ASSESSING BARRIERS TO OPIOID PHARMACOTHERAPY FOR CHRONIC PAIN IN MONTANA

by

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ABSTRACT

Chronic pain affects an estimated 76.2 million people in the United States yet health care providers face significant barriers to provision of safe and effective chronic pain management. Research has identified pharmacotherapy as an important component of a multi-disciplinary care plan for chronic pain management, but complexities associated with pain pharmacotherapy are also a source of barriers to chronic pain management. Little is known about barriers to provision of chronic pain management that may be unique to rural settings such as Montana. The primary goal of this research effort was to develop a questionnaire to assess barriers faced by health care providers to the use of pharmacotherapy for chronic pain in Montana. Following a comprehensive literature review of barriers to chronic pain management, a draft questionnaire containing 24 questions was developed and submitted to an expert panel of providers with prescriptive authority in Montana. A tailored Delphi technique was used to gather input about the proposed questionnaire from the expert panel. The results confirmed the importance of assessing barriers in Montana and the presence of significant barriers to opioid pharmacotherapy for chronic pain. The responses provided key information for revision of the questionnaire, improving the questionnaire clarity and relevance to Montana. This project represents an essential first step in the development of an assessment tool for use in Montana to identifying the existence and relative impact of barriers to chronic pain management. Understanding the relative influence and impact of these barriers will help mitigate barriers that impede adequate chronic pain management and help identify support needs of health care providers in chronic pain management.

INTRODUCTION

According to the National Institutes of Health, pain is the most common reason Americans use the health care system (NIH, 2009). The American Pain Foundation (2009) estimates that 76.2 million people in the U.S. adult population suffer from pain and 42% of adults 20 years of age or older reported having pain that lasted longer than one year. Health care costs from chronic pain are estimated to be $86-100 billion annually (American Pain Foundation, 2009c; Trescott et al, 2008). Chronic pain is considered a chronic disease with multiple bio-psychosocial factors that influence the success of pain management and add complexity to the pain management plan (Boswell & Giordano, 2009; Gatchel & Okifuji, 2006). Current evidence-based practice guidelines recommend treating chronic pain with a diversified care plan that combines interventions from multiple disciplines and does not rely solely on pharmacological management (Chou et al, 2009; American College of Occupational and Environmental Medicine, 2008). Research has identified the use of pharmacotherapy is often an important component of management of chronic pain, but providers frequently mention that pharmacotherapy treatments are challenging because of provider discomfort with managing opioids and other controlled substances often used in pain management (Fishman, 2007; Zacharoff et al, 2010). In fact, some providers across the U.S are unwilling to treat chronic pain patients at all due to fear of abuse, diversion and addiction even if opioid use is medically indicated by the history and physical exam (Nwokeji, Rascati, Brown & Eisenberg, 2007; Fontana, 2007). While evidence for long term opioid

efficacy in management of chronic pain is considered weak to moderate unless pain is moderate to severe, the use of opioids is still considered an important option in treatment because many patients rely on them for improvement of their function and relief of their symptoms (Fishman, 2007). This suggests that provider concerns involving the use of controlled substances may prevent chronic pain patients from having access to cornerstone pharmacological therapy, potentially negatively impacting the success of their chronic pain management.

The prevalence of chronic pain, the difficulties faced by providers in managing chronic pain (Jamison, Gintner, Rogers, & Fairchild, 2002; Rosenblum, Marsch, Joseph & Portenoy, 2008) and the extent of under treatment of chronic pain as reported by patients has increasingly highlighted the importance of improving chronic pain management. Across the United States advocates for safe and effective chronic pain management have created state pain initiatives to identify state chronic pain treatment issues and educate providers about chronic pain management. Similarly, in Montana, the state legislature created The Montana Pain and Symptom Management Task Force (MPSMTF) to explore the status of chronic pain management across the state (MPSMTF, 2008a). MPSMTF drafted a report *"Recommendations for improving pain and symptom management in Montana"* which identified provider practice improvement as a priority project. MPSMTF recommended the establishment of the Montana Pain Initiative and charged MTPI with the role of assessing chronic pain in Montana and working to provide education and support to providers and patients (MPSMTF 2008a). In Montana there is still little information about the prevalence and impact of chronic pain in patients, the

types and numbers of providers treating chronic pain, and the barriers providers face in effectively managing chronic pain. In a rural state where many individuals lack health insurance coverage, patients often lack access to multi-disciplinary interventions (behavioral psychologist, physical therapy, chiropractor, massage therapist, or acupuncturist) for chronic pain. Access to a provider knowledgeable in appropriate chronic pain pharmacotherapy and access to pain medication via a pharmacy may therefore be core components of a rural patient's treatment plan.

The purpose of this thesis is to develop a questionnaire to assess barriers among health care providers to the use of pharmacotherapy in management of chronic pain in Montana. Future implementation of the questionnaire could assist the Montana Pain Initiative in designing interventions to improve the safety and efficacy of pharmacotherapy in chronic pain management at a patient and provider level.

LITERATURE REVIEW

Introduction to Primary Barrier Categories

This chapter reviews the current state of knowledge regarding chronic pain management, highlights the need for assessing barriers to pharmacotherapy in treating chronic pain patients and outlines how this might be implemented in Montana via a prescriber survey. A review of the research on chronic pain management identified a number of consistently reported barriers preventing pharmacotherapy in chronic pain management. Research suggests that many of these barriers are related to the use of opioids in pain management. The primary barriers to pharmacotherapy in chronic pain are outlined in Table 1 and discussed in more detail below:

Table 1. Summary of Barrier Categories Identified in the Literature

Primary barrier categories
Inadequate knowledge of opioid pharmacotherapy and prescribing guidelines
Inadequate knowledge of controlled substance regulation
Inadequate knowledge of chronic pain pathophysiology
Reluctance to prescribe controlled substances
Lack of access to a pain specialist or pain consult
Health care coverage and reimbursement issues

Inadequate Knowledge of Opioid Pharmacotherapy and Prescribing Guidelines

The Clinical guidelines for the use of pharmacotherapy in chronic non-cancer pain identify provider knowledge of the safe use of medications including controlled substances as essential to effective chronic pain management (Chou et al., 2009; Zacharoff, McCarberg, Reisner & Venuti, 2010; Fishman, 2007). Pain management

expert Dr. Frederick W. Burgess discussed in an interview his perception of the barriers facing primary care physicians in pain management (Kelman, 2007). Among other barriers, Dr. Burgess identified inadequate physician education in pain management as a key barrier to effective chronic pain management. This issue was well identified in a 1999 survey of patients with chronic pain in which almost half of chronic pain sufferers changed doctors since their pain began for reasons including: a) the doctor did not take their pain seriously enough, b) the doctor was unwilling to treat it aggressively, and c) the doctor lacked knowledge about pain and the patient still had too much pain (American Pain Society, 1999).

A decade has passed since this research, however, the complexity and challenge of pain management is still echoed in recent texts directed at aiding primary care providers in chronic pain management (Fishman, 2007; Zacharoff et al, 2010) and in more recent research. Clark and Upsher (2007) interviewed 14 family practice physicians to identify what the respondents felt were priorities for improvement of chronic pain management. The group identified provider chronic pain education, tool kit and guidelines as significant areas of support they needed in place to improve their management of chronic pain. A study involving 504 General Practitioners (GP) in the United Kingdom (UK) identified that a majority (81%) of respondents expressed a desire for additional education and training in pain management to support their management of chronic pain patients (Stannard & Johnson, 2003). Texas physicians also identified lack of knowledge about key aspects of pain and its treatment among 30-50% of the 386 respondents (Weinstein, et al. 2000).

