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## Original article

# Pain, health related quality of life and healthcare resource utilization in Spain

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#### Abstract

#### Objectives:

The aim of this paper is to consider the relationship between the experience of pain, health related quality of life (HRQoL) and healthcare resource utilization in Spain.

#### Methods:

The analysis contrasts the contribution of pain severity and frequency of pain reported against respondents reporting no pain in the previous month. Data are from the 2010 National Health and Wellness Survey (NHWS) for Spain. Single equation generalized linear regression models are used to evaluate the association of pain with the physical and mental component scores of the SF-12 questionnaire as well as health utilities generated from the SF-6D. In addition, the role of pain is assessed in its association with self-reported healthcare provider visits, emergency room visits and hospitalizations in the previous 6 months.

#### Results:

The results indicate that the experience of pain, notably severe and frequent pain, is substantial and is significantly associated with the SF-12 physical component scores, health utilities and all aspects of healthcare resource utilization, which far outweighs the role of demographic and socioeconomic variables, health risk factors (in particular body mass index) and the presence of comorbidities. In the case of severe daily pain, the marginal contribution of the SF-12 physical component score is a deficit of -17.86 compared to those reporting no pain (population average score 46.49), while persons who are morbidly obese report a deficit of only -6.63 compared to those who are normal weight. The corresponding association with health utilities is equally dramatic with a severe daily pain deficit of -0.186 compared to those reporting no pain (average population utility 0.71). The impact of pain on healthcare resource utilization is marked. Severe daily pain increases traditional provider visits by 208.8%, emergency room visits by 373.0% and hospitalizations by 348.5%.

#### Limitations:

As an internet-based survey there is the possibility of bias towards those with internet access, although telephone sampling is used to supplement responses. Respondents are asked to describe their experience of pain; there is no independent check on the accuracy of responses. Finally, while certain acute pain categories are omitted, the study focuses on pain in the last month and not on pain chronicity.

#### Conclusions:

The societal burden of severe and frequent pain in Spain is substantial. Although not reported on before, at a national level, the deficit impact of the experience of pain far outweighs the contribution of more traditional explanations of HRQoL deficits as well as being the primary factor associated with increased provider visits, emergency room visits and hospitalizations.

#### Introduction

At the national level, estimates of the quantitative importance of the impact of pain experience on health related quality of life (HRQoL) and healthcare

resource utilization in Spain are limited, although this does not mean that aspects of the experience of pain have been neglected. An early study by Català et al. focuses on persons experiencing recent pain<sup>1</sup>. Although population prevalence estimates and the correlates of pain are described together with the degree of activity limitations imposed, the study does not attempt to quantify the societal burden of pain. Another early study by Carmona et al. reports on the prevalence of musculoskeletal conditions but not on their quantitative impact<sup>2</sup>. A more recent study by Fernández-de-las-Peñas et al. has utilized the 2006 Spanish National Health Survey to assess the prevalence and respondent characteristics of those with neck and low-back pain<sup>3</sup>. The prevalence and impact of fibromyalgia in the Spanish population to include HROoL has been reported on by Mas et al. with a further study predicting healthcare resource use in fibromyalgia by Pastor Mira et al. 4,5. In the former study the authors reported scores on the SF-12 as being significantly lower in fibromyalgia patients while in the latter study pain intensity significantly predicted the use of health resources. In estimating quality of life weights in Spain, Garcia-Altés et al. found that pain limitations had a greater negative impact on HRQoL than chronic diseases<sup>6</sup>. The prevalence and characterization of neuropathic pain in primary care has recently been reported on by Pérez et al.7. There is both a high prevalence of neuropathic pain and also a need to improve management of outpatients. Other studies by Bassols et al. and Miró et al., are limited by region and by demographic group<sup>8,9</sup>. As far as the prevalence, correlates and treatment of pain in Spain at the national level are concerned, a recent study by Langley et al. has addressed these issues utilizing the same data set that is used in the present study<sup>10</sup>.

Outside of Spain the picture is somewhat different. At the pan-European level the prevalence, severity and correlates of pain that include chronic pain have been reported on by Breivik et al. and, more recently, for the UK, France, Spain, Germany and Italy by Langley<sup>11,12</sup>. Quantitative or modeled assessments have been conspicuous by their absence. However, two recent studies by Langley et al. have provided, again for the five countries noted above, quantitative assessments of the burden of pain in the context of HRQoL and healthcare resource utilization and employment status, absenteeism and presenteeism<sup>13,14</sup>. Both studies conclude that the burden of pain experience is not only substantial but underappreciated by policy makers. Although Spain is one of the countries included in these analyses, with data from the 2008 National Health and Wellness Survey (NHWS), it is not reported on separately<sup>15</sup>.

The absence of comprehensive national and pannational assessments of the burden of pain does not mean that the association of pain experience with HRQoL has not been a focus of attention. Generic

health-related quality of life (HRQoL) instruments have been used on a number of occasions to assess the prevalence of pain. In the Grampian study of chronic pain Smith et al. use the SF-36 instrument to evaluate the quantitative importance of pain experience 16. Konig et al. report on health status in six European countries using the EQ-5D instrument and found that the most frequently reported problem was pain (28.5% of respondents)<sup>17</sup>. The association of neuropathic pain with quality of life has been the subject of community studies by Smith et al. 18. Recent reviews by Jensen et al., Sadosky et al., and O'Connor found that those experiencing neuropathic pain in three UK communities recorded significant differences on all dimensions of the SF-36 compared to those reporting no pain 19-21. These studies show that neuropathic pain is associated with significant HRQoL deficits in multiple domains - including physical and emotional suffering. Using the EQ-5D instrument as a reference McDermott et al. point to substantial differences in the deficits associated with levels of pain severity<sup>22</sup>.

