



United States National Pain Strategy for Population Research: Concepts, Definitions, and Pilot Data

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Abstract: National Pain Strategy population research objectives include: estimating chronic pain prevalence, studying pain treatment with electronic health care data, and developing metrics to assess progress in reducing chronic pain impact. In this article, the National Pain Strategy Population Research Workgroup reviews concepts relevant to achieving these aims. High-impact chronic pain was defined as persistent pain with substantial restriction of life activities lasting 6 months or more. In pilot work, we tested a brief assessment of high-impact chronic pain, and used electronic health records data to describe pain-related health care. A mail survey of adult health plan enrollees (N = 770) reported that 14% had high-impact chronic pain. Relative to persons with lower-impact chronic pain, those with high-impact chronic pain were more often frequent users of health care for pain, reported lower quality of life, greater pain-related interference with activities, and more often reported pain at multiple anatomic locations. Analyses of health care data (N = 289,464) reported that pain patients had higher health care costs compared with others and that pain services were typically delivered in primary care. These results support the feasibility of developing data on chronic pain through national health interview surveys and large electronic health care databases.

Perspective: Pilot analyses supported the feasibility of brief chronic pain assessments suitable for national health surveys and use of electronic health care databases to develop data regarding trends

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in the delivery of pain treatments, costs, and effectiveness. These methods are relevant to achieving the aims of the US National Pain Strategy.

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In 2016, the United States' Department of Health and Human Services and the Interagency Pain Research Coordinating Committee of the National Institutes of Health (NIH) released the National Pain Strategy.⁵ The development of the National Pain Strategy was undertaken by an oversight committee and 5 working groups, each tasked with addressing 1 thematically defined area related to pain. The strategy seeks to "provide a comprehensive, population health-level strategy for pain prevention, treatment, management, education, reimbursement, and research that includes specific goals, actions, time frames and resources."⁵ Further, it concluded that, "Understanding the significance of health problems in a population is a core public health responsibility."

The Population Research Working Group convened for the National Pain Strategy developed plans for addressing key research issues including: how to increase the precision of information about chronic pain prevalence overall, for specific types of pain, and in specific population groups; how to develop the capacity to gather information electronically about pain treatments, their usage, costs, and effectiveness; and, how to track changes in pain prevalence, impact, and treatment over time, allowing evaluation of population-level interventions and identification of emerging needs. Specifically, the National Pain Strategy sets 3 objectives for population research:

1. Estimate the prevalence and incidence of chronic pain and high-impact chronic pain in the general population and in primary care settings.
2. Refine and use standardized electronic health care data methods to determine the extent to which people with common pain conditions, including those from vulnerable groups, receive various treatments and services, the costs of those services, and the extent of use of treatments that best evidence suggests are underused, overused, effective, and ineffective.
3. Develop a system of metrics for tracking changes in pain prevalence, impact, treatment, and costs over time that will enable assessment of progress, evaluation of the effectiveness of interventions at the population health level, and identification of emerging needs.

Population data can be used to evaluate the effectiveness of preventive interventions to ameliorate the impact of chronic pain, including primary prevention (efforts to reduce conditions that may result in pain), secondary prevention (interventions designed to reduce the likelihood that acute pain transitions into chronic pain or to shorten the duration of chronic pain via early identification and effective treatment), and tertiary prevention (interventions that limit the development of disabilities and other complications of chronic pain after it has developed).

Such interventions may include public policy initiatives, demonstration projects in the organization or reimbursement of care, interventions intended to reduce the impact of chronic pain on a population basis, or public education efforts, among others. Better data are needed on the impact of chronic pain and how persons with chronic pain are treated in the US population.

This article reviews the concepts and definitions underlying the National Pain Strategy for population research. In addition, we report pilot test data developed to inform initial steps taken to achieve these population research objectives.

Concepts and Definitions

The World Health Organization (WHO) International Classification of Function, Disability, and Health (ICF) considers determinants of health and disability from the perspective of the biopsychosocial model.⁴² The ICF has been used to assess a wide range of chronic pain conditions.^{18,30,31,35} The following ICF concepts and definitions⁴² are relevant to chronic pain assessment:

Impairments: Problems with body structure or function. Pain is an impairment.

Activities: An individual's execution of a task or action.

Activity limitations: Difficulties an individual may have in executing activities.

Participation: An individual's engagement in a life situation or social role.

Participation restrictions: Problems experienced in life situations or in social role engagement.

Three inter-related manifestations of chronic pain can be used to define its individual psychosocial and societal impacts: 1) pain perception, 2) pain-related activity limitation, and 3) pain-related participation restriction. Pain perceptions typically are assessed through measures of pain intensity or severity. Of course, individuals differ markedly in the degree to which pain severity interferes with life activities. For example, most people find long-lasting pain at moderate to severe intensity/interference levels, defined as 4 or greater on 0 to 10 rating scales, to be unacceptable.³⁴ Some, however, are able to minimize the effects on daily functioning of such levels of pain intensity. Therefore, to differentiate low-to-intermediate levels of chronic pain severity from highly disruptive chronic pain conditions, the association of pain intensity with pain-related activity limitations and participation restrictions must be considered.^{19,26,27,37}

Consistent with recommendations of the NIH Low Back Pain Research Taskforce,⁶ the Population Research Working Group defined chronic pain as "pain that occurs on at least half of the days for 6 months or more".

