Attachment E: ERB Protocol (PPMQ)

Physician Pain Management Questionnaire Pilot Study
NCHS ERB Protocol #2021-04

PROJECT OVERVIEW

Title: Physician Pain Management Questionnaire Pilot Study

Protocol Summary:
The Physician Pain Management Questionnaire (PPMQ) pilot study is a non-representative survey, although national in scope, of non-federally employed, attending physicians (excluding those in the specialties of radiology, and pathology) legally practicing in the United States (U.S.). It is designed to collect information on physicians' awareness of and adherence to varying types of clinical guidelines for prescribing opioids for pain management.

Strict procedures will be utilized to prevent disclosure of data collected from this pilot study, and to uphold the assurance of confidentiality provided under section 308(d) of the Public Health Service Act (42 U.S.C. 242m(d)) and the Confidential Information Protection and Statistical Efficiency Act of 2018 (Pub. L. No. 115-435, 132 Stat. 5529 § 302)).

This protocol seeks an ERB waiver of documentation for informed consent for the upcoming data collection procedures for the PPMQ, expected to run over a period of 12 months.

Investigators/Collaborators/funding source/funding mechanism(s)/Federal wide Assurance numbers/" engagement in research" status:
Principal Investigator:

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Funding sources:

National Center for Complimentary Integrative Health, National Institutes of Health, Department of Health and Human Services

National Center for Health Statistics, Centers for Disease Control and Prevention, Department of Health and Human Services

Conflicts of Interest:
Financial**:** Not applicable.

Other**:** Not applicable.

INTRODUCTION

Literature review/current state of knowledge about project topic:
Along with the novel coronavirus (COVID-19) pandemic, one of the greatest public health issues currently facing the nation is the opioid epidemic. Between 1999 and 2019, there was an increase in opioid induced overdose deaths occurring across 3 waves. The first wave was associated with prescription opioids (i.e., natural, semi-synthetic opioids and methadone) and began in 1999. Increased mortality involving heroin marked the second wave in 2010 and most recently there has been a third wave starting in 2013 involving synthetic opioids (which in part include the prescribed opioid fentanyl).

The rise in overdose deaths due to prescribed opioids heralded the opioid epidemic and was attributed to increased prescribing of opioids for chronic pain that began in the 1990s. In response, the public health community devised strategies to combat the epidemic. The Department of Health and Human Services (DHHS) deployed a National Pain Strategy in 2011, with safe delivery of pain therapies as one of its goals. In March 2016, the Centers for Disease Control and Prevention (CDC) developed a national guideline for prescribing opioids for chronic pain. Additionally, several professional medical associations, as well as U.S. states and health organizations, have developed their own independent guidelines for pain management.

Despite these efforts, overdoses involving prescription opioids accounted for 41 deaths per day in 2018, indicating that prescription opioids continue to play a role in the ongoing opioid epidemic. Consequently, it is important to understand physicians' awareness of and use of clinical guidelines when prescribing opioids. Only a few studies currently exist that address this topic; however, they are limited in that they focus on institutional or state-based guidelines, have small sample sizes and are not national in scope.

From 2017 to 2018, the American Academy of Pain Medicine Foundation convened a panel of 15 physician experts to identify and address the challenges with implementing the CDC guideline on prescribing opioids.[1] While the panel was nationally drawn and multidisciplinary, members of the panel were already aware of the guidelines, and awareness was not measured by this study. Given such limitations, further exploration of this topic remains necessary.

Justification for study:
The purpose of this study is to test survey questions using a brief questionnaire that would collect reliable data to assess physicians' awareness of and adherence to national, local and/or professional clinical guidelines for prescribing opioids. Along with others, the CDC guideline for prescribing opioids was developed to facilitate effective and safe treatment of patients with chronic pain, while reducing the incidence of opioid misuse and overdose. Though these guidelines exist, the level to which they are implemented remains unknown. To date, no surveys or data systems exist that collect national data on this topic; therefore, methodological development of a survey that could be implemented for these needs is essential.

[1] Kroenke K, Alford DP, Argoff C, et al. Challenges with Implementing the Centers for Disease Control and Prevention Opioid Guideline: A Consensus Panel Report. *Pain Med*. 2019;20(4):724-735.

As previously mentioned, the National Pain Strategy, an interagency effort, has a focus on implementing safe approaches for treating pain. The National Center for Complementary and Integrative Health (NCCIH) at the National Institutes of Health (NIH) has been involved in this effort. One of CDC's roles in combatting the opioid epidemic is through supporting health care providers with guidance and tools to improve opioid prescribing and patient safety through evidence-based approaches. As such the NCCIH and National Center for Health Statistics (NCHS) entered into an interagency agreement (IAA) to: evaluate survey questions on physician knowledge, awareness and use of prescription opioid guidelines, assess the feasibility of a national physician survey to gain a better understanding of physician opioid prescribing practices for pain management by implementing a pilot study of physicians. Through this agreement, NCCIH will fund this study to be conducted by the NCHS.