While community studies and reviews have pointed to the association of pain, chronic pain and neuropathic pain with, for example, HRQoL deficits, the existing observational study literature suffers from two main weaknesses. First, in attempting to assess the burden of pain, there has been a failure to compare pain populations with those not experiencing pain as a control group. Second, there has been a lack of analyses to evaluate the independent contribution of pain in its impact on outcomes such as HRQoL and healthcare resource utilization and whether pain has a substantive impact above and beyond other potential determinants of these outcomes.

The purpose of this study is to provide, for the first time, a comprehensive assessment of the burden of pain in Spain. This is presented in terms of the impact of both pain severity and frequency, on (i) HRQoL and (ii) self-reported healthcare resource utilization in the previous six months. As such, it complements the Langley *et al.* assessment of the impact of pain on HRQoL and healthcare resource utilization in five EU countries based on the earlier 2008 NHWS survey and further develops the pain prevalence analysis of Spain by Langley *et al.* <sup>10,13</sup>.

#### Methods

The principal research question is to assess the association between the severity and frequency of pain and self-reported HRQoL and healthcare resource utilization. This is achieved through the specification of generalized linear regression models – ordinary least squares models in the case of HRQoL and negative binomial models in the case of healthcare resource utilization. This multivariate framework allows an assessment of the independent or marginal contribution of the severity and frequency of

pain on outcomes. At the same time the models take account of the possible contribution of respondent socio-demographic and economic characteristics, the presence of health risk behaviors and respondent comorbidity status.

Two models are presented. Model 1 considers only the reported severity of pain experience on HRQoL and resource utilization; Model 2 assesses the contribution of pain severity and frequency. This approach is taken in order to see whether or not the frequency of pain experienced adds an additional dimension to our understanding of the burden of pain experience. While the presence of pain is expected to have a significant and negative effect on both HRQoL and resource utilization, it is also of interest to assess whether the HRQoL deficits and resource utilization impacts are attenuated with less severe and less frequent experience of pain.

#### **National Health and Wellness Survey**

The National Health and Wellness Survey (NHWS) is an annual and biannual, internet-based, cross-sectional survey of the healthcare attitudes, behaviors, and characteristics of the adult population<sup>15</sup>. It is undertaken in the US, UK, France, Spain, Germany, Italy, urban China and Japan. Since its initiation in 1998, over 600,000 survey responses across approximately 140 conditions have been collected. In addition, several supplementary studies have been conducted in which NHWS respondents were re-contacted and asked further questions.

Respondents to the 2010 NHWS who indicated that they had had pain (included fibromyalgia) in the last 12 months were asked if they had experienced pain in the last month and the condition(s) that had caused pain. If respondents indicated that they had only experienced menstrual pain, migraine, dental pain or headache in the last month, they were excluded from the pain category. This eliminated purely acute pain categories. Pain categories included cover back pain, broken bones, cancer, fibromyalgia, joint pain, neck pain, neuropathic pain, post-herpetic pain and neuralgia. These conditions are detailed in Langley *et al.* <sup>10</sup>.

The 2010 NHWS survey of Spain yielded a total of 5039 respondents 18 years of age and over. The overall weighted population experiencing pain was estimated to be 6.10 million, a prevalence of 17.25% <sup>10</sup>. Pain severity and pain frequency reported are detailed in Table 1. Overall, of those experiencing pain, 11.69% reported severe pain, 24.14% mild pain and 64.17% moderate pain. Overall, 40.29% of respondents reported experiencing daily pain, with 9.45% reporting severe daily pain and 28.41% moderate daily pain.

Table 1. Pain severity and frequency, 2010 NHWS weighted estimates, Spain.

Distribution (%)
24.14
64.17
11.69
100.00
40.29
12.75
17.74
29.22
100.00
9.45
28.41

Source: NHWS, 2010.

#### Dependent variables

All respondents to the 2010 NHWS were asked to complete the SF-12 HRQoL instrument together with a series of questions to identify their use of healthcare resources in the last six months: traditional healthcare provider visits, emergency room visits and hospitalizations. Three dimensions of HRQoL are identified: SF-12 physical and mental summary scores and SF-6D health utilities.

#### SF-12 and SF-6D

The SF-12 is a multipurpose, generic HRQoL instrument comprising 12 questions<sup>23</sup>. The instrument is designed to report on eight health concepts. These are:

- Physical functioning
- Role physical (accomplishment)
- Bodily pain
- General health
- Vitality (energy level)
- Social functioning
- Role emotional (accomplishment)
- Mental health (feeling)

The SF-12 questions are all selected from the SF-36 health survey<sup>24,25</sup>. A key objective in developing the SF-12 in the early 1990s was to construct the shortest possible form that would replicate the physical and mental health summary scores generated from the SF-36 with at least 90% accuracy. A further objective was to replicate each of the eight SF-36 health concepts with at least one questionnaire item to set the stage for scoring an eight-scale profile from SF-12 responses.

It is worth noting that the SF-12 bodily pain item does not ask respondents to indicate either the severity or the frequency of the pain. Rather, the question asks respondents 'How much did pain interfere with your normal work (including both work outside the home and housework)?'

Table 2. Distribution of physical and mental component SF-12 SCORES, 2010 NHWS, weighted estimates, Spain.

Range	Physical Component Score (%)		Mental Component Score (%)		
	Persons reporting no Pain	Persons reporting pain	Persons reporting no Pain	Persons reporting pain	
60 and over	4.09	*	12.74	5.60	
50 to 59	56.32	23.38	35.35	24.35	
40 to 49	26.80	34.27	30.15	31.80	
30 to 39	9.81	25.07	16.79	25.51	
Under 30	2.99	16.14	4.97	11.74	
Average (SD)	49.88 (8.30)	41.52 (10.79)	48.13 (10.19)	43.66 (11.07)	

\*N < 30. SD = standard deviation.

Source: NHWS 2010.

with the response choice (five items) from 'not at all' to 'extremely.'