Research has also identified similar knowledge deficits among non-physician providers. Fontana (2007) reported that all responding nurse practitioners felt that their program education was inadequate and that improved education would help them meet better patient needs. A study of 279 self-selected Veterans Administration (VA) physicians, nurse practitioners and other VA primary care providers gathered information regarding the comfort level of the providers in managing chronic pain (Mitchinson, Kerr & Krein, 2008). Of the respondents, 36% felt that they had inadequate training in pain management, and 74% felt they were expected to manage or treat chronic pain conditions that were beyond their scope of practice or training and experience. The research described above demonstrates a provider desire for education regarding chronic pain management in multiple practice settings and with multiple provider types.

In Montana, patients have also identified a need for improved chronic pain management education in providers. A small convenience sample of 239 Montana health care consumers found that the majority (81%) felt that lack of access to a healthcare provider trained in pain management was a barrier in finding adequate chronic pain management (MPSMTF, 2007).

In addition to providers expressing inadequate knowledge of chronic pain management, research suggests that physicians are also unaware of chronic pain practice guidelines that may help them in designing a plan of care. Wolfert (2010) found that most physician respondents were unaware of existing clinical practice guidelines for use in treating chronic pain and those physicians unaware of clinical practice guidelines were less likely to treat chronic pain patients.

This research suggests that many physicians think their ability to treat chronic pain would improve with increased education in chronic pain management. In rural areas or areas where providers with training in chronic pain are fewer and/or where there are fewer chronic pain patients, providers may not have an opportunity outside of formal training to increase their familiarity and comfort with chronic pain pharmacotherapy. Lack of awareness of chronic pain management guidelines or resources could further hinder chronic pain management.

In lieu of formal education, experience treating chronic pain patients may increase familiarity with chronic pain pharmacotherapy. Wolfert et al (2010) and Weinstein (2000) both found that the more frequently a physician prescribed opioids and the more chronic pain patients they reported treating, the more comfortable and knowledgeable they were with opioid prescribing. In the Emergency Department (ED) setting Wilsey (2008a) found that ED physicians did not think that lack of comfort with controlled substance, and specifically opioid prescription, was a barrier because prescribing opioids was a common part of their daily practice. Lin, Alfandre and Moore (2007) surveyed 132 physicians in a large urban hospital system. In this study, Geriatricians and attending-level physicians were more likely to have completed formal training in chronic pain management and geriatricians were least likely to express uncertainty regarding opioid dosing. One in four respondents reported that they were hesitant to prescribe opioids because of uncertainty about the correct dose and geriatricians were less likely to express this hesitancy (Lin et al.). This research suggests that experience treating chronic pain

patients and formal or informal training e.g. geriatrician vs. attending level physician both may influence chronic pain management.

Inadequate Knowledge of Controlled Substance Regulation

In his interview, Dr. Burgess (Kelman, 2007) identified fear of litigation as a key barrier to primary care chronic pain management, especially in rural areas where a physician may have fewer support systems and chronic pain management procedures in place. Pain management guidelines outline the importance of treating pain based on individual patient characteristics and sound clinical judgment (American College of Occupational and Environmental Medicine. 2008; Chou et al., 2008; Fishman, 2007; Zacharoff, 2010). Inaccurate beliefs about controlled substance regulation have the potential to move a provider's clinical decision away from what is indicated by the assessment of the patient and toward treatment decisions based on fear of litigation. This is confirmed by a survey by the American Pain Foundation (2009a) which found that of 240 primary care physicians, nurse practitioners and physicians assistants who completed an online questionnaire, only 9% felt comfortable with their understanding of opioid prescription regulation, 77% felt that those regulations impacted their prescribing practices, 45% felt that most physicians make decisions regarding opioid prescription on societal or legal rather than clinical considerations, and 27% felt they would benefit from guidance on monitoring of opioid patients for legal reasons. Wolfert et al (2010) identified that respondents who answered questionnaire items related to opioid regulation demonstrated a poor understanding of controlled substance regulation at state and federal levels, with over 40% answering "don't know" to almost all regulatory questions and the

majority demonstrating an inaccurate understanding of which agencies regulate prescribing and licensure. For example, over 40% answered incorrectly when asked to identify the number of days schedule II prescription need to be limited to and 38% believed erroneously that it was illegal to prescribe methadone for pain treatment (Wolfert et al.). Additionally, while 59% of respondents denied concern about investigation of prescribing practices, a significant portion of respondents, > 46% in Wisconsin (Wolfert et al) reported changing their prescribing practices at least occasionally in order to avoid investigation by regulatory agencies. Surveying 899 Washington pharmacists, Joranson & Gilson (2001) found that 36% erroneously believed that extended opioid prescribing for chronic pain was illegal or against acceptable medical practice. Additionally 32 % of pharmacist respondents felt their education about controlled substance regulation was only fair or poor and 50% felt their education specific to opioids in pain management was fair or poor. Approximately 20% held misconceptions about regulation for opioid prescribing in the terminally ill. Joranson & Gilson (2001) suggested that as pharmacists may advise providers or patients on medication use, inaccurate knowledge of any aspect of controlled substances or their use may act as a barrier to pain medication access. According to Fontana (2007) of nine Advanced Practice Nurse respondents, most who prescribe opioids reported frequently modifying their opioid prescribing practice out of concern of legal scrutiny and diversion of controlled substances, rather than from patient clinical information.

In summary, an assessment of knowledge regarding opioid regulation, involving all provider types with prescriptive authority may help identify educational needs for

providers in Montana. This would allow the MTPI to address knowledge deficits that might impede appropriate pharmacotherapy in chronic pain such as misconceptions of opioid regulation.

Inadequate Knowledge of Chronic Pain Pathophysiology

The Montana Board of Medical Examiners defines chronic pain as pain persisting "beyond the usual course of an acute disease or healing of an injury or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years" (BME, 2009). In this statement the BME identifies that chronic pain can still exist for a patient, even without an identifiable physiological cause. This sentiment is also represented in the texts by Fishman (2007) and Zacharoff et al (2010) when discussing the often absent diagnostic indicator for pain aside from patient report. However, research has identified that many providers are reluctant to prescribe opioids in situations where a physiological cause cannot be identified via diagnostic testing. Wisely et al (2008a) reported that a physician's inability to identify an existing pathology (e.g. a herniated disc) to explain the pain via diagnostic tests increased the physician's reluctance to prescribe opioids. Respondents for Remster and Marx (2008) identified lack of an objective measurement of pain as a barrier to chronic pain management. Fontana (2007) found that APRN respondents would first attempt to isolate an etiology for the pain and would then rarely prescribe opioids if a cause could not be identified. This belief, that an identifiable pathology or other objective measurement must be present to justify treatment of pain with controlled substances, represents inadequate knowledge of chronic pain pathology and may inhibit a provider

from prescribing controlled substances in chronic pain where identifiable pathology may be absent.