NCHS has structured its health care surveys into a family of nationally representative surveys of health care providers called the National Health Care Surveys. The surveys comprising the National Health Care Surveys include the National Electronic Health Records Survey (NEHRS, OMB No. 0920-1015), the National Ambulatory Medical Care Survey (NAMCS, OMB No. 0920-0234), the National Hospital Ambulatory Medical Care Survey (NHAMCS, OMB No. 0920-0278), the National Hospital Care Survey (NHCS, OMB No. 0920-0212), and the National Post-acute And Long-term Care Study (NPALS, OMB No. 0920-0943). This family of surveys generates data that permit analyses of the relationship between the use of health services and characteristics of providers and patients at both national and regional levels. They are conducted under authority of Section 306(b)(1)(F) of the Public Health Service Act (42 U.S.C. 242k) (**Appendix B**).

Conducted since 1973, the National Ambulatory Medical Care Survey is the nation's premier study on the provision of ambulatory care in the United States. NAMCS uses a nationally representative sample of visits to U.S. non-federal office-based physicians and providers in community health centers. NAMCS is used to inform health policy, medical practice, quality of care research, and education for health professionals. NCHS has conducted numerous NAMCS supplements on physicians to provide data on emerging health topics. Notably, the Electronic Medical Records (EMR) Mail Survey to track the Nation's progress in adopting and using EHR systems was added to NAMCS in 2008 (which in 2012 became the National Electronic Health Records Survey), and in 2016 a supplement on National Culturally and Linguistically Appropriate Services in Health and Health Care Standards to understand physicians' awareness of these Standards (i.e., National CLAS Standards; OMB No. 0920-119). These and other supplements have provided timely data on relevant public health topics. Though the proposed pilot study will not be a NAMCS supplement, it will borrow methodological aspects and lessons from NAMCS, and leverage the knowledge gained from the implementation of these NAMCS supplements.

Intended potential use of study findings:
As defined by §46.102, public health surveillance activities include the collection and testing of information or biospecimens that are conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals,

risk factors, patterns in diseases, or increases in injuries from using consumer products). The PPMQ meets these criteria as it is conducted by NCHS, a public health authority, and collects information necessary to identify and assess the provision of clinical guidelines for prescribing opioids, an issue of public health importance given the current opioid epidemic.

Although the questionnaire in this study is intended to primarily collect information on physician knowledge of and adherence to different types of opioid prescribing guidelines, the questions are also designed to collect additional information that can be broadly used. This information includes but is not limited to: physician specialty, the proportion of patients undergoing pain management for each physician, physician's clinical approach to pain management and the knowledge and use of non-pharmacologic treatment methods for pain. This information is expected to be beneficial for several research and development purposes such as: understanding how to assess the utility of clinical guidelines for prescribing opioids, determining surveillance methods that can best explore the characteristics of physicians that use and don't use established guidelines and most importantly for developing further studies to reliably collect more data on this critical topic. The survey's ability to collect this type of information is important to both NCCIH and associated stakeholders, who are involved with the development of clinical guidelines for safe and efficacious pharmacologic treatment of pain, and others concerned with planning, monitoring, and managing how healthcare providers prescribe opioids for pain management.

As mentioned earlier, NCCIH is a part of the interagency National Pain Strategy Implementation Team, under the National Pain Strategy, commissioned by DHHS. Along with NCCIH, the Interagency Pain Research Coordinating Committee (IPRCC) and the NIH Pain Consortium have a vested interest in the methodological findings from this study. The IPRCC is a DHHS Federal advisory committee designated to enhance pain research efforts and promote collaboration across government with the goal of advancing the fundamental understanding of pain and improving pain-related treatment strategies. The NIH Pain Consortium promotes collaboration among NIH centers and researchers conducting programs and activities addressing pain. The findings from this study will be shared with the NIH Pain Consortium, the IPRCC and the National Pain Strategy Implementation Team to be used to determine the feasibility of a larger scale, nationally representative study on physician opioid prescribing patterns and to secure funding.