High-impact chronic pain was defined as persistent pain with "substantial restriction of participation in work, social, and self-care activities for 6 months or more."⁵

From an individual and societal perspective, it is essential to differentiate persons with less severe chronic pain from those with enduring participation restrictions in major life activities including work, social, recreational, and self-care activities. Persons with high-impact chronic pain account for a large share of the societal costs of chronic pain, and they bear the greatest personal costs. Although pain persistence or chronicity is important, it is only moderately correlated with pain-related interference with activities in general population samples.³⁷⁻⁴⁰ For these reasons, it is important to distinguish between persons with high-impact chronic pain and those for whom pain has less impact on engagement in life activities.

Over 40% of the adult population, an estimated 100 million Americans,¹² experiences chronic or recurrent pain.³³ However, fewer have severe, disabling chronic pain, with prevalence estimates ranging from 6% to 14% in general population samples.^{3,21} Further research is needed to clarify the prevalence of high-impact chronic pain in the population overall and in key groups (for example, in children and older adults). Research also is needed to identify the characteristics of those most likely to suffer from high-impact chronic pain. Finally, research is needed to determine how to reduce the impact of pain on people's lives, for the common chronic pain conditions affecting 40% or more of the general population, and for the less common but more severe and disabling chronic pain conditions.

Because persons with chronic pain may not necessarily seek treatment, it is important to measure the incidence, prevalence, and consequences of chronic pain in the general population and among those who seek health care. For the general population, morbidity surveys in representative population samples can help answer key questions:

How common is chronic pain in general? How common is high-impact chronic pain? Which population groups are most likely to develop chronic pain and/or high-impact chronic pain?

What are the societal and personal costs of chronic pain and high-impact chronic pain in terms of health care, activity limitations, disabilities, personal suffering, and reduced quality of life?

What are the most commonly treated chronic pain conditions? Which pain treatments are most commonly provided for these conditions? What are the costs and benefit to risk ratios of providing specific chronic pain treatments?

Which groups are more or less likely to receive effective services for chronic pain and for high-impact chronic pain? What explains these differences (eg, differences in pain severity, socioeconomic, or racial/ethnic disparities, differences in insurance coverage, differential accessibility of treatment services)?

The World Health Organization ICF model suggests that the individual and societal consequences of high-impact chronic pain may be reduced by interventions that prevent or reduce participation restrictions, even when pain perceptions cannot be substantially improved. However, well-intentioned interventions aimed at pain relief that, instead, occasion participation restrictions may be counter-productive. For example, unselective use of back surgery may result in significant participation restrictions without benefits for long-term pain outcomes.⁷ For this reason, evaluations of chronic pain treatments should consider over- and underused treatments, defined according to best evidence. Electronic health care data can elucidate how pain is being treated currently and can guide efforts to enhance the value of health care for chronic pain. Meta-analyses and structured reviews can clarify the usefulness of widely used pain treatments. Using all of these approaches, policy implications could be derived if over- or underused pain treatments were found to fit any of the following categories:

Overused, rarely effective: Treatments that are commonly used, but rarely effective for the condition(s) treated.

Overused, sometimes effective: Treatments that are commonly used, but that are appropriate only for carefully selected and treated patients (with specified criteria for appropriateness).

Underused and effective, but not cost-effective: Effective treatments that may be underused, but that need innovations in service delivery to improve cost-effectiveness.

Underused and cost-effective: Treatments that are currently cost-effective, but with barriers to wider use (eg, provider training, insurance coverage).

With the described conceptual framework, the Population Research Working Group devised and pilot-tested a brief assessment of chronic pain impact and an analysis of electronic health care data. The goal was to lay the groundwork for assessment of chronic pain in national health interview surveys and through use of large electronic health care databases.

Methods

After refining the National Pain Strategy goals for population research, and the concepts and definitions guiding its work, the Population Research Work Group for the National Pain Strategy identified candidate questions and scales to assess chronic pain, pain-related participation restrictions, and pain outcomes in population survey and health services research. The candidate items were adapted from items proposed by the NIH Chronic Low Back Pain Research Task Force,⁵ Patient-Reported Outcomes Measurement Information System items,¹ the Pain, Enjoyment, General activity (PEG) pain scale^{13,14} and the Patient Health Questionnaire-15 (PHQ-15) symptom scale.¹⁶ Because there was not a validated set of items that could meet all population research needs, brief sets of items and simple response options with face validity for assessing chronic pain and pain-related participation restrictions were considered, recognizing that additional evaluation and modification

of items should take place before they are used in national surveys or health services research. A large pilot study, described in the following sections, was carried out as an initial step toward assessing the performance of these items.

Pilot Test Items

The pilot test assessed a total of 11 questions asking about pain in general and 14 questions asking about anatomically defined pain conditions (Supplementary Appendix 1). Questions were asked in a sequence that permitted assessment of whether responses differed substantially before versus after specific questions about diverse anatomically defined pain conditions. The pilot test questions were asked in the following order:

- Four general questions about being bothered by pain, pain persistence, severity of pain-related interference with life activities, and persistence of pain-related interference with life activities.
- Fourteen questions about specific anatomically defined pain conditions.
- Seven general questions about pain persistence and pain-related interference with activities.

Pain Persistence

Following the recommendation of the NIH Low Back Pain Research Task Force, the pilot test used a 6-month time frame for assessing pain persistence.⁶ This time-frame allowed identification of persons with pain persisting for 3 months or more, continuously or intermittently, as long as pain was present on at least half of the days in a 6-month period. Assessment of days with pain has been used in previous pain surveys,³⁸ and has been validated relative to diary data.^{24,29} It has shown prognostic value for predicting long-term pain outcomes.^{8,36,38} To simplify reporting of pain days, categorical responses were used.⁶ Two different pain persistence questions were asked:

- 1) A yes/no question: "Over the past 6 months, have you had pain on at least half of the days?"
- 2) A question about days with pain in the past 6 months with 5 response options: "I have not had pain (in the past 6 months)"; "I have had pain, but on less than of half the days"; "I have had pain on more than half of the days, but not every day"; "I have had pain every day, but not all the time"; "I have had pain all day, every day, without break", and a "Don't know" response option.