While it is possible to develop a health profile utilizing the item responses corresponding to these eight concepts, the focus here is on the two summary scores that can be generated from the respective SF-12 item responses. These are (i) the physical component summary (PCS) and (ii) mental component summary (MCS). Details of how the links are established and the scoring algorithms are given in Ware et al. 23.

For the purpose of the present analysis, the PCS and MCS summary scores are utilized as normed scores. This is achieved by transforming the raw scores for the items to a mean of 50 and a standard deviation of 10 for the US population. Normed scores can be calculated for both the eight SF-12 scales as well as for the PCS and MCS summary scores. The appropriateness of using the US as a standard benchmark has been demonstrated for nine European countries (including the five countries in the NHWS)<sup>23</sup>.

The distribution of the normed SF-12 PCS and MCS scores are given for the pain and no pain populations for Spain in Table 2. In the case of the PCS average score, there is a substantial difference between the score for the two populations (no pain 49.88 vs. pain 41.52). The difference for the MCS score is less marked (no pain 48.13 vs. pain 43.66). These differences are reflected in the distribution of scores by class interval. In the case of the PCS 56.32% of respondents in the no pain category score in the range 50 to 59 compared to only 23.38% of those reporting pain. In the case of the MCS the corresponding figures are 35.35% vs. 24.35%.

As well as generating profile and summary PCS and MCS scores, the SF-12 can also be used to generate absolute utilities. This is achieved through application of the SF-6D, which utilizes six items from the SF-12. The SF-6D is a preference-based single index measure for health using general population values<sup>26,27</sup>.

The SF-6D describes 18,000 health states. It comes with a set of preference weights obtained from a sample of the UK general population using the recognized standard gamble valuation technique. The SF-6D index has interval scoring properties and yields summary scores on a 0-1 scale

Table 3. Distribution of SF-6D utility scores, 2010 NHWS, Spain, weighted estimates

Utility Score	Persons reporting no pain (%)	Persons reporting pain (%)
0.90 and over	19.25	5.77
0.80 to 0.89	19.89	9.68
0.70 to 0.79	17.46	13.10
0.60 to 0.69	34.07	37.21
0.50 to 0.59	7.84	25.85
Less than 0.50	1.48	8.40
Average (SD)	0.75 (0.13)	0.65 (0.13)

SD = standard deviation. Source: NHWS, 2010.

(practically 0.29 to 1 with a floor effect). The preference weights have recently been revised<sup>28</sup>.

Estimated SF-6D preference scores or health utilities for the pain and no pain populations are presented in Table 3. The average utility score for the no pain population is 0.75. This contrasts to the lower score of 0.65 for the pain population. This difference is statistically (p < 0.05) and clinically meaningful. The distribution of scores for the no pain population is noticeably skewed to the right (higher utility scores) compared to the pain population.

#### Healthcare resource utilization

The 2010 NHWS also asks respondents about their use of healthcare resources. Resource utilization is considered in terms of visits or events as they relate to:

- Number of visits in the last six months to traditional healthcare providers
- Emergency room visits in the last six months
- Number of times hospitalized in the last six months

Traditional healthcare providers include general practitioner/family practitioners, internists and dentists as well as more specialized physicians. The distribution of visits reported for the no pain and pain populations are summarized in Table 4. Overall, the number of traditional provider visits reported by the pain group (8.82) was almost twice that for the no pain group (4.58) (p < 0.05). A similar picture is presented for emergency room visits

Table 4. Healthcare resource utilization distributions for persons reporting pain and no pain, weighted estimates 2010 NHWS, Spain.

Resource utilization events	Traditional healthcare provider visits (%)		Emergency room visits		Hospitalizations	
	Persons reporting no pain (%)	Persons reporting pain (%)	Persons reporting no pain (%)	Persons reporting pain	Persons reporting no pain	Persons reporting pain
Nil	18.37	7.95	78.20	68.05	92.26	87.10
1	13.33	4.83	14.61	14.94	5.66	9.54
2	14.90	9.31	3.64	8.24	1.05	*
3	11.36	9.50	1.50	3.51	*	*
4	8.08	8.02	*	*	*	*
5 or more	33.95	60.40	1.54	3.70	*	*
Average (SD)	4.58 (6.29)	8.82 (9.77)	0.41 (1.33)	0.74 (1.65)	0.13 (0.73)	0.21 (0.80)

<sup>\*</sup>N < 30. SD = standard deviation.

Source: NHWS 2010.

(0.74 vs. 0.41; p < 0.05) and hospitalizations (0.21 vs. 0.13;b < 0.05). However, in the last two healthcare resource categories, the overwhelming majority of respondents fail to report either an emergency room visit or a hospitalization.

#### Independent variables

Table 5 presents a summary of the non-pain independent variables applied in the various regression models. Previous research has indicated that each of the variables considered has the potential to impact significantly on both HROoL and healthcare resource utilization. The variables are:

- Socio-demographic variables
- Health risk behaviors
- Comorbidity status

The relationship between age and HRQoL and healthcare resource utilization is well established. National population surveys such as the Behavioral Risk Factor Surveillance System (BRFSS) in the US have shown that on a range of measures, HRQoL declines with increasing age, while healthcare resource utilization increases. As shown in Table 5, the pain population tends to be older than the no-pain population. Controlling for age, therefore, is important in any assessment of the independent impact of pain on quality of life or resource utilization. Overall, females tend to report a higher HRQoL than males. They also report higher healthcare utilization.

The relationship between educational attainment, HRQoL and healthcare resource utilization is less well established, although a Spanish study has demonstrated a positive relationship between HRQoL and educational attainment <sup>29</sup>. Educational attainment and its association with income may be expected to result in more risk-adverse behaviors, but the accompanying increased

Table 5. Distribution of independent variables, 2010 NHWS, Spain, weighted estimates.