Additionally, the results of this study will provide valuable information regarding the feasibility for NCHS to use these survey questions to collect data on this topic at a broader scale, whether it be through its own independent survey, or as a part of an established survey such as NAMCS. This study is seeking OMB clearance under the Generic Information Clearance (GenIC): Developmental Studies to Improve the National Health Care Surveys (OMB No. 0920-1030, Exp. Date 06/30/2023), which currently allows for developmental studies on survey design and data collection activities that are part of the National Health Care Surveys. Under this GenIC, NCHS is precluded from publishing any national estimates from data collected: therefore, although the study will be national in scope, national estimates will not be produced. However since one of the purposes of this pilot is to assess the feasibility of a nationally representative survey, the success of the methods used in this study to draw a national sample will be beneficial if a nationally representative survey were to be conducted as a result of this pilot. Furthermore,

the physician database of which the sampling frame used in this pilot will be drawn from, is distinct from the source files used in other physician surveys within the National Health Care Surveys. The benefit of successfully drawing a national sample using this method extends beyond this pilot study and may be applied for future physician provider surveys at NCHS.

Objectives:
The objectives of this pilot study are as follows:

1. Assess the feasibility of a nationally representative survey of physicians to gain better understanding of their practices regarding prescribing opioids for pain management.
2. Collect data on physician awareness of and adherence to various types of clinical guidelines for prescribing opioids.
3. Collect data on the physicians' approach to pain management using opioids.

Hypotheses or questions:
The aim of this pilot study is to assess the feasibility of a nationally representative survey of physicians that could facilitate gaining a better understanding of physician opioid prescribing practices. As this is a methodological study, it does not focus on a specific hypothesis, but rather whether the survey questions on the questionnaire will be an effective means of collecting this information.

General approach:
The Physician Pain Management Questionnaire consists of a sample of 1,000 physicians across all 50 states and DC. Within each of the four U.S. census regions, physicians will be selected using stratified random sampling of physician lists arrayed by specialty. Data will be collected through a paper-based self-administered mail questionnaire. The data collected will be processed, coded, transferred into analytical software and analyzed. The analysis will yield descriptive statistics on physician prescribing patterns and use of guidelines. No weights or survey design variables will be developed, as no national estimates will be produced from these data.

PROCEDURES/METHODS

DESIGN

Study design/locations:
This is a mailed cross-sectional paper-based survey of U.S. physicians, designed to collect data on physician awareness of and use of clinical guidelines when prescribing opioids. The target sample for the PPMQ is drawn from non-federally employed, allopathic (MD) and osteopathic (DO) attending physicians legally practicing in the 50 U.S. states and the District of Columbia (DC). The database from which the sampling frame is created, and the sample is drawn, is the National Provider Identifier (NPI) datafile provided by the Centers for Medicare and Medicaid Services (CMS). A random sample of 1,000 eligible physicians will be selected from the final sampling frame. Exploratory and descriptive analysis will be computed for tabulation and methods reports. Since this is a methodological study, neither state nor national estimates are to be produced.

Statement of purpose:
The purpose of this pilot study is to assess the feasibility of collecting data on physician awareness and use of opioid guidelines, and to assess the performance of the cognitively tested questions in the field. The study will be conducted through a self-administered paper-based mail survey, in a one-time data collection effort, over an anticipated period of 6 to 12 months.

How study design or surveillance system addresses hypotheses and meets objectives:
The first objective of this pilot study is to assess the feasibility of a survey of physicians intended to collect data on opioid prescribing practices. The study is designed to collect information from physicians in all 50 states and DC . The sampling design also ensures that physician specialties (those within inclusion criteria) are proportionally represented within the sample.

The questions have been designed to collect data on physician's knowledge of different types of prescribing guidelines and their adherence to them. In addition to this, the questionnaire includes general information that could be broadly used to answer different research questions. These include physician specialty, the proportion of patients being treated for pain, the physician's clinical approach to pain management and the knowledge and use of non-pharmacological treatment methods for pain.

The initial questionnaire has undergone rigorous cognitive testing by the NCHS Collaborative Center for Questionnaire Design and Evaluation Research (CCQDER). **Appendix C** contains the report from the cognitive testing. The report raised two main concerns. Response error attributed to physicians who only manage acute pain, and questions that did not apply to certain specialties. Based on these findings the questionnaire has been revised to include skip patterns, which ensure that respondents only answer questions relevant to: their specialties, their pain management approach, and whether they treat pain at all. Furthermore, the sampling strategy considers the fact that some specialties are more involved in the treatment of pain compared to others. The revised questions, including the sampling strategy, have been reviewed by the CCQDER representative responsible for the cognitive testing (**Appendix D**) to determine that the revisions mitigated concerns raised during testing. The questions are now expected to perform optimally and reliably from a cognition perspective, and collect the information listed in the objectives.