Participation restrictions were assessed using Patient-Reported Outcomes Measurement Information System response options: never, rarely, sometimes, usually, always. Responses of "usually" or "always" were considered to indicate high impact. The items used a 6-month reporting period to distinguish enduring restrictions (usually or always present over 6 months) from transient (rarely or sometimes present). The stem questions asked how often pain limited: 1) life or work activities including household chores; 2) doing work for pay, work around the home, volunteer work; and 3) regular social and recreational activities. The same response options were offered

for an item assessing how often pain affected self-care: "I have had trouble taking care of myself (for example, dressing, bathing, or feeding myself)." Respondents were also asked a general question about how much pain interfered with life activities, with response options including no interference, mild interference, moderate interference, and severe interference.

Pain severity was assessed using the PEG scale.^{13,14} PEG items assess features of pain that matter to persons with pain (pain intensity, impact on enjoyment of life, and interference with daily activities), and are responsive to change.¹³ These items differentiate levels of pain severity continuously (on 0–10 ratings) or categorically—mild (0–3), moderate (4–6), and severe (7–10). They provide an efficient means of assessing response to treatment and tracking pain outcomes over time. A 7-day reporting period is used for these items because of their potential use to track changes in pain severity.

Anatomically Defined Pain Conditions

These questions were adapted from the PHQ-15 scale assessing physical symptoms¹⁶ to assess pain at specific anatomical locations. Fourteen items ask about common sites of pain, organized anatomically. The sum score of this scale measures the extent of widespread pain, which has high prognostic value for chronic pain outcomes, comparable with measures of pain intensity and interference with activities.³⁶ This scale can be shortened by reducing the number of anatomical sites to include only the most common pain sites. For example, the NIH Chronic Low Back Pain Research Task Force recommended assessing 4 common pain sites to assess widespread pain.⁶ A 6-month reporting period was proposed to be consistent with pain persistence and participation restriction items.

Depression, Anxiety, and Sleep Disturbance

The Population Research Work Group recommended assessment of mood and sleep disturbance as important features of the experience of chronic pain. However, standardized sets of items were not proposed for these domains so as to avoid conflict with questionnaires and surveys that already include standardized scales assessing these domains. Items assessing depression and sleep have been proposed by the NIH Chronic Low Back Pain Research Task Force,⁶ suitable for use in research concerning chronic pain in general.

Pilot Test Setting and Methods

Group Health (GH)²⁵ is a large health plan in Washington State, serving approximately 600,000 persons, with comprehensive electronic health care data. The pilot test survey and analyses of electronic health care data were carried out among GH's integrated group practice enrollees, comprising approximately two-thirds of its total enrollment. Electronic health care data were also analyzed for all GH group practice enrollees age 18 years or older. The pilot test survey and analyses of electronic health care data were approved by GH's institutional review board. Persons participating in the pilot

survey indicated their agreement to participate in the anonymous survey by returning the questionnaire after being provided informed consent materials with the mailed survey. Analyses of deidentified electronic health care data were conducted with a waiver of informed consent approved by the GH institutional review board.

Pilot Test Inclusion/Exclusion Criteria

Adults age 18 years or older who had been continuously enrolled in the GH integrated group practice in Western Washington for at least 2 years were potentially eligible for the pilot test mail survey. We excluded persons who had received cancer diagnoses on 2 or more medical encounters or who received opioids from an oncologist in the previous year to limit the survey to assessment of chronic noncancer pain. We also excluded persons who received hospice care in the previous year to exclude terminally ill persons.

Stratified Sample

In November 2014, random samples were drawn from 2 sets of adult GH enrollees: persons with and persons without frequent use of chronic pain services. Frequent users of chronic pain services were defined by meeting either of the 2 following criteria:

1. Persons receiving chronic opioid therapy, defined as receiving at least a 70-day supply of opioids in at least 2 quarters in the previous year and at least a 45-day supply of opioids in the other 2 quarters.
2. Persons who in the previous 2 years had made 12 or more visits with pain-related diagnoses in the following pain-related diagnostic groups: back pain, neck pain, widespread pain, headache, orofacial pain, abdominal pain, urogenital pain (see [Supplementary Appendix 2](#) for diagnostic group case definitions).

Of 217,307 adult GH enrollees eligible for the pilot test, 10,194 (4.7%) met either or both of these criteria for frequent use of pain services. From these 10,194 persons, we sampled 800 persons at random for inclusion in the pilot test.

Among the remaining 207,113 adult GH enrollees (95.3% of the adult enrollment) who did not meet either of these criteria for frequent use of chronic pain services, we sampled 900 persons at random for inclusion in the pilot test.

Mail Survey

In November and December 2014, mail surveys were sent to persons sampled for the survey. An advance letter was mailed before the pilot test questionnaire explaining the purpose of the survey, and that the survey was anonymous and voluntary. The questionnaire was mailed with a cover letter that said that the survey would take about 5 minutes to complete and that the purpose was to learn about how pain affects people's lives to help find better ways to prevent, manage and care for pain. The mailing included a \$2 bill as a preincentive for participation. Because of budget constraints and the anonymity afforded study participants, it was not possible to use

US National Pain Strategy for Population Research follow-up telephone calls to remind participants to return the questionnaire or to ask nonrespondents to complete the survey by telephone interview. Pilot test survey data were not linked to electronic health care data, other than recording a code for the sample stratum the subject belonged to on the questionnaire so that information could be used in subsequent analyses (that is, the presence or absence of frequent use of health care services, as defined previously).