	Weighted estimates		
Independent Variables	No Pain (%)	Pain (%)	
Socio-Demographic Variables Age: 18–39 years Age: 40–59 years Age: 60 years and older	32.49 34.59 32.92	24.49 47.17 28.34	
Gender: female Gender: male	49.25 50.75	60.33 39.67	
Education: University or higher Education: High school completed Education: Other Income: Under €20,000 Income: €20,000 to €39,999 Income: €40,000 and above Income reporting declined	25.17 55.05 19.77 29.02 44.45 10.89 15.64	23.19 53.68 23.13 28.75 47.02 11.20 13.03	
Health Risk Behaviors BMI: Underweight BMI: Normal weight BMI: Overweight BMI: Obese or morbidly obese Current smoker Alcohol user (>2 days month)	2.01 38.47 42.13 17.39 21.97 10.38	2.05 32.18 41.90 23.87 23.81 9.00	
Morbidity/Comorbidity Status Charlson Comorbidity Index (SD)	0.328 (0.820)	0.575 (1.060)	

SD = standard deviation. Source: NHWS, 2010.

awareness of the value of preventive measures may increase healthcare utilization. HRQoL would be expected to increase with educational attainment and income.

Three health risk behaviors are identified: body mass index (BMI), current smoking and current alcohol consumption. The NHWS does not allow a more detailed assessment of actual alcohol consumption or number of cigarettes per day and duration of smoking behavior.

The relationship between BMI and HRQoL is well established. A recent paper by Søltoft *et al.*, utilizing data from the 2003 Health Survey of England, found a significant association between BMI and HRQoL<sup>30</sup>. The study found that after controlling, among other variables, for gender, age and obesity-related comorbidities, HRQoL was at a maximum with a BMI of 26.0 in men and 24.5 in women. There was a negative association for both underweight and overweight individuals. In the present case, BMI is represented by a series of categorical variables. These capture the standard BMI categories ranging from underweight to morbidly obese. In the regression models, normal weight is the reference category.

The relationship between smoking and HRQoL is more nuanced. Sarna *et al.*, for example, conclude that among female nurses who have recently smoked, the number of cigarettes per day and the time since quitting were associated with significantly lower PCS and MCS scores from the SF-36<sup>31</sup>. A more recent study based on data from the 2008 BRFSS survey finds that among adults, only certain HRQoL characteristics are impacted<sup>32</sup>. These were worse among smokers who unsuccessfully attempted to quit. In contrast, other characteristics were better among former smokers than among those who made no attempt to quit. At best, the expectation here is that smoking is expected to have a negative, but probably small, impact on HRQoL and a positive impact on resource utilization.

Assessing the impact of alcohol consumption on HRQoL depends on the measures of alcohol consumption used. Evidence to date would suggest a non-linear relationship<sup>33</sup>. Moderate drinking is associated with similar or higher HRQoL scores compared to non-drinkers. Substantial HRQoL deficits are associated with higher levels of daily alcohol consumption and binge drinking. The picture is further clouded if former drinkers are included in the assessment<sup>34</sup>. Given the NHWS definition of alcohol use, it is difficult to argue for an expected relationship with either HRQoL or resource utilization.

The presence of morbid/comorbid conditions is captured by the Charlson Comorbidity Index (CCI). The CCI was originally designed as a measure of the risk of one-year mortality attributable to comorbidity in a longitudinal study of general hospitalized patients<sup>35</sup>. The CCI contains 19 categories of comorbidity, which are primarily defined using ICD-9-CM diagnoses codes (a few procedure codes are also employed). Each category has an associated weight, taken from the original Charlson paper, which is based on the adjusted risk of one-year mortality. The overall comorbidity score reflects the cumulative increased likelihood of one-year mortality; the higher the score, the more severe the burden of comorbidity. In the present analysis it is anticipated that the more co-morbidities reported (the higher the CCI) the greater the deficit impact on HRQoL and the greater the utilization of healthcare resources. The CCI for the pain group is 0.58 versus 0.33 for the no pain group.

#### **Estimation**

In the case of both PCS and MCS, the distribution of scores indicated that an ordinary least squares (OLS) estimator was appropriate. In the case of the SF-6D health utility scores, with the possibility of a ceiling effect, both OLS and Tobit estimators were considered. As there was no discernible difference between the two, the OLS was utilized. Both Poisson and negative binomial models were assessed for the three healthcare utilization models. As the alpha score was substantially greater than zero, the negative binomial was selected. All models are estimated: (i) for persons reporting severity of pain (Model I); and (ii) persons reporting severity and frequency of pain as dependent variables (Model II). In both models the no-pain respondents are the reference category. All models were estimated using the STATA v.11 statistical package. All regressions have been weighted.

Because of the limited number of observations, the frequency impact is only considered for severe and moderate pain. The two categories (with no pain as the reference category) are (i) daily pain experience and (ii) pain experience 4 to 6 times a week or less.

#### Results

#### Health related quality of life

The results for the three aspects of HRQoL are presented in Table 6. Estimated regression coefficients are given for each of the two models for the SF-12 PCS and MCS scores and the SF-6D utility scores. In all cases, the respective regression coefficients are interpreted as independent or marginal impacts on the respective PCS, MCS or utility scores.

#### SF-12 physical component score

In Model 1, with a coefficient of -17.917, the experience of severe pain in the last month is over twice that for moderate pain (-7.394). It is also over four times that for the impact of persons age 60 years and over (-4.323) and morbid obesity (-3.572). All other independent variables are significant at the 5% level with all health risk behaviors (excluding alcohol use) and the CCI entering with an expected negative sign. Even so, their impact on PCS is relatively slight. Age, as expected, enters with a negative sign, with the negative association increasing with age. Income, as expected, enters with a positive sign for the higher income groups (increasing in its positive

Table 6. Regression results: health related quality of life, 2010 NHWS, Spain.

