Persistent Pain and Well-being

A World Health Organization Study in Primary Care

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Context.—There is little information on the extent of persistent pain across cultures. Even though pain is a common reason for seeking health care, information on the frequency and impacts of persistent pain among primary care patients is inadequate.

Objective.—To assess the prevalence and impact of persistent pain among primary care patients.

Design and Setting.—Survey data were collected from representative samples of primary care patients as part of the World Health Organization Collaborative Study of Psychological Problems in General Health Care, conducted in 15 centers in Asia, Africa, Europe, and the Americas.

Participants.—Consecutive primary care attendees between the age of majority (typically 18 years) and 65 years were screened (n = 25 916) and stratified random samples interviewed (n = 5438).

Main Outcome Measures.—Persistent pain, defined as pain present most of the time for a period of 6 months or more during the prior year, and psychological illness were assessed by the Composite International Diagnostic Interview. Disability was assessed by the Groningen Social Disability Schedule and by activity-limitation days in the prior month.

Results.—Across all 15 centers, 22% of primary care patients reported persistent pain, but there was wide variation in prevalence rates across centers (range, 5.5%-33.0%). Relative to patients without persistent pain, pain sufferers were more likely to have an anxiety or depressive disorder (adjusted odds ratio [OR], 4.14; 95% confidence interval [CI], 3.52-4.86), to experience significant activity limitations (adjusted OR, 1.63; 95% CI, 1.41-1.89), and to have unfavorable health perceptions (adjusted OR, 1.26; 95% CI, 1.07-1.49). The relationship between psychological disorder and persistent pain was observed in every center, while the relationship between disability and persistent pain was inconsistent across centers.

Conclusions.—Persistent pain was a commonly reported health problem among primary care patients and was consistently associated with psychological illness across centers. Large variation in frequency and the inconsistent relationship between persistent pain and disability across centers suggests caution in drawing conclusions about the role of culture in shaping responses to persistent pain when comparisons are based on patient samples drawn from a limited number of health care settings in each culture.

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PAIN is one of the most common[1] and among the most personally compelling reasons for seeking medical attention. People seek health care for pain not only for diagnostic evaluation and symptom relief, but also because pain interferes with daily activities, causes worry and emotional distress, and undermines confidence in one's health. When pain persists for weeks or months, its broader effects on well-being can be profound. Psychological health and performance of social responsibilities in work and family life can be significantly impaired.[2]

Despite evidence that pain affects well-being, little is known about how common persistent pain is among primary care patients. There is evidence that the effects of persistent pain on psychological health and functional status are similar for pain problems at different anatomical sites.[3] However, it is not known whether impaired emotional well-being and increased disability are consistent correlates of persistent pain, or whether the impacts of persistent pain on well-being are consistent across cultures. Several recent studies have compared pain perceptions and coping across cultures,[4-6] but cross-cultural research on pain has typically studied relatively small numbers of patients in convenience samples. Comparison groups of pain-free controls have often been lacking.

This article reports data from a World Health Organization (WHO) survey of primary care patients, the WHO Collaborative Study of Psychological Problems in General Health Care.[7] As part of a broader assessment of health and mental health status, this cross-national survey collected information on persistent pain. This report estimates the prevalence of persistent pain among primary care patients in different countries, and determines the association of persistent pain with health perceptions, psychological distress, and activity limitations. (*Persistent pain* was defined as pain present most of the time for a period of 6 months or more during the prior year.) This article provides the first cross-national data on the prevalence of persistent pain among primary care patients, and is also the first large-scale cross-national study to assess whether persistent pain shows consistent relationships to impaired well-being and functioning among primary care patients in many different countries. While this study was not designed or intended to test specific hypotheses about cross-cultural differences in the prevalence or impacts of persistent pain, it provides new information on the frequency and the impacts of persistent pain among primary care patients in a range of cultural settings.

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METHODS

The WHO Collaborative Study of Psychological Problems in General Health Care was conducted at 15 centers in 14 countries.[7,8] A detailed account of the methods of this study is provided elsewhere[9]; results from this study concerning the relationship between psychological illness and disability were previously reported in this journal.[10] The 15 participating centers in 14 different countries were selected to represent broad diversity of culture and socioeconomic development. Centers were selected on the basis of previous successful collaboration with WHO, experience with research in primary care settings, access to primary care patient populations, availability of appropriately skilled personnel to ensure full adherence to the study protocol, and approval for the study by local ethics committees. Each center was required to identify health care facilities that could be regarded as prototypical of primary health care services in that country.