Audience and stakeholder participation:

NCCIH and NCHS are in an IAA to fund and conduct the study respectively. The questions used in this instrument were a result of a collaborative effort between NCCIH, NCHS and the National Pain Strategy Implementation Team within the Department of Health and Human Services (DHHS). NCHS will continue to work closely with stakeholders through the duration of the study. A list containing the names of collaborators is provided in **Appendix D.**

Summaries of findings and analyses will be made available to designated NCCIH staff for development of further studies and surveillance on this topic. These data should serve as a useful tool for individuals and groups involved with the development of clinical guidelines for prescribing opioids, and others concerned with planning, monitoring, and managing the clinical provision of opioids for pain management.

This project fully complies with all guidelines of 5 CFR 1320.8(d).

Study Protections:
The NPI datafile from which the sample is drawn, contains multiple forms of identifiable information. This includes the NPI number (identifier for health care providers), their business addresses, phone numbers and email addresses. The main risk to the individual is disclosure of this confidential information. Since the NPI number for any physician is publicly available information, a breach of NPI would allow identification of the physician.

The data collected with identifiable information will only be viewed by NCHS project staff. The NPI numbers or any other identifying information will not be released as part of a public use data set, or in any published form. Survey findings will also be reported on the aggregate level. Given these precautions, this study will not pose a disclosure risk to the physician once the data have been collected.

Assurances of confidentiality are provided to all physicians about the protection of their identity, according to Section 308(d) of the Public Health Service Act (42 U.S.C. 242m(d)) and the Confidential Information Protection and Statistical Efficiency Act (CIPSEA, Title III of the Foundations for Evidence-Based Policymaking Act of 2018 (Pub. L. No. 115-435, 132 Stat. 5529 § 302)). Strict procedures will be utilized to prevent disclosure of confidential data. NCHS will take measures to ensure that all data are kept confidential during the study and minimize any risk of a breach in confidentiality.

Anticipated benefits to the research participant:
There are no direct benefits to physicians; however, a physician could benefit to the extent that results from this study may improve the understanding of how physicians use clinical guidelines when prescribing opioids for pain and inform and improve future data collection efforts on this topic. The data collected have the potential to redefine clinical guidelines on a national scale, which could have a positive impact on clinical practice and be instrumental in mitigating the opioid epidemic.

Description of potential risks to anticipated benefit ratio:
Should the data be accessed by unauthorized personnel, the risks of disclosing physician information are minimal. Only NCHS project staff will have access to the raw data that includes identifiable information, which will be stored on the secure and restricted NCHS CIPSEA server designated for personally identifiable information (PII) data. This study presents no more than minimal risk. In contrast to the small risks of this survey, the greater understanding of the use of clinical guidelines in prescribing opioids could result in new strategies for mitigating the opioid epidemic. This could help physicians in providing quality patient care. In addition, physicians could become direct benefactors, should they become patients.

Study timeline:
The duration of activities for the survey will span 12 months. The timetable for key activities for the pilot survey is as follows:

12/2020	Physician sample selection
03/2021	Receive OMB clearance

04/2021	Begin data collection
08/2021	End of data collection, begin data editing
09/2021	End of data editing
10/2021	Quality Control File
11/2021	Final files/data available

STUDY POPULATION

Description and source of study population and catchment area:
The Physician Pain Management Questionnaire universe consists of non-federally employed, MD and DO attending physicians legally practicing in the 50 U.S. states and DC. The universe from which the sampling frame is created, and the sample is drawn, is the NPI datafile provided by the Centers for Medicare and Medicaid Services (CMS). There are approximately 800,000 physicians in the universe.

Participant inclusion criteria:
The sampling frame for the PPMQ pilot study consists of physicians in the NPI datafile provided by the CMS. Physicians included meet the following criteria:

1. Legally employed attending physicians in the 50 states and the District of Columbia
2. Active NPI
3. Non-federally employed
4. Active license in one of the 50 states or the District of Columbia

Justification for involving vulnerable participant populations:
Not applicable. This study does not involve vulnerable participant populations.

Participation exclusion criteria:
Physicians who meet the following criteria will be excluded from the final sampling frame.

1. Physicians practicing in the United States territories
2. Physicians with a deactivated/inactive NPI
3. Resident physicians and or interns.
4. Federally employed physicians
5. Physicians sampled in any of the National Health Care Surveys in the past two years
6. Physicians specializing in radiology, pathology and their related sub-specialties
7. Physicians without a documented medical license number

Justification for exclusion of any sub-segment of the population:
Not applicable; no sub-segments of the population are excluded.

Estimated number of participants:
The estimated sample size is 1,000. The expected response rate for this pilot survey is approximately 30%, which is based on recent response rates from NEHRS (2017: 36% , 2018: 42.4%). Since the PPMQ resembles NEHRS methodology, a similar response rate is expected. However, due to challenges presented in the context of the COVID-19 pandemic, there has been a notable decrease in survey response rates. Because of this, our expected response rate (30%) is

lower than that of NEHRS. To achieve a target response rate of 30%, we are using a sample size of at least 1,000 physicians.