Reluctance to Prescribe Controlled Substances

Despite clinical guidelines outlining appropriate controlled substance pharmacotherapy in chronic pain management and despite patient report of chronic pain, many physicians remain reluctant to prescribe controlled substances, particularly opioids. Many factors contributing to this reluctance have been identified in the literature.

Lin, Alfandre & Moore (2007) found that 58% of physicians were reluctant to prescribe opioids due to concerns of side effects. Side effect assessment management is considered integral to monitoring of patients on opioids (Zacharoff, 2010; Trescott, 2008; Fishman, 2007). The respondents were not questioned on their knowledge of mitigation of side effects but their responses seem to indicate that they were unaware that side effects can be managed and in general, tolerance develops to all side effects of opioid use except constipation, which can be mitigated with medication.

Physician and nurse practitioner reluctance to prescribe opioids may stem from fear of patient addiction and medication diversion or misuse. Wilsey et al (2008a) reported concerns of addiction and drug seeking as a barrier to managing chronic pain in the emergency department setting. However, research has demonstrated that many providers have incomplete knowledge about risk for addiction, and prevalence of addiction and diversion. The majority of nurse practitioners surveyed by Fontana (2007) incorrectly defined addiction yet reported that fear of causing addiction influenced their prescribing practices by limiting which medications they would prescribe and the amount

they prescribed. Some respondents refused to prescribe opioids at all due to their concerns, a practice that could severely limit access in areas with health care provider shortages (Fontana, 2007). Wolfert et al (2010) found that only 19% of respondents were able to correctly define characteristics of addiction and that inaccurate characterization of addiction correlated with infrequent prescribing of opioids. Weinstein (2000) found that physicians practicing in communities < 100,000 were significantly more likely to have increased prejudice against opioids, less pain management knowledge and increased negative views towards pain patients. Wolfert et al. and Weinstein et al. suggest that in areas where pain patients are fewer, physicians are less knowledgeable about addiction and more reluctant to prescribe opioids. Joranson & Gilson (2001) surveyed 557 pharmacists by mail in 1998 and found that 88% of pharmacist respondents incorrectly defined addiction. Joranson and Gilson suggest that pharmacists who misunderstand addiction may confuse patient characteristics with addiction and may refuse to dispense legitimate prescriptions, limiting patient access to pain medication.

Controlled substances do have addiction and misuse potential (Zacharoff, 2010; Fishman, 2007). However, expert opinion as outlined in clinical guidelines is that this risk is one that should be assessed, managed and mitigated through appropriate knowledge of risk and an individualized patient treatment plan (American College of Occupational and Environmental Medicine. 2008; Chou et al., 2008; Trescott, 2008, Fishman; Zacharoff). In contrast, research demonstrates a trend toward provider avoidance of controlled substance use even when clinically indicated, rather than mitigation of risk.

In summary, past research suggests that provider beliefs about opioid side effects, addiction and diversion may influence prescribing practice, even if these beliefs are incorrect. Yet, the relative influence of reluctance to prescribe controlled substances for chronic pain in Montana is unknown.

Inadequate Access to Pain Specialists or Consultation

Research suggests that access to appropriate chronic pain pharmacotherapy may be impacted by availability of pain specialist consultation. As described above, providers are reluctant to prescribe opioids for many reasons. This reluctance seems to be assuaged by experience with treating chronic pain patients with opioids or via consultation with another provider. In locations where providers have less experience treating chronic pain and there is no access to a pain specialist, provider reluctance to prescribe opioids for chronic pain may be more prevalent. Mitchinson, Kerr & Krein (2008) identified inadequate access to pain specialists as a barrier with only 30% reporting satisfaction with availability of pain specialty consultation and only 35 % reporting satisfaction with the availability of other staff to assist with pain management. Remster and Marx (2008) identified inadequate access to pain specialists as a key barrier for rural areas in Ohio.

Health Care Coverage and Reimbursement Issues

Health insurance coverage appears to influence both patient treatment setting and provider pharmacotherapy choices. Wisely (2008a) reported that the majority of emergency department physician respondents felt that lack of health insurance coverage was the reason patients went to the emergency department for pain treatment rather than

their primary care provider. The physicians identified this as problematic because the emergency department does not provide ongoing monitoring for treatment efficacy or safety which increases the reluctance to provide long term controlled substance treatment (Wilsey, 2008a).

According to the American Pain Foundation (2009a), 45% of health care provider respondents reported limitations in reimbursement for various opioid options within their practice setting and 40% felt it important to have as many reimbursable options as possible in order to meet individual patient needs. Additionally, while insurance programs may cover medications or visits with the provider, coverage of other disciplines such as those recommended in the bio-psychosocial model may have partial or no coverage (American Pain Foundation, 2009b), causing increased reliance on pharmacotherapy options such as opioids.

Summary

Research suggests that a numbers of barriers prevent pharmacotherapy from being incorporated into a comprehensive pain management plan even though providers believe pharmacotherapy plays an important role. The primary barriers to chronic pain pharmacotherapy are related to the use of controlled substances, especially opioids. It is not clear, however, to what degree each of the barriers may impact chronic pain management in Montana. The development of a questionnaire to assess barriers to chronic pain pharmacotherapy in Montana is needed to identify barriers that are potentially most significant in Montana. Future implementation of this questionnaire will

allow for the design of interventions to overcome barriers (e.g. education, guidelines or other tools) and to assist providers with prescriptive authority to more effectively manage chronic pain.

METHODS

The development of a questionnaire to assess barriers to pharmacotherapy in chronic pain used a tailored Delphi technique, questionnaire based process which centered on expert consultation including a panel of providers with prescriptive authority in Montana and the committee for this thesis. The thesis committee was compromised of Dr. Wade Hill (Associate Professor, Montana State University College of Nursing) Dr. Kaye Norris (Program Director of the Montana Pain Initiative), and Dr. Linda Torma (Adjunct Assistant Professor, Montana State University College of Nursing). This chapter will identify and discuss the methods used to clarify questionnaire goals and objectives, identify questionnaire content, and select and sample the expert panel.

Clarification of Questionnaire Goals and Objectives

After an initial review of the literature, committee members were presented with a review of research and examples of similar published (Wolfert et al. 2010) and unpublished questionnaires that had been implemented in other states. Utilizing past research and expert assessment, objectives were identified to guide the selection of content for the questionnaire. The questionnaire was initially aimed at assessing general barriers to chronic pain management but committee members recommended focusing the survey specifically on pharmacological barriers. Pharmacological barriers were chosen because the literature review identified that the majority of the barriers reported by patients and providers were linked to pharmacotherapy. Inclusion of other important

chronic pain management interventions such as non-pharmacological or alternative therapy interventions were considered but were ultimately ruled out for a number of reasons. These include: 1) focus on one topic of primary importance in Montana, 2) need to develop survey that was of reasonable length to ensure adequate response, 3) focus on topics that could be adequately addressed for a Masters thesis. Hence, the committee agreed that the survey should focus on and be limited to barriers to pharmacotherapy in chronic pain management.