The study population was consecutive patients attending the participating primary care facilities, including both new and returning patients. Patients were included if they were between the age of majority (typically 18 years) and 65 years. Eligible subjects were not too ill to participate, had a fixed address, were attending the clinic for a medical consultation, and gave informed consent. Information on the presenting problems of patients enrolled in the study is presented for each center elsewhere.[7] The 12-item General Health Questionnaire (GHQ)[11] was administered as a screening instrument to obtain a stratified random sample in which patients who were psychologically distressed were sampled with higher probability than patients who were not distressed.

A total of 25 916 patients were successfully screened. This represented a response rate of 96%. Patients were selected for the second-stage assessment using stratified random sampling based on their GHQ score. Using center-specific GHQ score norms determined from a large pilot test in each center,[9] patients were placed in a low GHQ score stratum (approximately 60% of consecutive patients in a particular center), a medium GHQ score stratum (20% of patients), or a high GHQ score stratum (20% of patients). The high GHQ score stratum corresponds to a moderate to severe level of psychological distress, the medium GHQ stratum to a mild level of distress, and the low GHQ score stratum to a low level of psychological distress. All high GHQ scorers, 35% of medium GHQ scorers, and 10% of low GHQ scorers were randomly sampled for the second-stage assessments. The analysis of data from this stratified random sampling scheme was weighted taking the sample selection probabilities in each stratum into account (as explained below), so that unbiased estimates were obtained for the population of consecutive primary care attendees in each center. Sampled patients were interviewed at a place of their choice, commonly their home. Of 8729 eligible patients, 5447 completed the second-stage assessments (average response rate, 62%).

Assessment

Patients sampled for the second-stage evaluation were assessed by highly trained interviewers using the WHO primary care version of the Composite International Diagnostic Interview (CIDI).[12] This version assessed persistent pain in addition to identifying psychological disorders (eg, anxiety and depressive disorders) defined according to *International Statistical Classification of Diseases, 10th Revision* (*ICD-10*)[13] diagnostic criteria. Using this questionnaire, a *pain problem* was defined as current and persistent if pain was present most of the time for a period of 6 months or more during the prior year. To eliminate insignificant aches and pains, patients needed to report that at some time during their lifetime they talked to either a physician or other health professional about the pain, had taken medication for the pain more than once, or had reported that the pain had interfered with life or activities a lot. Although the CIDI obtained ratings of whether persistent pain was "medically explained" or not, these ratings were ignored for the purposes of this report. Review of these ratings indicated that the ratings of what conditions were medically explained were inconsistent across centers. Moreover, understanding the frequency of persistent pain is clinically important whether the pain is medically explained or not.

Disability was assessed using the "Occupational Role" section of the Social Disability Schedule (SDS).[14] The SDS is a semistructured interview that rates disability on the basis of work role performance relative to cultural expectations. Daily work activities (including gainful employment, volunteer work, or housekeeping), activities directed at securing a job for individuals not employed (study and job searching), and the structuring of daily activities for retired individuals were assessed. Interviewer ratings were made on a 4-point scale: 0 (no disability), 1 (mild disability), 2 (moderate disability), and 3 (severe disability). Interviewer-observer reliability of the SDS occupational role was assessed with 19 videotaped interviews circulated across the centers. An overall κ of 0.85 was obtained, with a range of 0.72 and 0.93 on items.[9] In addition, each subject was asked the number of days in the previous month they had been unable to carry out their usual activities.[15] Patients rated their overall health status as excellent, very good, good, fair, or poor.

The physician seeing each patient in the sample completed an encounter form that included a rating of the patient's physical health status at the time of the visit. Patients were rated by their physicians as completely healthy, having some symptoms but subclinical physical illness, mild physical illness, moderate physical illness, or severe physical illness. All participating physicians were instructed in the use of the encounter form in practice sessions with the local investigators. These ratings were used to control for severity of physical illness in multivariate analyses.

At non–English-speaking centers, questionnaires were translated by a panel of local bilingual experts. Back-translations to English were checked centrally at WHO. At least 1 English-speaking investigator from every center participated in a 5-day joint training session in the use of the instruments. In general, the interviewers who assessed study subjects had mental health training and experience.