Sampling, including sample size and statistical power:
As previously mentioned, the sampling frame for the PPMQ is constructed from the publicly available NPI datafile provided by the CMS. The universe consists of non-federally employed MD and DO attending physicians legally practicing in the 50 U.S. states and District of Columbia. Once constructed, the sampling frame of eligible physicians will be sorted by U.S. census region (i.e., Northeast, Midwest, West, and South) and then by medical specialty. Within each region, 250 physicians will be selected using stratified random sampling, with a higher proportion of physicians in ambulatory specialties being selected compared to non-ambulatory specialties. A total sample of 1,000 will be selected.

Recruitment and Enrollment:
This survey utilizes the Tailored Design Method (TDM), which was developed by Don A. Dillman and is known as the standard for conducting mail and telephone surveys.[2] This method has yielded positive response rates when previously used within NCHS for physician surveys. The PPMQ design uses the following key recruitment principles from the TDM: personalized letters, pre-paid return envelope included with the mailed questionnaire, thank you/reminder postcards and multiple duplicate packets sent to non-respondents over set time intervals to increase response rates. In accordance with the TDM, this study employs several survey mailings as the sole recruitment and enrollment strategy.

Following OMB clearance, recruitment begins with a mailed invitation to participate, sent to all 1,000 physicians in the sample. This invitation letter outlines the importance and purpose of the study and serves as an informed consent. The invitation letter can be found in **Appendix E.**

Within 2 weeks of sending the invitation, the 1st survey package will be mailed to each respondent. This package includes: an introductory letter **(Appendix E)** reiterating the purpose of the study and providing instructions and answers to frequently asked questions, the survey instrument **(Appendix F),** and a pre-stamped return envelope for the completed survey.

About 7-10 days following the 1st survey package mailing, a postcard **(Appendix E)** will be sent to all physicians in the sample. The postcard has several purposes: it thanks sampled physicians for their participation, reminds them of the necessity for participation, and allows them to request additional information including another copy of the survey instrument.

Within 4 weeks of the 1st survey mailing, non-respondents will receive a follow-up package. This 2nd mailing includes a follow-up letter, the survey instrument and a pre-stamped return envelope. Physicians who do not respond within 4 weeks of the 2nd mailing will receive a 3rd package. This 3rd mailing includes a modified follow up letter**,** a pre-stamped return envelope, and the questionnaire. This will be the final mailing attempt. A post-card reminder and thank-you will be sent after the last survey mailing. Data collection will continue until the study period is

[2] The Tailored Design Method (TDM) is regarded as the standard for mail surveys. TDM emphasizes focus on several aspects of mail survey design including sending a personalized letter, the questionnaire with return postage, a follow-up postcard, and multiple packets to non-respondents

complete. All recruitment materials (follow up letters and post-cards) are included in **Appendix E**.

Description and justification of reimbursement or incentives that will be used:
Physicians will not receive incentives or reimbursement for participation in this study.

Statement of extra costs to participants due to involvement in the study:
There are no costs to physician respondents selected for the survey, although there will be a burden on participating physicians with respect to their time to complete the questionnaire.

Procedures for implementing and documenting informed consent:
The physician will be sent an invitation letter explaining the voluntary nature of the survey, that non-participation will have no negative consequences, and our commitment to confidentiality. No written consent is obtained; it is assumed that if the respondent completes the survey, consent has been given. NCHS will use the information it collects for public health purposes only.

Justification for waiver or alteration of informed consent:
Not applicable, as the physician letter will have all elements of informed consent.

Justification for waiver of documentation of informed consent:
A waiver of the documentation of informed consent from physicians is requested. The principal risk for the survey is potential harm resulting from a breach of confidentiality. Physicians will be informed that their privacy will be protected under Section 308(d) of the Public Health Service Act (42 USC 242m). As discussed above, the physician will be sent a letter with the questionnaire explaining the voluntary nature of the survey and our commitment to confidentiality. All elements of consent, including the time required to conduct the survey, the risks and benefits are addressed in all letters (**Appendix E**) and on the survey (**Appendix F**).

Given the methodological design of the PPMQ, it is not practical to obtain written informed consent. This study will not obtain documentation of consent from each physician. Instead, the physician's consent is obtained by agreeing to complete the survey. Justification for this waiver describes how the study presents no more than minimal risk of harm to physicians and involves no procedures for which written consent is normally required outside of the research context.