Identification of Potential Questionnaire Content

Questionnaire items were developed from the findings of the literature review, with oversight from the thesis committee and with expert advice from the Montana Pain Initiative Policy Committee. Committee members met via teleconference over a 9 month period to identify key content, review drafts of the questionnaire and discuss each individual item in relation to the overall questionnaire goals and issues identified in the literature. The thesis committee was presented with a summary of identified barriers, a draft questionnaire and an outline of applicability of each question to key barriers. Permission was granted by Dr June Dahl to use questions from a 2006 Wisconsin questionnaire (Wolfert et al, 2010) as a starting point in the hope that when the final Chronic Pain Management Questionnaire (CPMQ) was implemented there would be potential to compare data between states. Other questions were formulated from barriers identified in the literature review and via committee discussion. Each individual questionnaire item was discussed with the committee via a teleconference editing

process. A draft of the CPMQ was presented to the Montana Pain Initiative (MTPI) Policy Committee for approval, content ideas and feedback. The questionnaire draft was approved by the policy committee with no significant changes other than a notation that the questionnaire should be as short as possible to facilitate higher response rates (Dr. Kaye Norris, personal correspondence, Feb 25th, 2009).

Expert Panel Participant Selection

The target population for the final questionnaire is health care providers with prescriptive authority in Montana who have the potential to provide health care to chronic pain patients. In a rural state such as Montana many patients will depend on their primary care provider for pain management (MPSMTF, 2008a), rather than a pain specialist. While most research has been conducted on physicians, in Montana, physician assistants and nurse practitioners have prescriptive authority and may provide primary care; and certified nurse anesthetists and pharmacists may also hold prescriptive authority. Our goal for the demographic content of the expert panel was to include two representatives from each of these disciplines with prescriptive authority, and have participants from both rural and urban practice settings. Contact information was obtained from the Montana Pain Initiative (MTPI) database of providers who had expressed interest in pain management in Montana in the past. Dr. Kaye Norris provided a list of candidates from which the thesis committee chose the potential participants.

Expert Panel Sampling Procedure

Institutional Review Board approval was obtained from Montana State University prior to any contact with participants. Initial contact occurred via personal telephone call to the individual's participant phone number provided by the MTPI. Once the potential participant was reached, the project was introduced including an explanation of the project, key protection of human subjects information and an invitation to participate. Frequently, messages were left with the office receptionist, nurse or on voice mail. In many cases it required 3 attempts over a 2-3 week period to reach the potential participant by phone. If, after 3 attempts, there was no contact, a new potential respondent was selected from the list until at least 12 participants had agreed. Once verbal permission was received from the potential participant, mailing address was confirmed and they were instructed to await the questionnaire packet in the mail. Each participant was mailed a cover letter, copy of the draft chronic pain questionnaire (CPMQ) (Appendix A) and a separate expert panel questionnaire (EPQ) designed to elicit feedback about the draft CPMQ. The purpose of the EPQ (Appendix B) was to assess the overall efficacy of the CPMQ (i.e. were the questions clear) and to clarify issues specific to individual questions that could not be resolved via discussion within the thesis committee. Envelopes were coded in order to track who had responded and allow for telephone reminders to those whom had not yet responded. If after 2 weeks participants had not yet responded, they were contacted once every 7-10 days for 3-4 weeks with a reminder and an offer to address any questions or concerns.

RESULTS

Overview of Responses

Expert panel questionnaires were returned from ten of thirteen participants and provided individual feedback about the CPMQ. Participants included: two physicians, one osteopathic physician, two pharmacists, two certified nurse anesthetists, one physician assistant, one nurse practitioner and one advanced practice nurse/clinical nurse specialist with pain management expertise. Three of ten respondents were from rural areas. Of the ten respondents, the three that did not return questionnaires were: an osteopathic physician and physician assistant who never responded to follow up calls and a nurse practitioner who declined to participate once he had seen the questionnaire because he felt it did not apply to his practice in the Emergency Department. Participants were supportive of the intent to assess barriers to pharmacotherapy in chronic pain. Responses were summarized in writing for thesis committee members and discussed via teleconference with Dr. Norris and Dr. Torma, and in person with Dr. Hill. Respondent comments for each question on the Expert Panel Questionnaire are summarized and discussed below.

Expert Panel Questionnaire Section One

Section one of the expert panel questionnaire sought feedback regarding general characteristics of the questionnaire as a whole. Please see Appendix B for a full copy of the questionnaire.

Table 2. Appropriateness of the Questions to the Questionnaire Purpose

Question 1. How well do the items in the CPMQ address the purpose of the questionnaire?		
Positive	Negative	Total
8	2	10
Example comments 1. "The purpose appears to be met; however, I question why non-opioid pharmacologic options/adjunctive therapies are not included?" 2. The questionnaire is "addressed towards a prescriber audience and not pharmacist. But it serves its purpose".		

Committee discussion of these comments agreed with the two important points: the title of the questionnaire does not reflect its focus on barriers to opioid use in pharmacotherapy for chronic pain, and the questions may not be appropriate for pharmacists, even those with prescriptive authority.

Table 3. Appropriateness of the Intended Population

Question 2. The population intended for the CPMQ includes all persons with prescriptive authority in Montana. Is this the appropriate population for the questionnaire?		
Positive	Negative	Total
10	0	10
Example comments 1. "Yes, but (Clinical Nurse Specialists) CNS in general do not prescribe. But they serve as consultants so would be good to administer to them" 2. "I would include pharmacists and counselors" 3. "I would include nursing staff as well; they often offer a good perspective on the patients, sometimes seeing more prescription trends than prescribers".		

The previous comment about the current questionnaire's applicability to pharmacists, the comments here about CNSs and the reluctance of the emergency department nurse practitioner to complete the questionnaire suggests that the questionnaire may not be appropriate for all provider types with prescriptive authority. This topic will be discussed further in the discussion section.

Table 4. Capture of the Important Issues in Chronic Pain Pharmacotherapy

Question 3. Please describe how well the CPMQ assesses the important issues on pharmacological chronic pain management in Montana			
Positive	Negative	No Response	Total
6	3	1	10
Example comments 1. "I believe it addresses the majority of issues but fails to assess non-opioid pharmacological options". 2. "May need info or questions re: opiate contract". 3. "I think we need to address the cannabinoid issue a little more".			

The committee agreed that the questionnaire may benefit from questions to assess use of pain medication agreements but that this would need to be weighed in light of other comments regarding the excessive length of the questionnaire. Cannabinoid and non-opioid pharmacology topics warrant their own questionnaire and inclusion of them here would excessively lengthen this questionnaire.

Table 5. Assessment of the Clarity of the Questions

Question 4. Are any questions unclear or confusing?		
Positive	Negative	Total
5	5	10
Example comments 1. "I think Q23 and Q24 are a little too long. I would consider trying to decrease" 2. "Q13 could include a non-opioid question" and Q19 may need to elaborate about what is legal or not by including requirement to send written script." 3. "Q13, I would consider a dose increase and evaluate for misuse and abuse, but you could argue that if I believe it is tolerance I already did that. I believe we need to convey this decision is not black or white". 4. Q12, 21, 22: CRNAs routinely administer these drugs but don't write prescriptions routinely, may add a does not apply category". 5. "Q22 – At first I answered with a patient at higher risk for abuse/diversion – would then answer often/always. But then I thought it could mean my overall practice – so this could be clarified".		

Question 13 was identified as confusing by two respondents because different interpretations of the word tolerance could lead to different answer choices. Discussion among committee meetings further demonstrated the tendency of this question to be interpreted differently. In the literature, Rosenblum et al (2008) also discuss confusion among providers with the term tolerance. Use of this question in the final questionnaire would require rewording for clarity.