Data Analysis

Because this study used a stratified random sampling plan, the estimates we report are based on weighted data. Weighted data from the second-stage assessment provide unbiased estimates for the base population of consecutive primary care attendees. The weighting accounts for the stratified sampling scheme and differentials in response rate by GHQ stratum, sex, and center to control nonresponse bias associated with these variables.[9]

Whether there was greater variation in the prevalence rate of persistent pain across centers than expected by chance was evaluated by a Wald statistic estimated for the center indicator variables from a logistic regression model that controlled for age and sex. Odds ratios (ORs) estimating the effect of sex (women vs men) and their confidence intervals (CIs) were estimated for each center and for all centers combined. Whether ORs differed from unity more than expected by chance was evaluated by the Wald statistic. Using logistic regression, we contrasted the rates of having the impairments of interest (eg, work disability) for persons with persistent

Table 1.—Subjects With Persistent Pain by Sex, World Health Organization Psychological Problems in General Health Care Survey, 1991-1992 (Weighted Data)

Participating Center (No. of Cases/No. of Subjects)	Men, % (n = 1919)	Women, % (n = 3519)	All Patients, % (n = 5438)	Adjusted OR (95% CI)*	P
Santiago, Chile (130/274)	13.5	40.8	33.0	3.87 (1.87-8.02)	<.001
Berlin, Germany (140/400)	27.1	36.8	32.8	1.44 (0.92-2.26)	.11
Rio de Janeiro, Brazil (149/393)	17.6	35.8	30.8	2.38 (1.36-4.18)	.002
Ankara, Turkey (154/400)	21.1	32.9	28.9	1.77 (1.08-2.93)	.02
Paris, France (124/405)	16.9	37.3	26.5	3.15 (1.96-5.06)	<.001
Mainz, Germany (130/400)	28.5	24.7	26.3	0.86 (0.55-1.35)	.51
Groningen, the Netherlands (127/340)	19.7	29.3	25.5	1.84 (1.06-3.20)	.03
Manchester, England (149/428)	26.4	18.1	20.7	0.68 (0.41-1.11)	.12
Bangalore, India (109/398)	14.1	23.8	19.0	1.53 (0.89-2.62)	.13
Seattle, Wash (88/373)	9.4	21.2	17.3	2.80 (1.40-5.61)	.004
Verona, Italy (49/250)	3.9	18.6	13.3	5.81 (1.90-17.82)	.002
Shanghai, China (106/576)	8.7	14.9	12.6	1.97 (1.11-3.50)	.02
Athens, Greece (34/196)	5.4	15.5	12.0	3.47 (1.06-11.33)	.04
Nagasaki, Japan (53/336)	9.2	14.2	11.8	1.68 (0.84-3.37)	.14
Ibadan, Nigeria (27/269)	6.2	5.3	5.5	0.92 (0.28-2.95)	.88
All centers (1569/5438)	16.2	24.8	21.5	1.69 (1.47-1.95)	<.001

*The adjusted odds ratio (OR) measures the risk of having persistent pain among women relative to the risk of persistent pain among men, after adjusting for age. The all centers OR was adjusted for age and center. CI indicates confidence interval.

pain vs those without persistent pain after controlling for center, sex, age, physician-rated physical health status, and whether a CIDI-diagnosed anxiety or depressive disorder was present in the prior month. For these analyses, we report the estimated ORs, CIs, and *P* values for all centers combined. In addition, we report the percentage with each impairment comparing patients with and without persistent pain for each center, and indicate whether the difference was greater than expected by chance at the .05 significance level for a 2-sided test. These significance tests were based on Wald statistics from logistic regression models controlling for age, sex, physician-rated severity of physical disease, and the presence of a depressive or anxiety disorder.

RESULTS

Prevalence of Persistent Pain

Persistent pain was common among primary care patients across a wide range of settings in different countries. The prevalence of persistent pain for all centers combined was 21.5%, with prevalence rates varying from 5% to 33%. Sex-specific prevalence rates are shown in Table 1, with the centers ordered from the highest overall prevalence rate to the lowest. The difference in prevalence rates across centers was highly significant after adjusting for age and sex (Wald statistic = 217.7, df = 14, P<.001).