Pilot Classification of Chronic Pain Impact

For purposes of pilot test analyses, the presence of chronic pain was determined by a yes response to a question asking whether pain was present on at least half of the days in the past 6 months. High pain impact was identified by either of the following: 1) a response of "usually" or "always" to the question about how often pain interfered with life activities, including household chores, or 2) a response of "severe interference" to the question about how much pain interfered with life activities. Among persons without high-impact chronic pain, moderate impact was identified by a rating of "moderate interference" to the question about how much pain interfered with life activities, or a rating of "sometimes" to the question about how often pain limited life or work activities, including household chores. Persons whose pain did not meet criteria for high- or moderate-impact pain were classified as having mild-impact pain.

For the pilot test analyses, the assessment of chronic pain and level of impact was limited to the 3 items described to test the feasibility of identifying respondents with high-impact chronic pain on the basis of a very brief assessment. This constraint was used because of the limited number of pain assessment items likely to be included in a multi-purpose national health survey, such as the National Health Interview Survey. The intent was not to definitively establish methods for classification of high-impact chronic pain, but rather to provide proof-of-concept that it would be possible to assess high-impact chronic pain with a very brief assessment.

Weighting

To derive population prevalence estimates from the stratified random sample, we estimated weights proportional to the probability of inclusion in the study. Analyses using sample weights provide unbiased estimates of population means, standard deviations, and percentages, although the survey oversampled frequent users of health care for pain.

Analyses

We report weighted data when estimating prevalence rates for the entire adult population. We estimated agreement statistics (κ statistic¹⁷) and report numbers with missing data using unweighted data.

Among persons with chronic pain, using weighted data, we assessed the concurrent validity of the classification of low-, moderate-, or high-impact chronic pain by

comparing the cumulative distribution of the three 0 to 10 PEG ratings (pain intensity, pain-related interference with activities, interference with enjoyment of life). Finally, we compared the cumulative distribution of the number of pain sites that bothered the respondent "a lot" in the past 6 months using weighted data.

enrolled in the health plan for the entire year, but no other exclusion criteria were applied. The electronic health care data were analyzed separately from the self-report survey data.

Pain-related diagnostic groups can be used to standardize research with electronic health care data to determine the proportion of a population receiving care for conditions within each diagnostic cluster. The diagnostic groups summarized in [Supplementary Appendix 2](#) define 11 sets of pain conditions, with provisional diagnostic codes within each of the 11 diagnostic groups. These diagnostic groups and associated diagnostic codes were assembled by the Population Research

Electronic Health Care Data

Pilot analyses of electronic health care data were carried out for adult GH enrollees (age 18 years or older) who received their care in the integrated group practice during 2013. Persons included in these analyses were

Table 1. Demographic and Pain Status Characteristics of Respondents, National Pain Strategy Pilot Test, GH Cooperative Adult Enrollees, 2014

<i>ITEM</i>	<i>PERCENTAGE OF POPULATION SURVEYED (N = 770, WEIGHTED ESTIMATES)</i>	<i>PERCENTAGE OF HIGH USERS OF PAIN SERVICES (N = 365, UNWEIGHTED ESTIMATES)</i>	<i>NUMBER OF PERSONS WITH MISSING ITEM DATA (OUT OF N = 770)</i>
Female sex	57.4	71.0	1
Age, y			
18 to 44	16.9	12.0	
45 to 64	41.6	44.3	8
65 and older	41.6	43.7	
Bothered by pain (Q3)	78.9	97.8	2
Pain at least half of the days in past 6 mo (screening Q4)	44.1	82.6	3
Pain days in past 6 mo (Q21)			
No pain	11.2	1.1	
Less than half of the days	42.1	12.5	
At least half of the days, not every day	15.0	14.7	18
Every day, but not all the time	24.4	48.1	
Every day, all the time, without break	7.2	23.6	
How much has pain interfered? (Q5)			
No interference	30.7	5.2	
Mild	40.3	23.4	2
Moderate	23.2	42.3	
Severe	5.9	29.1	
How often did pain limit activities (Q6)			
Never	27.0	4.1	
Rarely	28.8	11.0	0
Sometimes	30.6	32.0	
Usually	10.1	26.2	
Always	3.5	22.3	
Trouble doing usual work (Q22)			
Never	36.0	9.2	
Rarely	25.9	10.3	14
Sometimes	25.8	32.0	
Usually	8.0	26.2	
Always	4.4	22.3	
Trouble doing social recreational activities (Q23)			
Never	47.2	13.7	
Rarely	23.0	14.0	16
Sometimes	20.8	33.3	
Usually	5.0	19.1	
Always	4.1	19.9	
Trouble taking care of self (Q24)			
Never	77.0	46.1	12
Rarely	13.6	25.7	
Sometimes	6.4	15.4	
Usually	1.5	7.0	
Always	1.5	5.9	

Abbreviation: Q, question.

Working Group on the basis of the American Pain Society Taxonomy⁹ and from classifications developed by Health Care System Research Network investigators,²³ Veteran's Administration researchers,¹¹ and diagnostic clusters in the Ambulatory Care Group System.^{28,41} The pain-related diagnostic groups were: back pain, neck pain, limb/extremity pain (including arthritic conditions), widespread pain, headache, orofacial pain, abdominal pain, chest pain, urogenital pain, fractures or contusions, and other painful conditions.

