It can be used systematically to assist the physician in deciding the best allocation of clinical resources for patients with back pain (see the example cases accompanying [Fig. 3](#)).

Reproducibility of predictors is an important consideration in building a prognostic instrument.<sup>68</sup> The fact that 5 of the variables included in our final model are items drawn from well-validated measurement instruments is reassuring. The 2 other items, radiating pain and previous back surgery, are relatively “hard” events, measurement of which is likely to be highly reproducible.

Because the baseline interviews were conducted some 3 weeks after the related medical consultation, it is possible that some variables may have changed during that period, improving the predictive potential over data that would have been collected, had the interviews been held at the time of consultation. However, variables measured at 6 weeks and 12 weeks offered no better prediction than the baseline measures, which is reassuring.

Traditionally, physicians look for clinical decision rules that have high positive predictive value, and attribute generally less importance to negative predictive value. However, it is the nature of the outcome that must determine the most important measures of validity for a given clinical decision tool. Considering the frequency of back pain and the resources that are spent on benign cases, an instrument that allows identification of a group of subjects who are at low risk of adverse outcomes may be quite useful.

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## Supplementary Material

[Online Appendix]

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## Acknowledgments

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## Appendix 1: List of constructs measured and considered as potential predictors

### Sociodemographic factors

- Age
- Current financial problems because of back pain
- Education
- Ethnic origin
- Gender
- Gross annual family income
- Living with spouse
- Maternal language
- Number of household members
- Number of children under 5 years of age

### Anthropometric factors

- Body mass index (kg/m<sup>2</sup>)
- Hand dominance
- Height
- Weight

### Psychological factors

- Aggressiveness
- Exposure to stressful events during the past 12 months: changed job for worse, divorced or separated, financial problems, got gravely ill, significant other became gravely ill, death of spouse, death of other significant person)
- Fear-avoidance beliefs — activity
- Fear-avoidance beliefs — work
- Health locus of control (internal, external, chance)
- Pain-control strategies
- Psychological trauma before age 18
- Self-efficacy with regard to work capacity
- Symptoms of depression
- Symptoms of somatization
- Social support outside work

### Health behaviour factors

- Alcoholism
- Cigarette smoking
- Coffee and tea consumption
- Physical activity and sports participation when not
- Regular meditation or relaxation
- Sleep during past 2 weeks
- Usual duration of sleep

### Clinical factors, history of back pain

- Age at menopause
- Average pain over the past 6 months
- Current functional limitations
- Current pain level
- Diagnostic category
- Duration of current episode at time of consultation
- Duration of pain, past 6 months
- Number of previous surgeries for back pain
- Number of days with pain since index consultation
- Number of times gave birth
- Pain radiating to upper or lower limb?
- Previous back pain episode(s) affecting work capacity, any, when?
- Reduction of daily life activities because of back pain, the past 6 months
- Reduction of work capacity because of back pain, the past 6 months
- Self-reported health status
- Self-reported type of back pain
- Site of pain
- Spitzer classification<sup>10,20</sup>
- Worst pain (level) in past 6 months
- Number of years since onset of back pain

Appendix 1.



## Appendix 1: List of constructs measured and considered as potential predictors (continued)

### Dramatization of diagnosis

- "The doctor asked you to get an x-ray, a CT scan, myelography, MRI (magnetic resonance imaging), or other radiological examination"
- "The doctor told you to stay in bed" (and no. of days recommended)
- "The doctor asked you to schedule a check-back visit"
- "The doctor mentioned that you might need surgery for your back problem"

### Utilization of health services

- Duration of index medical consultation
- Number of visits to the same clinic during the past 12 months
- Number of hospitalizations for back pain during the past 12 months
- Perception that doctor's diagnosis of back problem is correct
- Satisfaction with health services since the index consultation
- "The doctor asked you to undress for the physical examination of your back"
- "The doctor, physical therapist, or another health professional helped you learn exercises for your back to help in your recovery"
- "The doctor showed interest in you as a person"
- "The doctor asked about your lifestyle and stress that may affect your back pain"
- "The doctor discussed options with you, asked your opinion, and offered choices about the care of your back pain"
- "The doctor relieved any concern about the cause of your back pain"
- "Your visit to the doctor helped you feel that you could control your back pain"
- "You were treated like your back pain was an important problem, and not 'all in your head'"
- "The doctor listened carefully while you described your back problem"
- "The doctor took time to answer all your questions about your back pain"
- "The doctor asked you about your occupation and took time to give you advice"
- "Your doctor, physical therapist or another professional showed you how to work to protect your back from injury"
- Weight of the medical file

### Occupational factors

- Adaptation of work environment is possible
- Change of job or employer in the past 12 months
- Company size
- Current financial compensation for back pain
- Days of sick-leave permitted without a medical certificate
- Declared occupational disorder
- Effort-reward imbalance (Siegrist's model)
- Exposure to cold at work
- Job decision latitude (Karasek's model)
- Job satisfaction
- Job seniority
- Job status at time of consultation: permanent, occasional, seasonal, self-employed, other
- Likelihood of losing job during the next 2 years
- Number of days off work or with modified duties/schedule, over the past 12 months
- Number of jobs held
- Number of previous periods of sick-leave, modification of duties, or modified schedule because of back pain over the past 10 years
- Pace of work
- Physical demands of job: sitting and standing, forklift operation, lateral trunk flexion, rotation of the trunk, manipulation of loads, charges, efforts made with tools, lifting or transporting persons, whole-body vibration, physical strength
- Previous financial compensation for back pain
- Psychological demands of work (Karasek's model)
- Responsibility for household chores
- Satisfaction concerning possibilities of work adaptation
- Social support at work
- "Supervisor takes back pain seriously"
- Time to commute to work
- Unionized job
- "When did you modify work or stop working for the last episode of back pain?"
- Work schedule: full-time, part-time
- Work shift: day, evening, night, variable
- Work status at time of consultation: at regular job, completely off work, modified duties, modified schedule, modified job assignment

## Footnotes

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This article has been peer reviewed.

**Contributors:** Clermont Dionne initiated the study. Clermont Dionne, Renée Bourbonnais, Pierre Frémont, Michel Rossignol and Susan Stock designed the study protocol. All of the authors discussed core ideas, participated in analysis and interpretation of the data, and contributed to the writing of the paper under Clermont Dionne's lead. Clermont Dionne and Isabelle Larocque coordinated the study and data collection. All of the authors are guarantors for the paper.

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