Among the European centers, Athens, Greece (12%), and Verona, Italy (13%), had relatively low prevalence rates, while the remaining centers in Germany, France, the Netherlands, and England were found to have persistent pain prevalence rates in excess of 20%. The 2 Asian centers (Nagasaki, Japan, and Shanghai, China) had relatively low prevalence rates of persistent pain (12% and 13%, respectively), while the 2 South American centers (Rio de Janeiro, Brazil, and Santiago, Chile) had relatively high prevalence rates (31% and 33%, respectively). The center in Ibadan, Nigeria, had the lowest prevalence rates of persistent pain of any center for both men and women.

As shown in Table 1, persistent pain was significantly more common among women than men based on a pooled estimate for the 15 participating centers, with 25% of women compared with 16% of men reporting persistent pain. After adjusting for age, the prevalence of persistent pain was significantly higher among women than men in 9 of the 15 centers.

Anatomical Site

As shown in Table 2, among patients with persistent pain, the 3 most commonly reported anatomical pain sites (in order of frequency) were back pain, headache, and joint pain. The large majority (68%) of primary care patients with persistent pain reported pain in at least 2 anatomical sites (Table 2). Because pain was typically reported at multiple sites, the remaining analyses concern persistent pain without differentiation by anatomical site.

Persistent Pain and Well-being

Persons with persistent pain were substantially more likely to have an anxiety or depressive disorder meeting *ICD-10* diagnostic criteria than persons not experiencing persistent pain (Table 3). After adjusting for center, age, sex, and physician-rated severity of physical disease, the odds of having a psychological disorder meeting diagnostic criteria among persons with persistent pain showed a 4-fold increase over those not affected by persistent pain. The association of persistent pain was not specific to depression, as both anxiety and depressive disorders showed a comparable association with persistent pain.[16]

Table 2.—Subjects Reporting Current Pain at Different Anatomical Sites and the Number of Anatomical Sites With Pain Among Subjects With Persistent Pain, World Health Organization Psychological Problems in General Health Care Survey, 1991-1992 (Weighted Data)

Variable	Subjects Reporting Current Pain, %
Anatomical site	
Back pain	47.8
Headache	45.2
Joint pain	41.7
Arms or legs	34.3
Chest	28.9
Abdominal pain	24.9
Pain elsewhere	11.7
No. of anatomical sites	
1	32.1
2	27.5
3	22.8
≥4	17.5

For all 15 centers combined, the presence of persistent pain was associated with a modest increase in the likelihood of patients rating their overall health as fair or poor (Table 3). Unfavorable health perceptions were reported by 33% of those with persistent pain compared with 21% of those without persistent pain.

Work role disability was assessed by a semistructured interview protocol taking cultural norms into account in determining the extent of disability.[14] Across the participating centers, 31% of those with persistent pain were rated as having moderate to severe work role interference, compared with 13% among those without persistent pain. After adjusting for center, age, sex, psychological disorder status, and physician-rated severity of physical disease, the odds of work disability showed a 2-fold increase among those with persistent pain (Table 3). Simi-

larly, for data pooled across centers, patients with persistent pain were more likely to report 3 or more days in the prior month when they were unable to carry out their usual activities (Table 3).

Consistency of Results Across Centers

We examined the consistency of differences in psychological disorder, self-rated health, work role disability, and activity-limitation days for persons with and without persistent pain across the participating centers (Table 4). For all 15 centers, the difference in the percentage of patients with a depressive or anxiety disorder between patients with and without persistent pain was statistically significant. In contrast, the association of unfavorable ratings of health status with persistent pain was less robust across centers. This difference was statistically significant for only 5 of the 15 centers (significant differences are indicated by numbers in boldface type in Table 4). Interviewer-rated work disability was significantly more common among those with persistent pain for 5 of the 15 centers, and patients with persistent pain were significantly more likely to report 3 or more days of activity limitation in the prior month for 6 of the 15 centers. For the centers with nonsignificant differences in work disability or in activity-limitation days between those with and without persistent pain, patients with persistent pain almost always had a higher percentage with activity limitation than patients without persistent pain.