Minimal Risk: The survey presents minimal risks to physicians because the physician is informed that the information is being collected under the authority of Section 306 of the Public Health Service Act. Information which would permit identification of any individual or establishment is collected with a guarantee that it will be held in strict confidence, will be used for purposes stated in this study, and will not be disclosed or released to others except as stated above without the consent of the individual or establishment in accordance with Section 308(d) of the Public Health Service Act (42 USC 242m).

Written consent procedures: The methodology for the Physician Pain Management Questionnaire does not incorporate procedures for written consent. Instead, it is assumed that physicians who agree to participate have given informed consent. Physicians will receive an invitation letter, signed by the Director of NCHS, which explains in clear language the basics of the survey, that

participation is completely voluntary, that the physician will not be penalized for nonparticipation, and that NCHS takes full responsibility for all survey-related actions. All additional letters sent to respondents include this message. Phone numbers for the study coordinator and the NCHS Research Ethics Review Board are also included if the physicians have any questions or comments about the study.

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Each letter outlines instructions on how to decline participation. If the physician declines participation, they are requested to answer 2 survey questions regarding eligibility, which focus on their specialty and provider setting, prior to returning the survey. They are given the flexibility to stop the survey at any point, without penalty. Given the opportunities for physicians to decline participation, it can be safely assumed that physicians who return a completed survey, in effect, provided informed consent to participate in the PPMQ.

Much of the data used or collected in this study are not considered personally identifiable, however the data used to draw the sample consists of both personally identifiable information (PII) and information in identifiable form (IIF). A list of PII and IIF data items is highlighted below. These data items have all received prior approval by the NCHS Ethics Review Board through the NAMCS (OMB No. 0920-0234) data collections, the NEHRS (OMB No. 0920-1015) as well as other physician supplemental survey data collections. None of these data are released to the public or become part of public-use files.

Personally Identifiable Information:

- Physician name
- Physician NPI

Information in Identifiable Form Categories:

- Physician or office mailing address
- Physician or office telephone number
- Physician or office fax number
- Physician gender

Note that the NPI is a unique identifier for healthcare providers. This data element will allow for linkage of physician specialty information to other administrative sources of information to be used primarily for tracing and eligibility assessments.

The pilot study survey will include a routine set of measures to safeguard confidentiality. First, all staff, including contractors (if any), who have access to confidential information are given instruction by NCHS staff on the requirement to protect the confidentiality of respondents, and are required to sign a pledge to maintain confidentiality. Second, only authorized personnel are allowed access to confidential records, strictly for work requirements. Third, confidential information is stored in secure conditions when it is not actively in use. This commitment to confidentiality is explained both in the letters and at the top of the survey.

VARIABLES/INTERVENTIONS

Variables:

The following are examples of variables to be obtained from the PPMQ:
Baseline demographic and practice characteristics:

- Specialty/Practice eligibility
- Type of care provided
- Practice setting/type (e.g. outpatient, inpatient, emergency, etc.)

Characteristics of treatment approach for chronic pain:

- Characteristics of patients being treated for pain (number of patients)
- Use of guidelines for treating pain (e.g. are guidelines used, which guidelines, etc.)
- Pain management approach (e.g. pre-counseling, choice of medications, prescribing of non-pharmacologic therapy, etc.)

Study instruments, including questionnaires, laboratory instruments, and analytic tests:
As mentioned earlier, the instrument for this pilot study can be found in **Appendix F**. The initial questionnaire has undergone rigorous cognitive testing by the NCHS Collaborative Center for Questionnaire Design and Evaluation Research (CCQDER), followed by revision to ensure that the questions perform optimally and collect reliable data.

Data collection will occur by self-administered paper questionnaire. Any changes to the questionnaire during the survey will be made after consultation and agreement of NCHS and NCCIH staff and will be documented.

This is a mailed, self-administered, paper-based questionnaire which will utilize the TDM to optimize response rates. As highlighted in the recruitment and enrollment section, survey instruments will be sent on multiple occasions during the study period; packages will include personalized letters, pre-paid return envelopes and reminder postcards, all shown to increase response rates by the TDM. These recruitment materials can be found in **Appendix E.**

Intervention of treatment: Not applicable.

Outcomes and minimum meaningful differences: Not applicable.

Training for all study personnel:
All staff involved, including contractors, will complete confidentiality training which includes instruction on the requirement to protect confidentiality, and the signing of a mandatory pledge to maintain confidentiality. Only authorized personnel will be allowed to access the confidential data when their work requires it. During processing, NCHS staff will perform independent verification of all data entry and correct discrepancies.

Throughout the year, conference calls will be held among Ambulatory and Hospital Care Statistics Branch (AHCSB) staff of NCHS and the NCCIH to discuss issues relevant to the PPMQ data collection. Any trainings suggested at these meetings or other necessary trainings to maintain study integrity, will be attended as needed.