One of the CRNA respondents felt that questions 12, 21 and 22 did not apply to CRNAs and suggested a "not applicable" answer option. Committee members agreed that further investigation into CRNA practice in Montana would be necessary to decide whether CRNAs are an appropriate target population.

Question 12 is not intended to assess a barrier but is a demographic question intended to quantify experience with opioid prescription. Comfort with opioid regulation and prescribing opioids has been shown to correlate with number of opioid prescriptions a provider writes. Comparing a provider's reported quantity of schedule II prescriptions with their answers in other categories may give insight into the educational needs of providers with less experience prescribing schedule II opioids. Consideration could be given to assessing this topic in a shorter question format but the current example has already been tested and shown to provide useable information in other surveys.

Question 21 and 22 both intend to assess ways providers modify their prescribing practice out of fear of investigation, abuse or diversion. Based on respondent feedback and committee discussion, the question should be further clarified to ensure consistent

interpretation. Changes to questions 21 and 22 and the length of questions 23 and 24 will be discussed further in the discussion chapter.

Table 6. Assessment for Questions which should not be included

Question 5. Are there any questions you feel should not be included?		
Positive	Negative	Total
1	9	10
Example comments 1. "Q9 – You cannot prescribe without this (DEA number)"		

Question 9 mentioned above, was intended as a screening question so that those without prescriptive authority were identified and instructed not to proceed with the questionnaire. Inclusion of this question would depend on the whether the DEA status of the potential respondents was known or unknown.

Table 7. Assessment for Questions which should be added

Question 6. Are there any questions you feel should be added?			
Positive	Negative	No comments	Total
2	8		10
Example comments 1. "Yes- something about assessment for high risk. E.G. – Do they use a screening tool to assess for risk? Urine testing? Contract use (opioid agreement)? Some patients or all?" 2. "Do you know when a patient is addicted and it is time for them to get addiction treatment? Do you know the complete history of all your pain patients?" 3. "Dr. Shopping and what providers do now without electronic monitoring. Pain agreements or contracts with patients. Urine drug screens and how sensitive and to what medications.			

Recent research has highlighted increasing misuse and diversion of controlled substances over the last decade, coinciding with increasing prescription of controlled substances (CDC, 2010) Comments from respondents indicate that this is a topic important in their current practices. Inclusion of questions regarding pain medication contract, risk mitigation techniques such as urine screening; and provider ability to

recognize and respond to/manage addiction may be warranted in light of recent research. Please see the discussion section for recommendations.

Table 8. Assessment for Factors that may affect Response Rates

Question 7. Please comment on any aspects that might affect response rates:			
Positive	Negative	No comment	Total
2	6	2	10
Example comments 1. "length" 2. "This part is too long" 3. "Length. If you can get it to one page double sided that would be best". 4. "Q 19 and 20 should explain that we are looking for their understanding "to the best of your knowledge" as opposed to them researching the answer". 5. "Sounds funny but maybe age. But, maybe re-order 1st page: Q3, Q4, Q1, Q2, Q5, Q6, Q7". 6. See answer to "question #4" regarding CRNAs.			

Question 7 was the only expert panel question that received three convergent responses: the questionnaire was too long. Committee members were in agreement with these comments and felt the questionnaire content would require further prioritization and shortening prior to implementation. Dr. Hill also commented that the impact of the length could be mitigated with use of the Dillman method to increase response rates.

Table 9. Assessment of Overall Impression of the Questionnaire

Question 8. Please provide us with any other comments or impressions regarding the questionnaire:			
Positive	Negative	No comment	Total
2	1	7	
Example comments 1. "The 3 bullets on the purpose of the questionnaire broadly address pharmacological therapies, but questions only address opioids".			

This respondent included this same comment in other responses which are discussed elsewhere. Committee conclusion was to change the title of the questionnaire to reflect the content rather than expand the already lengthy questionnaire to include additional therapies.

Expert Panel Questionnaire Section Two

During discussion with the thesis committee, four questions were identified for which specific feedback on clarity or content was needed from the expert panel. Part two of the expert panel questionnaire contained questions specific to # 19, 20, 23 and 24.

Table 10. Issues Specific to Question 19

Question 19. Part A. Is this question adequately clear?			
Positive	Negative	No comment	Total
9	1	0	10
Example comments 1. "See answers to #4 and #7" above			
Question 19. Part B. Does this question identify all important misconceptions about prescription regulation/policy?			
Positive	Negative	No comment	Total
7	2	1	10
Example comments 1. "Electronic prescriptions and the need for software that meets requirements of DEA vs. hand signing of the controlled II prescriptions 21 C.F.R. part 1311". 2. "Quantity allowed for emergency script. Scripts need to be accurate as far as medication strength and FDA approved use".			

Committee members identified CPMQ question 19 as cumbersome and unclear. The expert panel identified the question as problematic because it did not fully represent the many regulations related to opioid use. As a result, the question was modified to

encompass all regulatory contingencies but is likely too complex to serve the purposes of this survey. Please see the discussion section for more details.

Electronic medical record (EMR) prescribing will not be added to the current questionnaire draft as it is considered a divergence from the current scope of the questionnaire and would only apply to those providers with EMR. Additionally, with new e-prescribing regulations on controlled substances issued by the DEA (2010), there is a great deal of uncertainty about electronic prescribing's affect on opioid pharmacotherapy in chronic pain.

Table 11. Issues Specific to Question 20

Question 20 Are the answer categories in this question (1.e. lawful yes/no, standard of practice yes/no) appropriate and clear?			
Positive	Negative	No comment	Total
6	4	0	10

Example comments

1. "I am not sure this question is necessary".
2. Lawful is. Standard of practice can be confusing. I could see a midlevel provider saying FNP's can't do this when the standard for their location is they can".
3. "If the intent is to determine understanding of regulation, it may not be useful necessary to address standard of practice."
4. "Not clear at first glance. Re-read it – got it."

Question 20 was also intended to identify inaccurate understanding of opioid regulation and standard of practice that might affect prescribing practice. This question had been discussed extensively by the thesis committee in an attempt to ensure clarity and also received several comments from the expert panel. Both the respondents and the committee agreed that the question was unclear and did not need to include both legality and standard of care.

Table 12. Issues Specific to Question 23

Question 23. Are there other barriers that you would add or ones you feel should be re-worded or removed?			
Add	Remove	No change	Total
3	0	7	10
Example comments 1. "Lack of availability of some opioids in rural areas, reservations". 2. "Get rid of: assessment, patient non-compliance, lack of physiological cause". 3. "I am not sure what inability to lead a pain team is".			

Question 23 was intended to identify barriers faced by providers and the degree to which each barrier impacted practice. The three line items suggested for removal in comment two above have been identified in the literature as important barriers and were included for this reason. Ability to lead a pain team was a line item suggested by committee members from their personal experience of seeing a deficit in pain team leadership in health care settings. Committee members agreed to remove "inability to lead a pain team" but retain the other items which are well supported in the literature.

Table 13. Issues Specific to Question 24

Question 24. Are there other facilitators you would add, or ones you feel should be re-worded or removed?			
Add	Remove	No change	Total
3	0	7	10
Example comments 1. "Information regarding contracts" 2. "Information on cannabinoid laws. This changes and was debated for 3 hours at the pain and chemical dependency meeting". 3. Educate the public about the problem with diversion of narcotics and protecting them from theft or misuse. DEA involvement with controlling diversion presented to providers. Maybe a meeting to hash out needs of the community".			