	SF-12 Physic	al Component	SF-12 Mental Component Score		SF-6D Health Utility Score	
Independent Variables	Model 1 Coefficient	Model 2 Coefficient	Model 1 Coefficient	Model 2 Coefficient	Model 1 Coefficient	Model 2 Coefficient
Pain level reported in last month <sup>#</sup>	-2.074		-2.188		-0.036	
Moderate Severe	-2.074 -7.394 -17.917		-2.166 -3.443 -8.955		-0.036 $-0.084$ $-0.200$	
Pain level and frequency <sup>#</sup> Severe pain and daily experience Severe pain less than daily experience Moderate pain and daily experience Moderate pain less than daily experience Mild pain		-18.317 -16.524 -10.988 -4.579 -2.065		-10.432 -2.971* -4.072 -2.952 -2.186		-0.211 -0.158 -0.111 -0.063 -0.036
Socio-Demographic Variables Age: 40–59 years <sup>a</sup> Age: 60 years and older <sup>a</sup> Gender: male <sup>b</sup> Education: high school completed <sup>c</sup> Education: university or higher <sup>c</sup> Income: €20,000 to €39,999 <sup>d</sup> Income: €40,000 and above <sup>d</sup> Income reporting declined	-1.598 -4.323 1.419 2.486 2.966 0.928 1.070 0.876	-1.550 -4.196 1.375 2.506 2.939 0.917 1.052 0.832	2.708 6.376 2.173 1.192 2.117 2.050 1.847 2.307	2.729 6.400 2.184 1.186 2.110 2.035 1.824 2.298	0.025 0.047 0.032 0.026 0.036 0.020 0.019 0.024	0.026 0.047 0.032 0.026 0.036 0.020 0.018 0.024
Health Risk Behaviors BMI: Underweight <sup>e</sup> BMI: Overweight <sup>e</sup> BMI: Obese & morbidly obese <sup>e</sup> Current smoker <sup>f</sup> Alcohol user <sup>g</sup>	-1.422* -1.356 -3.572 0.420* 1.459	-1.326* -1.304 -3.476 0.419* 1.486	-2.156 -0.074* -0.740* 0.060* 0.011*	-2.123 -0.093* -0.720* 0.068* 0.000*	-0.027 -0.010 -0.025 0.008* 0.009*	-0.026 -0.010 -0.025 0.008* 0.009*
Morbidity/Comorbidity Status Charlson Comorbidity Index Constant R <sup>2</sup> N	-2.172 50.044 0.328 4992	-2.147 49.967 0.341 4992	-1.553 42.028 0.119 4992	-1.542 42.023 0.121 4992	-0.025 0.687 0.165 4992	-0.025 0.686 0.169 4992

All variables significant at 5% level except (\*).

Reference categories: <sup>#</sup>no pain reported in last month; <sup>a</sup>age 18 to 39 years; <sup>b</sup>females; <sup>c</sup>not completed high school; <sup>d</sup>income under €20,000; <sup>e</sup>BMI normal weight; <sup>f</sup>non-smoker; <sup>g</sup>non-drinker.

impact with higher income). Education also enters with the expected positive sign.

The results for Model 2 parallel those of Model 1. The principal difference is seen in the association of pain severity and frequency on PCS. In particular: (i) the daily experience of severe pain (–18.317); (ii) the experience of less frequent severe pain is also substantial (–16.524); and (iii) the experience of moderate daily pain (–10.988) on PCS. As expected, there is a well defined negative pain gradient associated with the PCS score, declining with persons reporting less frequent mild and moderate pain. Even so, the experience of mild pain on PCS is still substantial (–2.065) and similar to that for the CCI (–2.172). The PCS models enter with an  $R^2$  of 0.328 and 0.341 for Models 1 and 2, respectively. Corresponding intercept values are 50.044 and 49.967.

#### SF-12 mental component score

The impact of pain severity and frequency on the MCS is less than the impact on the PCS components of the SF-12.

In Model 1, the estimate for severe pain (-8.955) is less than one half of the coefficient on the corresponding PCS. Similarly, the experience of severe daily pain in Model 2 is only -3.443 compared to the corresponding coefficient of -7.394 for the PCS. Once again, however, there is again a well defined negative gradient for pain severity and frequency on the MCS. Also, pain does not dominate the MCS models to the extent that it does in the PCS models. The MCS models enter with an  $R^2$  of 0.119 and 0.121 for Models 1 and 2, respectively. Corresponding intercept values are 42.028 and 42.023.

#### SF-6D health utilities

The results for health utilities for both Model 1 and 2 are similar to those for both PCS and MCS models. Once again, the experience of pain has a dominant negative effect on utility scores. Compared to the no-pain reference group, the association of severe pain in Model 1 reduces health utility by -0.200 (on a scale of 0 to 1) followed by moderate pain with an impact of -0.084. Where severity

and the frequency of pain are considered in Model 2, the effect of severe daily pain reduces utility scores by -0.211. The corresponding estimate for severe pain 4 to 6 times or less a week is -0.158. For moderate daily pain the deficit is -0.111.

The relative contribution of the health risk and comorbidity variables are, as expected, consistent with the results reported for PCS and MCS. The utility deficits associated with severe and frequent pain are substantially greater than those associated with not only health risk factors, but also age, gender, education and income. All coefficients are significant at the 5% level (except alcohol use and smoking behavior). The overall explanatory power is less than that reported for PCS in Model 1 with an  $R^2$  of 0.165 and an  $R^2$  of 0.169 in Model 2.

#### Healthcare resource utilization

The results for healthcare resource utilization are presented in Table 7. As a negative binomial model has been used, the regression coefficients are interpreted as the difference in the logs of expected counts for a one unit change in the predictor variable. As this is not an intuitively obvious interpretation, the regression coefficients have been transformed to percentages.

#### Traditional provider visits

The contributions of pain, at all levels of severity, dominate as determinants of the number of traditional provider visits. In Model 1, the experience of severe pain increases visits by 184.90% compared to the no-pain reference category. The combination of severe with daily pain has an even greater effect as shown in Model 2, where provider visits increase by 208.80%. The effect of moderate pain is also substantial, increasing provider visits by 71.70% in Model 1 and, combined with daily pain experience, by 101.30% in Model 2. These percentage contributions stand in contrast to those reported for health risk behaviors where obesity and morbid obesity increase provider visits by 12–30% and where the presence of comorbidities increase the provider visits by approximately 35%.