DATA HANDLING AND ANALYSIS

Data analysis plan, including statistical methodology and planned tables and figures:
This project is designed to assess the feasibility of collecting data on physician awareness and use of opioid guidelines. To assess the questionnaire's performance in the field, NCHS and NCCIH will collaboratively analyze the data collected in this study using descriptive analyses strategies and standard analyses for performing a methodological assessment of a survey questionnaire. Techniques used in this methods assessment may include: examining overall questionnaire response rates and item nonresponse; exploring percentage distributions to assess the ability of survey questions to capture variability across question response categories; examining responses across selected physician characteristics to identify systematic biases (if any); identifying potential patterns of item response error; and assessment of questionnaire skip patterns; all of which are common methodological assessments used in the survey methods field.

Since this is a methodological study, national estimates will not be produced, and the data will not be weighted. The study applies stratified random sampling to ensure proportional representation of medical specialties across regions. The analysis is to be performed using SAS and SAS-callable SUDAAN analytical software.

Data collection:
All data collection efforts will be carried out by designated NCHS staff. Since this is a paper-based, mail survey, all data collection activities will be carried out via mail. This data collection entails mailing several survey packages to respondents, sent over specified intervals, in order to maximize survey response rates. The process includes sending an invitation letter, followed by 3 survey mailings, sent every 4 weeks during the study period. In addition, post-card reminders are sent between the 1st and 2nd survey mailings, and after the 3rd mailing. All survey mailings include a pre-stamped envelope addressed to NCHS. Please refer to the recruitment and enrollment section for details on the enrollment strategy.

Returned surveys will be securely stored in a locked cabinet on the NCHS campus. NCHS project staff will review completed surveys, code the responses and enter them into an electronic datafile stored on the secure NCHS CIPSEA server. A strict coding and data entry protocol will be used to reduce entry errors, and an additional NCHS project team member will validate all entries. Once the data has been inputted electronically, software edit checks will be performed to further ensure accuracy.

Provisions for protecting privacy/confidentiality:
The Paperwork Reduction Act submission for the PPMQ has been reviewed by the Information Collection Review Office (ICRO), who determined that the Privacy Act does apply. The NCHS Privacy Act Coordinator and the NCHS Confidentiality Officer have determined that the Privacy Act is applicable because this study includes the collection of information in identifiable form.

The applicable System of Records Notice is 09-20-0167 Health Resources Utilization Statistics.

An assurance of confidentiality is provided to all respondents according to section 308 (d) of the Public Health Service Act (42 USC 242m) which states:

> *"No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section...306 (NCHS legislation),...may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose and (1) in the case of information obtained in the course of health statistical or epidemiological activities under section...306, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form,[...]"*

In addition, legislation covering confidentiality is provided according to section 513 of the Confidential Information Protection and Statistical Efficiency Act (PL 107-347) which states:

> *"Whoever, being an officer, employee, or agent of an agency acquiring information for exclusively statistical purposes, having taken and subscribed the oath of office, or having sworn to observe the limitations imposed by section 512, comes into possession of such information by reason of his or her being an officer, employee, or agent and, knowing that the disclosure of the specific information is prohibited under the provisions of this title, willfully discloses the information in any manner to a person or agency not entitled to receive it, shall be guilty of a class E felony and imprisoned for not more than 5 years, or fined not more than $250,000, or both."*

Control measures for protection of confidential data by NCHS:

Access Control Plan:

All project databases, file and database servers used to store electronic project files will be secure. Access to project files is controlled by user accounts; passwords must be complex, cannot be previously used, and are updated every 90 days.

Physical Storage Procedures:

As required, secure, locked storage for project-related sensitive documents will be maintained within NCHS. Only specific project staff will have access to these files. Servers and network hardware are kept in a locked room within NCHS, where access is restricted only to authorized personnel.

Limitations of Information Distribution or Disclosure:

All employees are required to sign a nondisclosure agreement that prevents the reproduction, transmission, or disclosure of data and project information without written consent.

Procedures for Destruction of Source Documents and Data Files:

All project materials and data files will be destroyed per NCHS protocol at the conclusion of the project.

Personnel Security Practices and Procedures:

NCHS staff working on this project have undergone extensive reference checks prior to gaining employment.

Statement about need or lack of need for Assurance or Certificate of Confidentiality:
Efforts to protect confidentiality have been outlined above under control measures for protection of confidential data. A statement for the Assurance of Confidentiality is provided at the top of the instrument (**Appendix F**).

Information management and analysis software:
Survey data are collected directly from the physician using a self-administered paper survey. The information will be entered by NCHS staff into a secure datafile. The statistical analysis is to be performed using SAS and SAS-callable SUDAAN software.