Question 24 was intended to identify ways to facilitate/help providers with pharmacological chronic pain management in Montana. The additional facilitators

suggested by respondents echo a theme suggesting a need for more provider information on risk assessment and risk mitigation for addiction in chronic pain management. Committee members also identified this need and agreed that addition of addiction risk assessment and risk mitigation techniques should be considered for inclusion in any final questionnaire.

Table 14. Disposition Summary of CPMQ Questions that Received Specific Feedback

Question	Number of Comments	Disposition
3		Change: Edited to reflect revised target population, moved to position one
9		Recommendation: consider removal if DEA status of respondent pool is known prior to survey
11b		Change: “degree” replaced with “post-degree” in stem of question
12		No changes at this time Recommendation: consider addition of “not applicable” answer option if indicated by final target population
13		Recommendation: question be removed or reworded for clarity
19		Change: edited to more accurately reflect prescription regulation
20		Removed from the questionnaire
21		Changed: “chronic pain” added to stem of question Recommendation: consider addition of “not applicable” answer option if indicated by final target population
22		Changed: “chronic pain” added to stem of question Recommendation: consider addition of “not applicable” answer option if indicated by final target population
23		No changes
24		No changes

DISCUSSION

Input from the expert panel provided firm agreement for the importance of assessing barriers to chronic pain management in Montana. The process of questionnaire development and review of expert panel feedback helped identify possible changes and additions to the questionnaire so that it may better address current issues. Based on expert panel feedback and further discussion with the graduate committee the following changes and considerations are recommended for the survey. A questionnaire incorporating agreed upon changes is provided in Appendix C.

Changes to Questionnaire Based on Panel and Committee Consensus

Chronic pain management using the preferred bio-psychosocial model would incorporate pharmacological and non-pharmacological interventions well beyond the sole use of opioids. However, the topic of chronic pain is too large for one questionnaire to address more than a small component of the full bio-psychosocial model. In the review of the literature regarding barriers to chronic pain management, issues around opioid prescription were the most frequently mentioned barriers. Therefore the title of the questionnaire was changed to reflect the focus on barriers to opioid pharmacology.

Initially the target population was considered to be all providers with prescriptive authority in Montana. Response from the expert panel made it clear that not all provider types with prescriptive authority would find these questions applicable to them. While pharmacists can have prescriptive authority in Montana and may be resources for

providers, many of the questions in this questionnaire do not apply to most pharmacists. Certified Registered Nurse Anesthetists (CRNA) have prescriptive authority but rarely write prescriptions in an outpatient setting and much of their pain management practice involves interventional methods not assessed in this questionnaire. Based on this information, it is recommended that Pharmacists and CRNAs be removed from the target population. Nursing staff will not be included because they do not have prescriptive authority. These populations may warrant a questionnaire addressing the barriers to chronic pain specific to their scope of practice. One nurse practitioner respondent declined to complete the expert panel questionnaire because he felt that the CPMQ did not apply to his ED practice setting. During further follow-up contact, the respondent was unwilling to provide feedback as to which aspects of the questionnaire were not applicable to his practice. As demonstrated by Wilsey et al. (2008) barriers to chronic pain pharmacotherapy do exist in the ED. Additionally, patients without health insurance coverage or a primary care provider may seek treatment for their chronic pain in an ED. For these reasons it is recommended that ED practitioners remain in the target population for the questionnaire.

The following changes have been made to the questionnaire with committee consensus: a) addition of the term “chronic pain” to the stem of questions 21 and 22 for clarity, b) replacement of “degree” with “post-degree” in question 11B, and c) removal of question 20 from the questionnaire. Line items for questions 23 and 24 will not be changed as each item is well supported by the literature and committee discussion. Question 12 will be retained as a key measure of a providers experience level with opioid

prescribing. Question 19 must be reworded to include all conditions of appropriate prescribing for each line item. An edited version of question 19 incorporating changes suggested by pharmacist respondents is provided in Appendix C for consideration in future implementations of this survey. The revised question 19 should be reviewed for clarity prior to use.

Areas for Further Consideration Prior to Implementation

Prior to implementation of the survey further consideration should be given to the target population. For example, non-nurse practitioner advanced practice registered nurses, including nurse-midwives and clinical nurse specialists, are not likely to manage chronic pain patients and may not find the questionnaire applicable to their practice. The refusal to complete the questionnaire by the nurse practitioner in the emergency department setting suggests that, either this individual did not want to complete the EPQ for their own reasons or perhaps emergency department providers may not find the questions applicable. Population selection within a provider type: e.g. selecting for only non-emergency department nurse practitioners may complicate demographic collection and analysis and is not recommended in this situation. However, exclusion of a specific practice type e.g. clinical nurse specialists may be more feasible. If CNSs and Nurse Midwives are included in the respondent pool, questions 12, 21 and 22 many need the addition of a Not Applicable answer option.

The current draft of the questionnaire, incorporating agreed upon changes, is 6 pages in length, much longer than the one double sided page suggested by a respondent.

As indicated by the expert panel questionnaire length may adversely influence response rates for busy providers. Prior to implementation of the questionnaire, the length should be reviewed and questions considered for deletion as appropriate for the key goals at the time and the method of survey implementation.

Concern about addiction and diversion has increased in focus recently, especially with the release of new national prevalence statistics (CDC, 2010). After reviewing the questionnaire draft the expert panel, Dr. Torma and Dr. Norris suggested the addition of questions to assess provider knowledge of addiction, knowledge of risk assessment and monitoring and use of screening and monitoring techniques for addiction/misuse. This could include questions related to the use of pain medication agreements as a risk mitigation tool. This information would assist the MTPI in providing education and support to providers on these topics. The creation of these questions is beyond the scope of this document but could be considered for inclusion prior to implementation.

Question 13 was intended to gauge knowledge of opioid pharmacotherapy by assessing understanding of the concept of tolerance. Tolerance to the analgesic effects of an opioid occurs with use of opioids. If a patient develops tolerance and their pain is no longer adequately controlled, their behaviors may be interpreted as drug seeking or addiction driven by providers with inaccurate understanding of tolerance. The current question allows for multiple interpretations, as evidenced by expert panel comments and committee discussion. If this question is to be used it is recommended that it be reworded and that a vignette or case study format may allow for better clarity. Alternately, it could be deleted to allow for shortening of the survey.

Question 9 will be retained at this time but should be considered for deletion as indicated by the potential respondent pool at the time of questionnaire implementation. If the final questionnaire is only sent to those with confirmed prescriptive authority then question 9 could be removed. However, if the prescriptive authority status of the respondent pool is unknown, this question would be an important demographic and screening question and should be included.

Conclusion

Health care providers face many barriers to provision of effective, safe chronic pain management for the more than 76 million people who suffer from chronic pain in the U.S. Research has demonstrated that many of these barriers relate to chronic pain pharmacotherapy. Understanding the relative influence and impact of these barriers in Montana is a first step toward mitigating barriers that impeded adequate chronic pain management and in identifying ways to support health care providers. While some barriers have been assessed in other states, there is no consistent instrument available for identifying barriers to management of chronic pain, nor one tailored to issues most relevant to Montana. This project developed a questionnaire specific to Montana health care providers to allow assessment of barriers to chronic pain pharmacotherapy, specifically opioid therapy.