#### Emergency room visits

The experience of pain also has a substantial association with emergency room visits. In Model 1, severe pain is associated with a 353.30% increase in the number of emergency room visits; for moderate pain, it is 34.90%. The combination of severity and frequency in Model 2 has an even greater contribution, with severe daily pain increasing visits by 373.00%. Even moderate daily pain increases visits by 58.10%. This is a far greater contribution than that estimated for the majority of socio-demographic, health risk factors or even the CCI.

#### Hospitalizations

Pain also has a substantial association with hospitalizations. In Model 1, the experience of severe pain increases hospitalizations by 305.50%. This is even more striking in Model 2, where the combination of severe and daily pain increases hospitalizations by 348.50%. Again, the magnitude of these impacts stands in contrast to those associated with socio-demographic characteristics, health risk factors and the CCI.

#### Discussion

This is the first analysis undertaken in Spain at the national level to assess the societal impact of pain utilizing multivariate modeling techniques. As such it complements and extends the work of a number of researchers. In terms of the prevalence of pain at the national level Pérez et al. in a single-day primary care study report that 30.7% of those receiving primary care experienced pain, with 11.8% experiencing neuropathic pain<sup>7</sup>. While this estimate is substantially higher than that presented here (17.25%) it should be noted that there is no claim in the Pérez et al. study that their results are intended to be nationally representative. The recent study by Fernández-de-las-Peñas et al. has the advantage of using data from the 2006 Spanish National Health Survey, reports a one-year prevalence of neck pain of 19.5% and neck pain 19.9%, and 12.1% for reporting both<sup>3</sup>. Although restricted to a bivariate assessment of respondent characteristics, a comprehensive profile is provided of respondent characteristics and chronic comorbid conditions. A multivariate analysis is not presented. A further limitation is that the frequency and severity of pain is not analyzed. The advantage of the NHWS approach, although clearly limited by the fact that it is an internet-based, self-reporting survey, is that it provides a national sampling framework with results than can be compared both between countries as well as over time with prior surveys. The range of attributes captured, for example the severity and frequency of pain, also means that it is an ideal vehicle for multivariate modeling and, with the control group of a no-pain population, allows an assessment of the societal burden of disease. The application of multivariate models has not been reported on before in national pain studies for Spain.

The models proposed in the present study are identical to those utilized in the recent study by Langley *et al.* of the burden of pain for the five EU countries (which included Spain)<sup>13</sup>. While the prevalence of pain reported for Spain (excluding acute pain categories) is somewhat less than the average of these five countries, the modeled results are very similar. The burden of pain is substantial and the impact of pain, notably among those reporting severe and frequent pain, dominates other independent variables in its impact on both HRQoL and in healthcare resource

Table 7. Regression results: healthcare resource utilization, 2010 NHWS, Spain.

Independent Variables	Traditional P	Traditional Provider Visits		<b>Emergency Room Visits</b>		Hospitalizations	
	Model 1 Percentage Change	Model 2 Percentage Change	Model 1 Percentage Change	Model 2 Percentage Change	Model 1 Percentage Change	Model 2 Percentage Change	
Pain level reported in last month <sup>#</sup> Mild Moderate Severe	23.20 71.70 184.90		49.10 34.90 353.30		31.20* 21.00* 305.50		
Pain level and frequency <sup>#</sup> Severe pain and daily experience Severe pain and less than daily Moderate pain and daily experience Moderate pain and less than daily Mild pain		208.80 89.70 101.30 48.20 23.20		373.00 272.90 58.10 16.30* 49.00		348.50 147.30* 47.10* 0.10* 31.20*	
Socio-Demographic Variables Age: 40–59 years <sup>a</sup> Age: 60 years and older <sup>a</sup> Gender: male <sup>b</sup> Education: high school completed <sup>c</sup> Education: university or higher <sup>c</sup> Income: €20,000 to €39,999 <sup>d</sup> Income: €40,000 and above <sup>d</sup> Income reporting declined	17.60 39.30 -27.00 3.20* -0.60* -3.80* -3.50* -17.60	17.40 38.80 -27.00 3.10* -0.20* -3.60* -3.11*	-43.30 -55.90 2.50* -34.60 -51.10 -11.40* 4.60* -14.90*	-43.30 -56.20 2.30* -34.70 -50.90 -11.50* 4.80* -14.80*	-26.50 -13.20* 11.00* -54.00 -59.40 0.90* 32.20* 10.70*	-27.10 -14.30* 11.40* -54.40 -59.40 1.40* 33.30* 10.60*	
Health Risk Behaviors BMI: Underweight <sup>e</sup> BMI: Overweight <sup>e</sup> BMI: Obese & morbidly obese <sup>e</sup> Current smoker <sup>f</sup> Alcohol user <sup>g</sup>	28.80 12.20 30.70 -5.90* 1.00*	28.90 12.00 30.20 -6.20* 0.80*	68.90 -4.60* 11.30* -2.40* -18.10*	68.80 -4.60* 11.20* -2.80* -18.40*	117.70 3.10* 2.50* -23.30* -26.20*	111.60* 2.90* 1.80* -23.60* -26.90*	
Morbidity/Comorbidity Status Charlson Comorbidity Index Alpha N	35.20 0.029 4992	34.80 0.029 4992	45.80 0.232 4992	45.10 0.232 4992	72.20 0.798 4992	71.60 0.798 4992	

All variables significant at 5% level except (\*).

Reference categories: #no pain reported in last month; age 18 to 39 years; bfemales; ont completed high school; dincome under €20,000; BMI normal weight; non-smoker; non-drinker.

utilization. This is, perhaps, the single most important finding from the present analysis. Compared to the other respondent characteristics, all of which have been shown to impact significantly on HRQoL measures and the utilization of healthcare resources, pain is by far the most important determinant.