Results

Survey Response Rates

Among the 800 persons selected as frequent users of chronic pain services, we received completed questionnaires from 365 (71% female, mean age 62.2 years, SD = 14.5), for a response rate of 45.6%. Among the 900 persons selected from GH enrollees who were not frequent users of chronic pain services, we received 405 completed questionnaires, for a response rate of 45.0% (56.7% female, mean age 60.7 years, SD = 15.8).

Item Response

The rates of missing item data on the 3 questions used to classify high-impact chronic pain were extremely low—less than .5% of respondents did not provide a usable response to these items (Table 1). The ratings of pain-related participation restrictions and pain persistence items that were not on the first page of the self-administered study questionnaire had somewhat higher levels of missing item data, but usable responses were available for more than 97% of the respondents (Table 1).

We examined prevalence rates for responses to key items included in the survey (Table 1), and compared the estimated distribution of item responses in the entire population to the distribution of item response among persons who were frequent users of chronic pain services. In this table, responses to the screening question on pain days in the previous 6 months (question [Q]4),

US National Pain Strategy for Population Research severity of pain-related interference with daily activities (Q5), and frequency of pain-related activity limitations (Q6) were asked before the 14 items about pain at specific anatomical locations. In contrast, the questions on frequency of pain in the previous 6 months, frequency of pain-related trouble with work activities, frequency of pain-related trouble with social activities, and frequency of pain-related trouble with self-care activities were asked after the 14 items asking about pain at specific anatomic locations. In the overall population, the estimated percentage of the population (on the basis of weighted data) reporting pain on at least half the days in the previous 6 months was only slightly lower on the item asked before the 14 pain-site items than on the similar item asked after (44.1% vs 46.6%). The percentage reporting that they usually or always limited activities because of pain, asked before the 14 specific pain site questions, was also similar to the percentage reporting that pain usually or always limited work activities, asked after the 14 specific pain site questions. These results suggest that self-reports of chronic pain and pain-related participation restrictions were not substantially influenced by the intervening questions about pain at specific anatomic sites.

Participation Restrictions

The weighted estimates of the percentage of the overall population who reported that pain limited self-care activities usually or always (3%) was substantially lower than the percentages reporting that pain usually or always limited work (12%) or social (9%) activities (Table 1). This likely reflects the lower occurrence of self-care disability in the general population of adults. Consistent with the validity of the participation restriction items, persons with frequent use of health care services for pain reported participation restrictions at much higher rates than the overall population of adults.

High-Impact Chronic Pain

In the overall population, we estimated that 13.7% of adults had high-impact chronic pain (Table 2). An

Table 2. Prevalence of Chronic Pain and Low-, Moderate-, and High-Impact Chronic Pain in the Overall Pilot Study Sample (Weighted Data) and Among High Users of Pain Services (Unweighted Data), National Pain Strategy Pilot Test, GH Cooperative Adult Enrollees, 2014

CHRONIC PAIN (Q4) AND LEVEL OF PAIN IMPACT (2-ITEM CLASSIFICATION: Q5 AND Q6)	PERCENTAGE OF POPULATION SURVEYED (N = 770, WEIGHTED DATA)	PERCENTAGE OF HIGH USERS OF PAIN SERVICES (N = 365, UNWEIGHTED DATA)
No pain	21.2%	2.2%
Pain other than chronic pain		
Low impact	22.9%	7.8%
Moderate impact	11.2%	6.1%
High impact	.8%	1.4%
With chronic pain		
Low impact	11.3%	4.2%
Moderate impact	18.9%	28.8%
High impact	13.7%	49.6%

Table 3. Agreement (κ Statistic) of Dichotomized Items Classifying Chronic Pain and Pain Impact of Pilot Study Participants (Unweighted Data), National Pain Strategy Pilot Test, GH Cooperative Adult Enrollees, 2014

	<i>IN THE PAST 6 Mo, HOW MUCH HAS PAIN INTERFERED WITH YOUR LIFE ACTIVITIES? (SEVERE)</i>	<i>IN THE PAST 6 Mo, HOW MUCH HAS PAIN INTERFERENCE WITH LIFE ACTIVITIES (USUALLY, ALWAYS)</i>	<i>OVER THE PAST 6 Mo BECAUSE OF PAIN, I HAVE HAD TROUBLE DOING USUAL WORK, INCLUDING WORK FOR PAY, WORK AROUND THE HOME, VOLUNTEER WORK (USUALLY, ALWAYS)</i>	<i>OVER THE PAST 6 Mo BECAUSE OF PAIN, I HAVE HAD TROUBLE DOING MY REGULAR SOCIAL ACTIVITIES (SUCH AS VISITING FRIENDS, GOING TO THE MOVIES, ATTENDING CLUBS OR RELIGIOUS ACTIVITIES) (USUALLY, ALWAYS)</i>	<i>OVER THE PAST 6 Mo BECAUSE OF PAIN, I HAVE HAD TROUBLE TAKING CARE OF MYSELF (FOR EXAMPLE DRESSING, BATHING, OR FEEDING MYSELF) (USUALLY, ALWAYS)</i>	<i>OVER THE PAST 6 Mo, ON APPROXIMATELY HOW MANY DAYS HAVE YOU HAD PAIN OF ANY TYPE? (AT LEAST HALF OF THE DAYS, EVERY DAY, EVERY DAY ALL THE TIME WITHOUT BREAK)</i>
Over the past 6 mo, have you had pain on at least half the days? (yes)	$\kappa = .207$	$\kappa = .393$	$\kappa = .375$	$\kappa = .293$	$\kappa = .084$	$\kappa = .882$
Over the past 6 mo, how much has pain interfered with your life activities (severe)		$\kappa = .573$	$\kappa = .535$	$\kappa = .571$	$\kappa = .394$	
How often has pain interfered with life activities (usually, always)			$\kappa = .791$	$\kappa = .684$	$\kappa = .289$	