The results of this questionnaire development process, including the expert panel responses, confirm the presence of significant barriers to opioid pharmacotherapy for chronic pain in Montana. The expert panel feedback gathered provided key information

for revision of the questionnaire, improving the questionnaire clarity and relevance to Montana. In addition, respondents expressed gratitude and encouragement, acknowledging the difficulty of the issues surrounding opioid pharmacotherapy in chronic pain management and the value of an assessment of barriers. This project represents an essential first step in the development of an assessment tool for use in Montana to identify the existence and relative impact of barriers to chronic pain management.

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APPENDICES

APPENDIX A

CHRONIC PAIN MANAGEMENT QUESTIONNAIRE

PHARMACOLOGICAL CHRONIC PAIN MANAGEMENT QUESTIONNIARE:

Part I. Please answer the following questions about yourself and your practice.

Q1 Age: _____

Q2 Gender
- ☐ Female
- ☐ Male

Q3 Profession:
- ☐ Physician
- ☐ Physician Assistant
- ☐ Advanced Practice Registered Nurse (Nurse Practitioner, Nurse Anesthetist, Certified Nurse Midwife, Clinical Nurse Specialists)
- ☐ Pharmacist

Q4 In your current role as a provider, how many years have you been in practice?
- ☐ < 5 years
- ☐ 5-10 years
- ☐ 10-15 years
- ☐ 15-20 years
- ☐ > 20 years

Q5 Please write in the zip code of the area where you currently practice.
Zip Code: _____

Q6 Please estimate the size of the community in which you practice:
- ☐ Less than 5, 000
- ☐ 5,000 - 10,000
- ☐ 10,000 - 25,000
- ☐ 25,000 - 50,000
- ☐ 50,000 - 100,000
- ☐ 100,000 - 150,000
- ☐ Over 150,000

Q7 Do you **accept** chronic pain patients in your practice?
- ☐ Yes
- ☐ No

Q8 Do you currently **treat** patients who have chronic pain?
- No
- Yes, < 10 patients per month
- Yes, 10-50 patients per month
- Yes, > 50 patients per month

Q9 Do you have a DEA (Drug Enforcement Administration) number?
- Yes
- No

Q10A Did you have formal training in prescribing opioids for chronic pain management **during** your degree program?
- Yes
- No If No, Skip Q 10B proceed to Q 11A

Q10B Please rate the adequacy of your degree program training in preparing you to prescribe opioids for chronic pain management:
- Inadequate
- Adequate
- More than adequate

Q11A Did you have formal training in prescribing opioids for chronic pain management **after** your degree program?
- Yes
- No If No, Skip Q 11B proceed to Q 12

Q11B Please rate the adequacy of your degree program training in preparing you to prescribe opioids for chronic pain management:
- Inadequate
- Adequate
- More than adequate

Q12 Approximately how many outpatient prescriptions for opioid analgesics do you write **per month**?

	None	1-5	6-15	Over 15
Schedule IV	□	□	□	□
Propoxyphene (e.g. Darvon)				
Propoxyphene with Acetaminophen (e.g. Darvocet, Wygesic)				
Schedule III	□	□	□	□
Codeine/Codeine combination products (e.g. Tylenol #2, #3, #4)				
Hydrocodone combination products (e.g. Vicodin, Lortab)				
Schedule II	□	□	□	□
Fentanyl (e.g. Actiq, Fentora, Duragesic)				
Hydromorphone (e.g. Dilaudid)				
Meperidine (e.g. Demerol)				
Methadone (e.g. Dolophine)				
Morphine (e.g. Avinza, Kadian, MSContin, Oramorph, Roxanol)				
Oxycodone or Oxycodone combination products (e.g. Oxycontin, Percocet, Percodan, Roxicet, Roxicodone)				

Part II. Please take a few moments to answer questions about topics related to chronic pain, opioids and prescription of opioids.

Q13 If, in your clinical judgment, you believe that a patient with chronic pain has developed tolerance to the analgesic effects of the current opioid therapy, what would be your next course of action?

□ Increase dose of the current opioid
□ Maintain dose of the current opioid and evaluate patient for potential misuse or abuse.
□ Reduce dose of the current opioid
□ Rotate to another opioid
□ None of the above

Q14 Research and clinical experience reveal that patients generally **do not** develop tolerance to which of the following side effects of opioid therapy? Check all that apply:

□ Nausea and vomiting
□ Respiratory depression
□ Constipation
□ Sedation
□ None of the above

Q15 Which of the following characteristics indicates that an individual is addicted to an opioid pain medication? Check all that apply:

□ Physical dependence/withdrawal symptoms
□ Tolerance
□ Compulsive use despite harm
□ None of the above
□ Not sure

Q16 In your individual clinical practice experience with patients with **chronic pain**, has opioid treatment, used either alone or as part of a interdisciplinary care plan:

	Yes	No	Not sure
Provided sufficient pain relief (i.e. at least 30% reduction in pain scores)?	□	□	□
Improved physical function (e.g. ability to engage in activities of daily living, resume exercise, or return to work)?	□	□	□
Improved patient quality of life?	□	□	□

Q17 In your opinion, is patient **diversion** of prescribed opioid medication a problem in Montana?

- □ Not a problem
- □ Minor problem
- □ Moderate problem
- □ Serious problem

Q18 In your opinion, is patient **abuse** of prescribed opioid medication a problem in Montana?

- □ Not a problem
- □ Minor problem
- □ Moderate problem
- □ Serious problem

Q19 Are the following prescribing practices legal in Montana:

	Yes	No	Not sure
A prescriber can, in an emergency, call in a prescription to a pharmacy for a schedule II opioid.	□	□	□
A prescriber can write for a refill for a schedule II opioid.	□	□	□
A prescriber can fax a prescription to a pharmacy for a schedule II opioid for any patient type.	□	□	□
A prescriber can prescribe more than a 30-day supply of a schedule II opioid at one time.	□	□	□
A prescriber can prescribe methadone for pain relief.	□	□	□

Q20 Please indicate, for the following patient types, whether prescribing opioids **for more than six months** is legal and/or accepted standard of practice (Check all that apply for each line item):

	Lawful		Accepted standard of practice	
A patient with chronic cancer pain	□ Yes	□ No	□ Yes	□ No
A patient with chronic non-cancer pain	□ Yes	□ No	□ Yes	□ No
A patient with chronic cancer pain **and** a history of substance abuse	□ Yes	□ No	□ Yes	□ No
*A patient with chronic non-cancer pain **and** a history of substance abuse*	□ Yes	□ No	□ Yes	□ No

Q21 Because of **concern about possible investigation** by a regulatory agency, how frequently do you change your opioid prescribing practices by doing the following?

	Never	Occasionally	Often	Always
Prescribe a lower dose	□	□	□	□
Prescribe a smaller quantity	□	□	□	□
Limit the frequency of refills	□	□	□	□
Prescribe a Schedule III or IV opioid rather than a Schedule II opioid	□	□	□	□
Choose not to prescribe a Schedule II opioid	□	□	□	□
Prescribe a shorter acting opioid rather than a longer acting formulation such as Oxycontin or MSContin.	□	□	□	□

Q22 Because of **concern about possible abuse or diversion** of opioids by the patient, how frequently do you change your opioid prescribing practices by doing the following?