Previous community assessments of pain have focused on the correlates of pain severity; but have often failed to include a no-pain control group. The presence of a control group is critical in any assessment of the societal burden of pain — whether it is in terms of HRQoL or healthcare resource utilization. This is seen in the Smith *et al.* assessment of the community impact of pain on HRQoL<sup>16</sup>. Compared to the majority of respondents who have not experienced pain in the last month, those with severe and frequent pain not only report a significantly lower HRQoL but also more frequent utilization of healthcare resources — notably in healthcare provider visits. These findings are echoed in the present analysis in the distribution of PCS, MCS and utility scores and in the patterns of resource utilization between the pain and no-pain groups. Of

interest, however, is the differential impact of pain on PCS and MCS scores where pain has a substantially greater impact on the former.

What has not been noted before in assessing the burden of pain, however, is the importance of separately identifying the severity and the frequency of pain. Focusing on pain severity levels is only part of the picture. The frequency with which pain is experienced can add dramatically to associated HRQoL deficits and the burden placed upon the healthcare system. Note that the majority of those reporting severe pain in Spain do so on a daily basis (40.27%). A major contribution of the present analysis is to provide robust estimates of the contribution of pain frequency in a framework which not only attempts to standardize for other pain correlates but also points to the dominant impact of pain severity and frequency on these outcomes. Indeed, the analysis points unequivocally to the overriding impact of pain and its frequency on HRQoL and resource utilization compared to the no-pain population in terms of both the presence of health risk behaviors and major comorbidities.

It should also be noted that the models presented here have not attempted to isolate the factors associated with the reported pain severity and frequency. Given the fact that severe and frequent pain is characteristic of a number of disease states, including musculoskeletal conditions, the purpose here was to consider pain as it impacts both society and the utilization of resources. Pain is considered the focus of potential interventions, irrespective of its etiology. For this reason, no attempt has been made to separately analyze nociceptive as opposed to neuropathic pain or to analyze, for example, the societal impact of frequently reported low back pain or osteoarthritis pain, etc. Given the richness of the NHWS database, these more specific analyses will be the subject of future research.

There are some important implications of the present study. First, severe and frequent pain is pervasive and this fact is not well appreciated even by clinicians. The clear implication of these findings is known intuitively by most practicing clinicians, namely that much pain goes untreated or is under-treated, causing considerable suffering as well as possible lost productivity. Indeed, it is now becoming widely accepted that chronic pain must be considered a disease in its own right and that effective pain management is also to be seen as a fundamental human right <sup>36,37</sup>.

Second, the experience of pain is quantitatively different from the HRQoL deficits and patterns of healthcare resource utilization attributable to individual chronic disease states. Pain is both pervasive and pernicious in its impact, a fact that can often be overlooked where the focus is on individual disease states.

Third, from the perspective of society, a focus on pain may have significant payoffs in improving both HRQoL and reducing health resource utilization. Fewer and better managed pain patients will require fewer healthcare resources. Increased understanding of the mechanisms of pain and its safe and effective treatment could lead to more cost-effective management of pain patients as well as reducing chronicity in the long-term pain experience. As an example, failure to meet guidelines for acceptable wait times in pain management can lead to a significant deterioration in HRQoL<sup>38</sup>. This study demonstrates that a better appreciation of pain and its true costs is urgently needed, particularly by the clinical community, and could have a profound impact on healthcare resources in the near-term.

Even so, there are a number of limitations to the present study that should be noted. First, as an internet-based observational study, there is the possibility of bias in the responses as only persons with internet-access will be asked to participate. To this should be added the potential impact of recall bias. While the extent of such biases is unknown, it is worth noting that internet penetration in Spain is in excess of 50% of individuals and households. In the case of the sampling for Spain, the internet interviews

were supplemented by telephone interviews in the older population. Second, respondents are asked to report on their experience of pain. Apart from the potential impact of recall bias, there is no clinical confirmation of, for example, reported pain severity or frequency. Third, respondents are also asked to recall their use of healthcare resources; there is no independent check on the accuracy of these responses. Finally, this study has focused on the experience of pain. Apart from excluding more obvious acute pain types there is no attempt to try and impose an arbitrary distinction between acute and chronic pain or between, for example, primarily neuropathic and primarily nociceptive pain. Nor is it possible to assess pain chronicity.

#### **Conclusions**

This study represents a useful contribution to our understanding of the association of the experience of pain by Spanish adults and its relation to HRQoL and healthcare resource utilization. It is clear that pain, in terms of both its severity and frequency, is strongly associated with both of these attributes of the burden of disease. To date, there has been a lack of appreciation of the burden imposed by pain severity and frequency. This has been due, in large part, to the absence of well specified and robust multivariate models directed towards the assessment of the independent contribution of pain and its frequency at the country level. This study has demonstrated that for Spain the societal impact of pain is considerable. Pain outweighs by far the contribution of more traditional explanations of HRQoL deficits as well as being a key element in increased provider visits, emergency room visits and hospitalizations.

### **Transparency**

#### Declaration of interest

This study was supported by the Grünenthal Foundation, Spain.

#### Declaration of financial/other interests

PCL has disclosed he is a consultant for Kantar Health, a company that undertook the analysis for the Grünenthal Foundation, Spain. CPH, CMF, DRH and MLL all disclose they are consultants for Grünenthal Foundation, Spain.