additional 18.9% of the adult population was classified as having moderate-impact chronic pain. Thus, approximately one-third (32.6%) of the adult population had either moderate- or high-impact chronic pain. The population prevalence of high-impact pain in the absence of chronic pain was low (.8%), but a larger share of the population had moderate-impact pain in the absence of chronic pain (11.2%), according to the definition of chronic pain in this study. Among frequent users of health care for chronic pain, the percentage with high-impact chronic pain was substantially higher (49.6%) and more than three-quarters of these persons (78.4%) reported either moderate- or high-impact chronic pain.

Item Agreement

Among all survey respondents, the item asking whether pain was present on at least half of the days in the previous 6 months showed extremely high agreement with the item asking about days with pain in the past 6 months, the latter being asked after probing about pain at 14 specific body sites (Table 3: $\kappa = .882$). However, concordance of the classification of pain chronicity with items assessing level of impact was in the slight to fair range (Table 3). This is consistent with previous research that has reported low to moderate correlation of items assessing pain persistence with items assessing pain severity.³⁷⁻⁴⁰

The agreement of alternative items asking about pain-related participation restrictions was generally in the good to substantial range (Table 3). As might be expected, the items using the frequency response scale (never, rarely, sometimes, usually, always) generally showed high levels of agreement with each other. In contrast, the item using severity response scaling (none, mild, moderate, severe) showed lower agreement with those rated never to always, likely reflecting differences in response scaling. The item asking about self-care participation restrictions showed lower levels of agreement with other items, possibly because of the lower rate of positive responses on this item.

Profiles of Low-, Moderate-, and High-Impact Chronic Pain

These analyses included only persons who reported pain on at least half of the days in the previous 6 months. On the basis of the PEG average pain intensity rating,^{13,14} persons classified as having low-impact chronic pain generally rated their average pain intensity in the 1 to 4 range, persons with moderate-impact chronic pain usually reported average pain intensity in the 2 to 6 range, and persons with high-impact chronic pain typically rated their average pain intensity in the 4 to 8 range (data not shown). Comparisons of activity interference ratings (0–10) yielded similar results (Fig 1), but the differentiation of activity interference levels appeared stronger across the 3 levels of pain impact than the differences in average pain intensity. For example, the median interference rating was 6 of 10 among persons with high-impact chronic pain, compared with less than 3 of 10 for persons with moderate-impact chronic pain, and

less than 1 of 10 for persons with low-impact chronic pain (Fig 1). The differences in profile for ratings of how much pain interfered with enjoyment of life among persons with low-, moderate-, and high-impact pain were intermediate between those observed for average pain intensity and for ratings of activity interference (data not shown).

We compared the number of body sites that bothered research participants “a lot” according to level of chronic pain impact. Almost three-quarters of persons with low-impact chronic pain reported no more than 1 body site that bothered them a lot (Fig 2). Among persons with moderate-impact chronic pain, the number of highly bothersome body sites typically fell between 1 and 4. Among persons with high-impact chronic pain, the number of highly bothersome body sites typically fell between 2 and 5.

Care According to Pain-Related Diagnostic Groups

The percentage of adults in the GH population (N = 289,464) receiving services in 2013 for diagnoses in each of the pain-related diagnostic groups is shown in Table 4. Limb/extremity pain (including arthritic disorders), back pain, fractures/contusions, and abdominal pain were the most commonly treated painful conditions. Although the average total costs of health care in the population was \$6,034 in 2013, persons with services for pain conditions had substantially higher total health care costs. For example, persons with services for back pain had mean costs of health care of \$11,932. As shown in Table 4, services in each of the pain-related diagnostic groups accounted for between 23% (chest pain) and 37% (limb/extremity pain) of total health care costs of persons treated for that condition. Most visits with pain-related diagnoses were in primary care. For example, 76% of back pain visits were in primary care, and 60% of visits with a painful urogenital condition were in primary care.

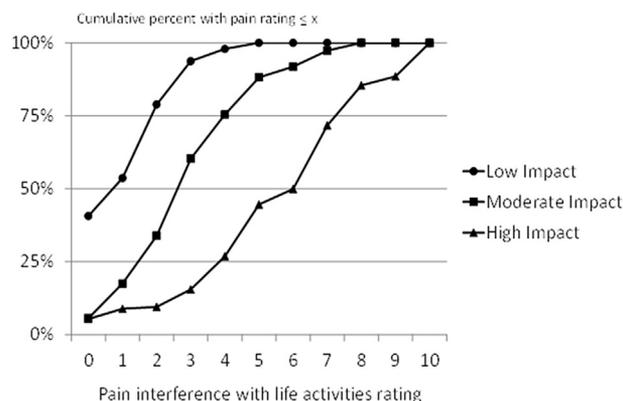


Figure 1. Cumulative percent with a 0 to 10 pain interference rating at the indicated level (or lower) for persons with low-, moderate-, and high-impact chronic pain (weighted data), including only persons with pain on at least half of the days in the previous 6 months. National Pain Strategy Pilot Test, GH Cooperative adult enrollees, 2014.