Data entry, editing and management, including handling of data collection forms, different version of data, and data storage and disposition:
All staff involved in this study will be required to complete the NCHS confidentiality training. Staff are trained on the requirement to protect confidentiality and must sign an affidavit of nondisclosure to maintain confidentiality. Only trained personnel with a signed affidavit will have access to confidential records and only for work related purposes.

Survey forms and any other confidential information (including letters with salutations) will be stored in a locked file cabinet at NCHS during the data entry, cleaning and analytical phases of the study. Only authorized personnel will have access. If confidential materials need to be moved, records will be maintained to ensure that there is no loss in transit; and when confidential information is not in use, it will be stored in secure conditions.

Designated NCHS staff will be responsible for data processing. This includes data entry, coding, edit checks and overall management. As data are entered into electronic files from paper survey forms, the created file is saved on the secure NCHS CIPSEA server. After data entry activities are completed, NCHS and CDC will retain and destroy records in accordance with the applicable CDC Records Control Schedule.

Quality control/assurance:
In order to reduce errors in coding and processing, the following quality control procedures will be applied: entries will be verified by at least one additional employee and computer edit checks performed for code ranges and inconsistencies. During processing, NCHS staff will perform verification of data entry and correct discrepancies.

Bias in data collection, measurement and analysis:

In the sampling design, physicians are selected from a sampling frame that is initially sorted by region and then specialty. From each region, 250 physicians are randomly selected using stratified random sampling, with a higher allocation of specialties of interest. Given that the distribution of specialties may vary by state, or region, overrepresentation of certain medical specialties is possible. This introduces a potential source of sampling bias.

Non-sampling errors include errors due to response bias, questionnaire and item nonresponse, recording, and processing errors. To the extent possible, non-sampling errors are kept to a minimum by methods built into the survey procedures. The TDM is used in effort to reduce unit non-response. A systematic approach to data entry, with measures to ensure accuracy in data entry and coding will be utilized to minimize processing errors. Skip patterns are incorporated in the survey instrument to reduce item nonresponse, burden and minimize breakoffs.

Intermediate reviews and analyses:
Data collection and processing is ongoing during the study period. Completed surveys will be manually reviewed and processed, and reclassification or re-coding of "other" entries performed as deemed necessary as the study period progresses. Computer edits for code ranges and inconsistencies are also performed as data is processed. A check for comparability with any other related studies conducted by federal or private agencies will be made if one exists.

Limitations of study:
As survey methodology has progressed, study designs using multiple modalities yield higher response rates. Several surveys at NCHS use multiple modes for this reason. This study is limited as it only uses one mode for both recruitment and enrollment of the study. Both the invitation and the survey are mailed and are paper based. Busy respondents may find an email invitation with a link to a web-based survey more convenient. Additionally, if incorporated into the design, email can be utilized as a low-cost reminder method. While mailed, paper-based surveys have several strengths, the exclusion of modern data collection methods such as web-surveys, text-surveys and computer assisted methods may contribute to limited response rates in this pilot study.

Identifying, managing, and reporting adverse events:
The adverse event of a breach in confidentiality is possible, although appropriate measures will be in place to ensure that no breaches occur. If breaches in confidentiality or deviations from the protocol do occur, within 24 hours of the breach, NCHS project staff will report the incident to Sonja Williams, Principal Investigator for this study, who will report them to the NCHS Confidentiality Officer (Donna Miller), NCHS Information System Security Officer (Brian McGough), and the NCHS ERB. Appropriate steps will be taken to address any problems or issues as they arise.

Anticipated products or inventions resulting from the study and their use: Not applicable.

Notifying participants of their individual results: Not applicable. Results are disseminated in the aggregate, and no information or analyses about individual physicians are produced.

Notifying participants of study findings: Physicians will not be notified about study results.

Disseminating results to the public:
NCHS and NCCIH will collaboratively analyze the data collected in this study. The results may be made available in publications such as journal articles or reports, and as oral or poster presentations at professional meetings, where only the methodological findings and implications would be discussed.

NCCIH is a part of the National Pain Strategy, an interagency effort. As such, NCCIH will be presenting findings to interagency Pain Committees to help inform the feasibility of using this questionnaire in a broader scale study on physician prescribing patterns for opioids.

LIST OF APPENDICES

Appendix A: Physician Pain Management Questionnaire ERB Protocol
Appendix B: Public Health Service Act, Section 306
Appendix C: Final Cognitive Report – Draft (PPMQ)
Appendix D: List of Consultants (PPMQ)
Appendix E: Recruitment Materials (PPMQ)
Appendix F: Survey Instrument (PPMQ)