COMMENT

This is the first large-scale cross-national study of persistent pain among primary care patients in which standard methods were applied to estimate its prevalence and impacts in a wide range of countries. Even though there was substantial variation in prevalence rates across centers, persistent pain was a common problem among patients consulting primary care physicians in every participating center. It should be noted that the patients eligible for this study were seeking professional health care, and that the care settings were generally in urban areas. Persons seeking health care are likely to have higher prevalence rates of persistent pain than a general population sample. In addition, the patient populations studied may differ from those seeking services from traditional providers or from persons seeking health care in rural areas. However, the kinds of primary care settings included in this study provide health care services to large segments of the population in each of the countries included in this study.

This study was not designed to explain cross-cultural differences in the prevalence or cross-cultural differences in the impact of persistent pain. However, the large variation in rates of occurrence of persistent pain across centers, the inconsistency in the relationship between persistent pain and disability, and the lack of a readily explainable pattern for the variation in results should give pause. This variability, and the lack of any clear pattern to the variation across centers, suggests that it may be difficult to draw meaningful conclusions about cultural differences from samples of patients drawn from a limited number of health care settings in each culture being studied. Prior cross-cultural research on chronic pain has often used samples of pain patients smaller than the numbers available for the individual centers participating in this study. In this study, 10 of the 15 participating centers had over 100 patients with persistent pain (Table 1). Most prior cross-national studies of pain patients

Table 3.—Indicated Quality-of-Life Impairment by Persistent Pain Status and the Adjusted Odds Ratio (OR) for Impairment for Persons With vs Without Persistent Pain, World Health Organization Psychological Problems in General Health Care Survey, 1991-1992 (Weighted Data)

Quality of Life Impairment	Persistent Pain Present, %	Persistent Pain Absent, %	Adjusted OR (95% CI)*	*P*
ICD-10 definition of anxiety or depressive disorder†	33.7	10.1	4.14 (3.52-4.86)	<.001
Health status rated fair to poor‡	33.4	20.9	1.26 (1.07-1.49)	.006
Interviewer-rated interference with work performance‡	31.4	13.0	2.12 (1.79-2.51)	<.001
≥3 Activity-limitation days in prior month‡	41.2	26.0	1.63 (1.41-1.89)	<.001

*The adjusted OR measures the risk of the indicated form of impairment among persons with persistent pain relative to those without persistent pain, after adjusting for covariates. CI indicates confidence interval.

†The ORs were adjusted for center, age, sex, and physician-rated severity of physical disease. *ICD-10* indicates *International Statistical Classification of Diseases, 10th Revision.*

‡The ORs were adjusted for center, age, sex, physician-rated severity of physical disease, and presence of an anxiety or depressive disorder.

Table 4.—Indicated Quality-of-Life Impairment Comparing Persons With and Without Persistent Pain, World Health Organization Psychological Problems in General Health Care Survey, 1991-1992 (Weighted Data)*

	Depressive or Anxiety Disorder		Health Rated Fair to Poor		Interviewer-Rated Work Interference		≥3 Activity-Limitation Days	
Participating Center	With Pain, %	Without Pain, %	With Pain, %	Without Pain, %	With Pain, %	Without Pain, %	With Pain, %	Without Pain, %
Santiago, Chile	**60.1**	**27.9**	**31.5**	**13.3**	25.5	13.1	9.0	12.0
Berlin, Germany	**23.1**	**8.8**	**48.1**	**24.0**	22.1	15.4	38.5	26.5
Rio de Janeiro, Brazil	**52.5**	**20.1**	11.6	11.9	15.2	13.2	38.7	28.4
Ankara, Turkey	**29.4**	**5.3**	46.9	27.2	13.1	3.1	39.3	22.8
Paris, France	**34.7**	**15.8**	22.8	12.8	19.4	13.6	27.4	22.6
Mainz, Germany	**27.6**	**11.5**	51.4	37.8	**37.7**	**18.3**	50.3	33.1
Groningen, the Netherlands	**37.8**	**10.6**	22.3	10.5	**51.1**	**20.7**	42.7	35.7
Manchester, England	**41.0**	**14.5**	**36.7**	**11.3**	**100.0**	**8.6**	**71.8**	**29.9**
Bangalore, India	**36.0**	**9.3**	43.1	29.5	**33.5**	**11.9**	**61.5**	**37.9**
Seattle, Wash	**18.5**	**5.4**	**27.8**	**5.4**	22.6	6.0	**48.8**	**20.7**
Verona, Italy	**27.5**	**4.0**	**40.9**	**29.7**	11.9	7.5	23.5	16.3
Shanghai, China	**13.3**	**3.9**	21.8	26.5	28.9	16.8	**31.6**	**17.0**
Athens, Greece	**39.1**	**14.6**	8.3	12.8	25.7	8.5	**53.5**	**25.2**
Nagasaki, Japan	**12.8**	**5.8**	44.1	38.1	**37.0**	**9.3**	**49.6**	**21.7**
Ibadan, Nigeria	**26.7**	**5.2**	6.9	13.3	21.4	26.6	46.7	40.6
All centers	**33.7**	**10.1**	**33.4**	**20.9**	**31.4**	**13.0**	**41.2**	**26.0**