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#### References

 Català E, Reig E, Artés M, et al. Prevalence of pain in the Spanish population; telephone survey in 5000 homes. Eur J Pain 2002;6:133-40

- 2. Carmona L, Ballina J, Gabriel R, et al. The burden of musculoskeletal diseases in the general population of Spain: results from a national survey. Ann Rheum Dis 2001:60:1040-45
- Fernández-de-las-Peñas C, Hernández-Barrera V, Alonso-Blanco C, et al. Prevalence of neck and low back pain in community-dwelling adults in Spain. Spine 2011:36:E213-19
- 4. Mas AJ, Carmona L, Valverde M, et al. Prevalence and impact of fibromyalgia on function and quality of life in individuals from the general population: results from a nationwide study in Spain. Clin Exp Rheumatol 2008:26:519-26
- 5. Pastor Mira M, Lledó Boyer A, López-Roig S, et al. Predictors of healthcare resource use in fibromyalgia. Psicothema 2010;22:549-55
- Garcia-Altés A. Pinilla J. Peiró S. An approach to 'quality-adjusted life years' quality of life weights from self-assessed health status. Gac Sanit 2006:20:457-64
- 7. Pérez C, Saldaña M, Navarro A, et al. Prevalence and characteristics of neuropathic pain in a primary-care setting in Spain; a cross-sectional. multicentre, observational study. Clin Drug Investig 2009;29:441-50
- Bassols A, Bosch F, Campillo M, et al. An epidemiological comparison of pain complaints in the general population of Catalonia (Spain). Pain 1999;83:9-16
- Miró J, Paredes S, Rull M, et al. Pain in older adults: a prevalence study in the Mediterranean region of Catalonia. Eur J Pain 2007;11:83-92
- Langley P, Ruiz-Iban M, Molina J, et al. The prevalence, correlates and treatment of pain in Spain. J Med Econ 2011;14:367-80
- 11. Breivik H, Collett B, Ventafridda V, et al. Survey of chronic pain in Europe: prevalence, impact on daily life and treatment. Eur J Pain 2006;10:287-333
- 12. Langley P. The prevalence, correlates and treatment of pain in the European Union. Curr Med Res Opin 2011;27:463-80
- 13. Langley P, Muller-Schwefe G, Nicolaou A, et al. The societal impact of pain in the European Union: health-related quality of life and healthcare resource utilization. J Med Econ 2010;13:571-81
- 14. Langley P, Muller-Schwefe G, Nicolaou A, et al. The impact of pain on labor force participation, absenteeism and presenteeism in the European Union. J Med Econ 2010:13:662-72
- 15. National Health and Wellness Survey. Available at: http:// www.chsinternational.com/
- 16. Smith BH, Elliott AM, Chambers WA, et al. The impact of chronic pain in the community. Fam Pract 2001;18:292-9
- Konig H. Bernert S. Angermeyer M et al. Comparison of population health status in six European countries: results of a representative survey using the EQ-5D questionnaire. Med Care 2009;47:255-61
- 18. Smith BH, Torrance N, Bennett MJ, et al. Health and quality of life associated with chronic pain of predominantly neuropathic origin in the community. Clin J Pain 2007;23:143-9
- 19. Jensen M, Chodroff M, Dworkin R. The impact of neuropathic pain on healthrelated quality of life: review and implications. Neurology 2007;68:1178-82
- Sadosky A, McDermott A, Brandenberg N, et al. A review of the epidemiology of painful diabetic peripheral neuropathy, postherpetic

- neuralgia, and less commonly studies neuropathic pain conditions. Pain Pract 2008:8:45-56
- 21. O'Connor A. Neuropathic pain: quality of life impact, costs and cost-effectiveness of therapy. Pharmacoeconomics 2009;27:95-112
- McDermot A, Toelle T, Rowbotham D, et al. The burden of neuropathic pain: results from a cross-section survey. Eur J Pain 2006;10:127-35
- 23. Ware JE, Kosinski M, Turner-Bowker DM, et al. How to score the version 2 of the SF-12 health survey (with a supplement documenting version 1). Lincoln, RI: Quality Metric Inc., 2002
- 24. Ware JE, Kosinski M, Keller SD. A 12-item short-form health survey (SF-12): construction of scales and preliminary tests of reliability and validity. Med Care 1996;32:220-33
- Ware JE. Kosinski M. Keller SD. SF-12: How to Score the SF-12 Physical and Mental Health Summary Scales. Lincoln, RI: QualityMetric Inc., 3rd, 1998
- 26. Brazier, JE, Roberts, JR. The estimation of a preference-based index from the SF-12. Med Care 2004:42:851-9
- 27. McCabe C, Brazier JE, Gilks P, et al. Using rank data to estimate health state utility models. J Health Econ 2006;25:418-31
- Kharroubi S, Brazier JE, Roberts JR, et al. Modelling SF-6D health state preference data using a nonparametric Bayesian method. J Health Econ 2007;26:597-612
- Regidor E, Barrio G, de la Fuente L, et al. Association between educational level and health related quality of life in Spanish adults. J Epidemiol Community Health 1999;53:75-82
- 30. Soltoft F, Hammer M, Kragh N. The association of body mass index and health related quality of life in the general population: data from the 2003 Health Survey of England. Qual Life Res 2009;18:1293-9
- 31. Sarna L, Bialous SA, Cooley ME, et al. Impact of smoking and smoking cessation on health-related quality of life in the Nurses' Health Study. Qual Life Res 2008;17:1217-27
- McClave AK, Dube R, Strine TW, et al. Associations between health-related quality of life and smoking status among a large sample of US adults. V Med 2009:48:173-9
- Stranges S, Notaro J, Freudenheim JL, et al. Alcohol drinking patterns and subjective health in a population-based study. Addiction 2006;101:1265-76
- Van Dijk AP, Toel J, Verdumen JE. The relationship between health-related quality of life and two measures of alcohol consumption. J Stud Alcohol 2004;65:241-9
- Charlson ME, Pompei P, Ales KL, et al. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. J Chronic Dis 1987:40:373-83
- 36. Niv D, Devor M. Chronic pain as a disease in its own right. Pain Practice 2004;4:179-81
- 37. Brennan F, Carr D, Cousins M. Pain management: a fundamental human right. Anesthesia Analgesia 2007;105:205-21
- Lynch M, Campbell F, Clark A, et al. A systematic review of the effect of waiting for treatment of chronic pain. Pain 2008;136:97-116