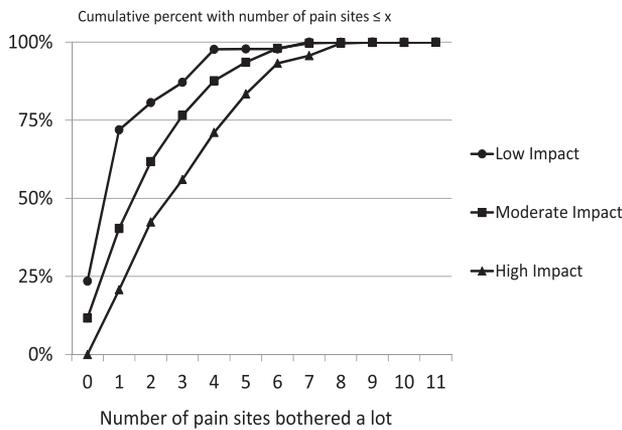


Figure 2. Cumulative percent reporting indicated number of pain sites (or fewer) that bothered the person a lot in the previous 6 months for persons with low-, moderate-, and high-impact chronic pain (weighted data). Figure includes only persons with pain on at least half of the days in the previous 6 months. National Pain Strategy Pilot Test, GH Cooperative adult enrollees, 2014.

Analyses of health care use among persons with pain-related diagnoses can provide insights regarding over- and underuse of services for chronic pain. Among all adults, 3.4% had received chronic opioid therapy in 1 or more quarters in 2013. Among patients with a fibromyalgia/widespread muscle pain diagnoses, 34% had received chronic opioid therapy, and 8% of patients with care for headache had received chronic opioid therapy.

Discussion

The US National Pain Strategy for Population Research provides conceptual and methodological bases for enhancing surveillance and evaluation capabilities for initiatives aimed at reducing the impact of chronic pain in the population at large. Although chronic pain is a leading cause of disability, national statistics for chronic pain are less well developed than morbidity and mortality statistics for cardiovascular disease and cancer. The

feasibility studies reported in this article suggest that brief assessment of chronic pain in national health interview surveys could improve our understanding of the contributions of chronic pain to the overall health burdens and costs in the US population. As health care organizations increase efforts to address chronic pain, routine collection of patient-reported outcomes for common chronic pain conditions can be used, in tandem with existing electronic health care data, to guide efforts to improve the effectiveness and safety of health care for persons with chronic pain.

Pilot testing a brief set of items for assessment of high-impact chronic pain was done to evaluate the feasibility of very brief assessment of high-impact chronic pain in survey research, and to examine initial measurement properties of potential items. Although this pilot test does not provide a definitive test of the reliability and validity of items for assessing high-impact chronic pain—further consideration and evaluation of potential survey research questions for assessing high-impact chronic pain is needed—initial results of the pilot survey were encouraging.

In the pilot test, persons classified as having high-impact chronic pain differed in multiple ways from persons with low-impact chronic pain: 1) they were more likely to be frequent users of health care for pain; 2) they reported substantially higher average pain intensity; 3) they were substantially more likely to report pain at multiple body sites; and 4) they described higher pain-related interference with activities, as well as higher interference with enjoyment of life activities on rating scales from the validated PEG instrument.^{13,14} Persons with moderate-impact chronic pain were intermediate between persons with low- and high-impact chronic pain on each of these indicators. The differences in pain profiles indicate that a simple classification of low-, moderate-, and high-impact chronic pain, on the basis of 3 items, differentiated between persons with chronic pain whose characteristics were distinctly different. Although the results of this initial pilot test

Table 4. Health Care Use, Costs, and Long-Term Opioid Use According to Pain-Related Diagnostic Group, Adult GH Enrollees in 2013

PRDG Dx	PERCENT OF ADULT POPULATION WITH CARE FOR PRDG Dx	AVERAGE HEALTH CARE COSTS IN YEAR-TOTAL, \$	PERCENT OF COSTS WITH PRDG Dx*	PERCENT OF VISITS FOR PRDG Dx THAT ARE IN PRIMARY CARE	PERCENT OF THOSE WHO RECEIVED CHRONIC OPIOID THERAPY IN YEAR*
Back pain	11.9	11,932	32.9	75.6	13.7
Neck pain	5.4	11,107	28.8	75.3	11.7
Limb/extremity pain	24.5	10,812	37.0	65.1	8.2
Widespread pain	3.6	18,066	25.2	61.7	34.1
Headache	5.0	12,016	29.4	67.8	8.1
Orofacial pain	1.4	10,448	22.8	69.1	5.1
Abdominal pain	8.9	14,590	31.7	59.6	7.2
Chest pain	5.9	16,457	22.7	56.7	7.8
Urogenital pain	2.1	10,583	27.1	60.0	5.3
Fractures, contusions	10.5	11,813	34.4	57.6	6.8
Other painful conditions	6.6	16,314	27.6	69.0	11.1
All persons (N = 289,464)		6,034			3.4

Abbreviation: PRDG Dx, pain-related diagnostic group diagnoses.

*Chronic opioid therapy defined as receiving 70 or more days' supply in at least one 90-day period in 2013.

need to be augmented by additional evaluation of survey research items and classification criteria, these data suggest that very brief assessment of high-impact chronic pain is feasible and of likely value in characterizing this important subgroup. For example, in the National Health Interview Survey, questions are asked about specific participation restrictions because of health conditions: working outside the home to earn an income; going to school or achieving educational goals; participating in leisure or social activities; getting out with friends and family; doing household chores such as cooking and cleaning; using transportation to get to places you want to go; participating in religious activities; and participating in community gatherings. These health-related participation restriction items may be used in tandem with items asking about chronic pain and pain-related participation restrictions to clarify the kinds of activities that persons with chronic pain are not doing secondary to health difficulties.