*Percentages in boldface type indicate that the percentage with the indicated quality-of-life impairment among persons with persistent pain exceeds those without persistent pain at $P<.05$, for a 2-sided test. Significance of differences between persons with and without persistent pain was tested by logistic regression adjusting for age, sex, physician-rated severity of physical disease, and (except for the comparison for psychological illness) the presence of a depressive or anxiety disorder.

have sampled patients from a limited number of health care settings and have lacked a pain-free control group. This points to the difficulty in differentiating true cultural differences from other sources of variation not related to culture. Sources of variation that could be confused with cultural differences may include random variation, variation due to sociodemographic differences, variation due to characteristics of the particular care settings included, and variation in the application of study methods across centers.

Differences in prevalence rates from surveys in different countries are often difficult to compare because of lack of comparability of study methods.[17,18] In this study, uniform sampling and assessment procedures were used to reduce variation due to study methods. However, it is difficult to guarantee uniform application of study methods in a widely dispersed multicenter study conducted in many different languages. It was only possible to study a limited number of care settings in each locale, so differences due to care setting are confounded with cultural differences. For these reasons, our results regarding differences in prevalence and impacts of persistent pain between countries are exploratory. While the differences in prevalence rates across centers were statistically significant after controlling for age and sex differences, this variation may be due to sociodemographic, care setting, and/or methodological differences rather than culture.

The observation that women tended to have elevated rates of persistent pain relative to men has been reported by others.[17-20] This study does not shed light on reasons for this sex difference, other than to suggest that it is not unique to Western societies. Prior research has suggested sex differences in pain prevalence for some anatomical sites and not for others,[19,20] but this study did not examine site-specific prevalence rates by sex.

Overall, persistent pain was associated with marked reductions in several different indicators of well-being, particularly psychological illness and interference with activities. Differences in self-rated health status were of smaller magnitude, although they were statistically significant for all centers combined. In the pooled analysis, patients with persistent pain were more likely to have impaired work role functioning and to have missed 3 or more days from their usual activities in the prior month. While patients with persistent pain were more disabled than those without persistent pain overall, this association was not consistently statistically significant across the participating centers. However, the trend was in the same direction in almost every center for both disability measures.

The commonly reported association of persistent pain with psychological illness[16,17,21,22] was confirmed by this study. A significant association was found in every participating center. This study does not address the direction of causality between persistent pain and affective illness. Prior studies have yielded differing results on this question.[16,23,24] The results of this study indicate that psychological disorder is a common correlate of persistent pain, and that this association is observed in a wide range of cultural settings.

In conclusion, persistent pain was common among primary care patients in many different cultures. Across all centers, persistent pain was associated with psychological disturbance and significant activity limitations. Further research is needed to better understand cross-national variation in the prevalence of persistent pain, and variation in the effects of persistent pain on well-being and functioning. The results of this study point to the difficulty in drawing conclusions about cultural differences in the frequency or the impacts of persistent pain from modest samples of pain patients sampled from a limited number of care settings in a particular culture. While further research is needed, this study shows that persistent pain is a common problem among primary care patients in a wide range of cultural settings.

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study suspect. I have coauthored publications and presented abstracts based on pharmaceutical industry–sponsored clinical trials for more than a decade. In no case were the results misrepresented. The articles cited by Barnes and Bero do not support their conclusion because of selection bias that is so different from the careful methods they used to support the primary claim of their article.

Pharmaceutical data are scrutinized by the US Food and Drug Administration (FDA) to a degree that is unimaginable to those outside the industry. When a study is used to gain approval for a drug indication, the FDA reviews all of the data, conducts independent analyses of the data, audits the sites from which the data were gathered, verifies that the data have been accurately reported, and often presents its findings publicly at advisory committees. The FDA audit reports are public information.

Although authors often question the integrity of pharmaceutically sponsored research, the integrity of research sponsored by governmental or other private organizations is rarely questioned. Ignoring the possibility that the granting agencies may have specific agendas for the research they sponsor, there are substantial pressures on scientists to publish and a well-known bias against publication of negative data. I wonder how publications not sponsored by the pharmaceutical industry would stand up to FDA-style scrutiny.

To the shame of the pharmaceutical industry, some companies have suppressed data from publication[4] or published data in a manner not consistent with that reviewed by the FDA.[5] Such cases have become public embarrassments that received widespread coverage in the popular press. These examples are the exception, not the rule. Physicians and the public should be assured of the validity of pharmaceutical clinical research and of the integrity of those who conduct and oversee it.

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1. Barnes DE, Bero LA. Why review articles on the health effects of passive smoking reach different conclusions. *JAMA*. 1998;279:1566-1570.
2. Cho MK, Bero LA. The quality of drug studies published in symposium proceedings. *Ann Intern Med*. 1996;124:485-489.
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In Reply.—Every independent scientific body that has reviewed the scientific evidence has concluded that exposure to passive smoke is harmful to health.[1] As the title of our article suggests, the goal of our study was to determine why many published review articles reach conclusions that differ from these independent scientific bodies. We investigated several factors in addition to quality and funding source that might be associated with outcome, including peer review, date of publication, and topic of review. The only factor associated with the conclusion of a review article was the affiliation of its author: 94% of reviews by tobacco industry–affiliated authors concluded that passive smoking is not harmful compared with 13% of reviews by authors without tobacco-industry affiliations.

We did not define tobacco-industry affiliation "generously," as Dr Heck states. Rather, we used strict, well-defined criteria: an author must have received funding from the tobacco industry, submitted a statement on behalf of the tobacco industry regarding the Environmental Protection Agency's risk assessment on passive smoking, or participated in (not simply attended, as misstated by Heck) at least 2 tobacco-industry–sponsored symposia. Moreover, our data are not "testament to the legitimate diversity of scientific opinion on the topic of ETS," as Heck suggests. Rather, our findings suggest that, among scientists who are not affiliated with the tobacco industry, there is consensus that passive smoking is harmful. The only diversity of opinion comes from the authors with tobacco-industry affiliations.

Dr Gorelick takes issue with 2 articles we cited to support our statement that original research articles sponsored by the pharmaceutical industry tend to draw proindustry conclusions. A careful reading of both articles reveals that they do support our statement. The article by Cho and Bero[2] did not examine "only articles from symposia sponsored by single drug companies." It examined 127 articles from symposia (of which 39% were sponsored by a single drug company) and 45 articles from peer-reviewed journals: 98% of the articles with drug company support favored the drug of interest compared with 79% of the articles without drug company support ($P<.01$).

In the article by Rochon et al,[3] the analysis was limited to manufacturer-associated trials due to "the scarcity of nonmanufacturer-associated trials." However, the authors found that the manufacturer-associated drug was reported as comparable or superior to the comparison drug in all cases and that the claims often were not supported by trial data.

We do not suggest that industry-sponsored research is always biased. However, to our knowledge, every study that has examined the relationship between sponsorship and outcomes has found that industry-sponsored research is more likely to draw proindustry conclusions than non–industry-sponsored research. We recommend that financial interests always should be disclosed and that readers of research articles should consider these disclosures when deciding how to judge an article's conclusions.

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1. Barnes DE, Bero LA. Why review articles on the health effects of passive smoking reach different conclusions. *JAMA*. 1998;279:1566-1570.
2. Cho MK, Bero LA. The quality of drug studies published in symposium proceedings. *Ann Intern Med*. 1996;124:485-489.
3. Rochon PA, Gurwitz JH, Simms RW, et al. A study of manufacturer-supported trials of nonsteroidal anti-inflammatory drugs in the treatment of arthritis. *Arch Intern Med*. 1994;154:157-163.

CORRECTION

Incorrect *P* Value.—An error occurred in the Original Contribution entitled "Persistent Pain and Well-being: A World Health Organization Study in Primary Care," published in the July 8, 1998, issue of THE JOURNAL (1998;280:147-151). On page 150, in Table 4, the *P* value in the first footnote should be $P<.05$ [not $P>.05$].