Analyses of electronic health care data for persons treated for conditions in 11 pain-related diagnostic groups showed that many persons in the study population received services for painful conditions. These persons had substantially higher health care costs overall, with a large part of their excess health care costs related to services involving the pain-related diagnoses for which care was sought. In this health care system, most of the visits for each of the pain-related diagnostic groups were delivered in primary care. Furthermore, large percentages of patients with fibromyalgia were using long-term opioids, a condition for which long-term opioid use is discouraged. These proof-of-concept analyses suggest that electronic health care data can be mined to improve understanding of who receives services for common pain conditions, what treatments they are receiving, and the costs of their care. If standardized brief assessments of chronic pain impact were documented in electronic medical records for evaluation and management of common chronic pain conditions, then these patient-reported outcomes could be used to assess the effectiveness services provided for care of chronic pain patients. The Mental Health Research Network of the National Institute of Mental Health uses brief, uniform assessments of depression (using the PHQ-9¹⁵) in their research. These data are recorded for hundreds of thousands of depression treatment episodes each year in large health care organizations with electronic health records. They are being used in research initiatives to improve the effectiveness of depression treatment and to prevent suicide attempts among patients with suicidal ideation.²⁰ Widespread adoption of a standardized brief chronic pain outcome measure, such as the PEG scale,^{13,14} could allow similar use of electronic health care data for evaluation of health care services for chronic pain.

Brief assessment and classification of high-impact chronic pain yielded a 14% population prevalence estimate. This estimate is within the range of previous population surveys estimating the prevalence of severe, disabling chronic pain (6%–14%).^{3,21} An additional 19% of the population was estimated to have moderate-impact chronic pain, an estimate also within the range of

US National Pain Strategy for Population Research previous surveys.^{3,21} Although hundreds of population surveys have been conducted to estimate the prevalence of specific chronic pain conditions⁴ (for example, low back pain, migraine headache, osteoarthritis), there have been few population-based surveys of the extent and burden of chronic pain overall. Because co-occurrence of multiple chronic pain conditions is the rule, not the exception, the paucity of data on the extent of chronic pain hinders efforts to effectively address chronic pain as a public health problem. It is encouraging that several recent population surveys have developed estimates of the prevalence and burden of chronic pain overall,^{4,10,32} and that these initial studies yielded results consistent with the pilot test prevalence estimates reported in this article.

The pilot analyses reported in this article have significant limitations. They were carried out in the adult population of a single health plan in 1 geographic area. The response rate of the pilot test survey was low because of budget constraints and the use of an anonymous survey method that precluded follow-up telephone calls to increase the rate of response. The survey sampling stratum of persons with frequent use of health care for pain included less than 5% of the total population, likely representing the segment of the population most severely affected by chronic pain. However, population estimates were weighted to reflect sampling strata proportionally, so that weighted population estimates provide unbiased estimates of the prevalence of high-impact chronic pain in the adult population surveyed.

The items used to assess chronic pain and high-impact chronic pain used stems and response options similar to those used in previous research, but the items had not been previously validated for the specific purpose of assessing and classifying high-impact chronic pain. The pain-related diagnostic groups used a provisional classification, so that the pain-related diagnostic groups and the diagnostic codes within each group will need to be reviewed and refined before their further use in research. Several classes of conditions frequently associated with chronic pain were not included (eg, cancer) because of the lack of International Classification of Disease (ninth revision) codes specifically identifying pain as an impairment. In addition, the diagnostic codes assigned to each group will need to be revised now that the 10th revision of the International Classification of Disease has been implemented in electronic health care databases in the United States. The analyses of electronic health care data reported in this article, therefore, are preliminary, proof-of-concept analyses intended to inform future efforts to achieve population research objectives of the National Pain Strategy. Although cognitive testing² carried out after the pilot test by the National Center for Health Statistics supported the feasibility of obtaining useful information on high-impact chronic pain using brief simple questions, testing suggested changes in the response options for chronicity (eg, never, some days, most days, every day).²² Cognitive testing also indicated that the use of example activities may result in some respondents focusing on the examples rather than life activities in general, detracting from the validity of those survey items.

Despite these limitations, the concepts, definitions, and initially proposed survey research items developed for population research have contributed to important steps toward achieving National Pain Strategy objectives for population research. The NIH Pain Research Interagency Coordinating Committee and National Institute of Neurological Disorders and Stroke intramural staff are analyzing existing National Health Interview Survey data for the US population from 2010 and 2011 to assess the prevalence and distribution of high-impact chronic pain in the adult population of the United States. With leadership of the Centers for Disease Control and Prevention and the National Institutes of Neurological Disorders and Stroke, the US federal government adopted development goals for Healthy People 2020 to reduce the prevalence of high-impact chronic pain in the US population. The NIH and the Centers for Disease Control and Prevention's National Center for Health Statistics have committed to the inclusion of items assessing chronic pain and high-impact chronic pain in the National Health Interview Survey in 2016 and 2017.

Conclusions

The results of the preliminary studies reported in this article support the feasibility of developing data on chronic pain and high-impact chronic pain through very brief assessment of chronic pain in national morbidity surveys. Preliminary analyses of electronic

health care data support the feasibility of developing data on health care for persons receiving services for conditions within pain-related diagnostic groups. Ultimately, health care organizations may routinely collect patient-reported outcomes on high-impact chronic pain for their patients, making it possible to monitor pain management approaches and outcomes in large populations over time. The National Pain Strategy provides a framework for developing population-based data that can be used to guide and evaluate efforts to reduce the impact of chronic pain through improved preventive services, educational initiatives, and enhanced health care services for common chronic pain conditions.

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Supplementary Data

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