	Never	Occasionally	Often	Always
Prescribe a lower dose	□	□	□	□
Prescribe a smaller quantity	□	□	□	□
Limit the frequency of refills	□	□	□	□
Prescribe a Schedule III or IV opioid rather than a Schedule II opioid	□	□	□	□
Choose not to prescribe a Schedule II opioid	□	□	□	□
Prescribe a shorter acting opioid rather than a longer acting formulation such as Oxycontin or MSContin.	□	□	□	□

Q23 Consider what circumstances may serve as **barriers** to pharmacological chronic pain management in your practice. (Check one box for each item.)

	Not a Barrier	Minor Barrier	Barrier	Major Barrier
Inadequate knowledge of pharmacotherapy for chronic pain	☐	☐	☐	☐
Inadequate or inconsistent pain assessment methods	☐	☐	☐	☐
Complex nature of chronic pain and chronic pain patients	☐	☐	☐	☐
Lack of adequate patient insurance or medication coverage	☐	☐	☐	☐
Inadequate access to chronic pain specialist consult	☐	☐	☐	☐
Discomfort with long-term use of opioid medication	☐	☐	☐	☐
Concerns of addiction to opioid pain medication	☐	☐	☐	☐
Concerns of drug diversion or misuse	☐	☐	☐	☐
Concerns regarding medication side effects	☐	☐	☐	☐
Patient non-compliance with medication regimen	☐	☐	☐	☐
Lack of a clear physiological cause for the pain	☐	☐	☐	☐
Inability to lead multidisciplinary pain management team	☐	☐	☐	☐
Inadequate understanding of controlled substance policy	☐	☐	☐	☐
Concerns of investigation for prescribing practices	☐	☐	☐	☐
Discomfort using opioids for patients with a history of substance abuse	☐	☐	☐	☐

Q24 Consider what would **facilitate or help** you to address pharmacological chronic pain management in your practice. (Check one box for each item)

	Less Helpful	Helpful	More Helpful	Uncertain
Access to chronic pain consultation service	☐	☐	☐	☐
Access to pharmacist knowledgeable in chronic pain management	☐	☐	☐	☐
Information on opioid pharmacotherapy for chronic pain	☐	☐	☐	☐
Information on non-opioid pharmacotherapy for chronic pain	☐	☐	☐	☐
Information on pain medication agreements/contracts	☐	☐	☐	☐
Information on controlled substance policy and regulation	☐	☐	☐	☐
Information specific to opioid use for patients who have a history of substance abuse or co-morbid psychiatric disorders	☐	☐	☐	☐
Information on non-pharmacological pain management	☐	☐	☐	☐
State-wide electronic prescription drug monitoring program	☐	☐	☐	☐

APPENDIX B

EXPERT PANEL QUESTIONNAIRE

Please answer the following general questions regarding the CPM questionnaire (green):

1) The purpose of the CPM questionnaire is to
    - Assess current knowledge of Montana providers about pharmacological chronic pain medication and policies that govern the prescription of opioid analgesics
    - Assess barriers providers face in pharmacological chronic pain management in Montana.
    - Inform the development of outreach, education, and training strategies for chronic pain management in Montana to be instituted by the Montana Pain Initiative a project of the American Cancer Society and the American Cancer Society Cancer Action Network.

    How well do the items in the CPM questionnaire address this purpose?

2) The population intended for the CPM questionnaire includes all persons with prescriptive authority in Montana. Is this the appropriate population for the CPM questionnaire purpose?

3) Please describe how well the CPM questionnaire assesses the important issues in pharmacological chronic pain management in Montana?

4) Are any questions on the CPM questionnaire unclear or confusing? Please specify which questions might be unclear or confusing and how they might be asked more effectively.

5) Are there any questions on the CPM questionnaire you feel should not be included? Please list and explain:

6) Are there any questions we have not asked that you feel should be added? Please list and explain:

7) Please comment on any aspects of the CPM questionnaire that might affect response rates.

8) Please provide us with any other comments or impressions regarding the CPM questionnaire or questions:

Please answer the following questions regarding specific questions on the CPM questionnaire. You may reference the copy of the CPM questionnaire (green) to view the original question as needed:

1) Q19: This question is intended to identify inaccurate understandings of opioid prescription regulation that may affect prescribing practice.

   1a) Is this question adequately clear?

   1b) Does this question identify all important misconceptions about prescription regulation/policy? If not please list what should be added or removed:

2) Q 20: This question is also intended to identify inaccurate understanding of opioid regulation that may affect prescribing practice. Are the answer categories (i.e. lawful yes/no, standard of practice yes/no) appropriate and clear?

3) Q 23: This question is intended to identify what barriers providers face in Montana to pharmacological chronic pain management. Are there other barriers that you would add, or ones you feel should be re-worded or removed?

4) Q 24: This question is intended to identify what might help or facilitate pharmacological chronic pain management in Montana. Are there other facilitators you would add, or ones you feel should be re-worded or removed?

Thanks you for your assistance with development of the CPM questionnaire.

APPENDIX C

REVISED QUESTIONNAIRE

OPIOID PHARMACOTHERAPY IN CHRONIC PAIN MANAGEMENT:

Part I. Please answer the following questions about yourself and your practice.

Q1 Profession:
- ☐ Physician
- ☐ Physician Assistant
- ☐ Nurse Practitioner

Q2 In your current role as a provider, how many years have you been in practice?
- ☐ < 5 years
- ☐ 5-10 years
- ☐ 10-15 years
- ☐ 15-20 years
- ☐ > 20 years

Q3 Age: _____

Q4 Gender
- ☐ Female
- ☐ Male

Q5 Please write in the zip code of the area where you currently practice.
Zip Code: _____

Q6 Please estimate the size of the community in which you practice:
- ☐ Less than 5, 000
- ☐ 5,000 - 10,000
- ☐ 10,000 - 25,000
- ☐ 25,000 - 50,000
- ☐ 50,000 - 100,000
- ☐ 100,000 - 150,000
- ☐ Over 150,000

Q7 Do you **accept** chronic pain patients in your practice?
- ☐ Yes
- ☐ No

Q8 Do you currently **treat** patients who have chronic pain?
- ☐ No
- ☐ Yes, < 10 patients per month

□ Yes, 10-50 patients per month
□ Yes, > 50 patients per month

Q9 Do you have a DEA (Drug Enforcement Administration) number?
□ Yes
□ No

Q10A Did you have formal training in prescribing opioids for chronic pain management **during** your degree program?
□ Yes
□ No If No, Skip Q 10B proceed to Q 11A

Q10B Please rate the adequacy of your degree program training in preparing you to prescribe opioids for chronic pain management:
□ Inadequate
□ Adequate
□ More than adequate

Q11A Did you have formal training in prescribing opioids for chronic pain management **after** your degree program?
□ Yes
□ No If No, Skip Q 11B proceed to Q 12

Q11B Please rate the adequacy of your post-degree program training in preparing you to prescribe opioids for chronic pain management:
□ Inadequate
□ Adequate
□ More than adequate

Q12 Approximately how many outpatient prescriptions for opioid analgesics do you write **per month**?

	None	1-5	6-15	Over 15
Schedule IV	□	□	□	□
Propoxyphene (e.g. Darvon)				
Propoxyphene with Acetaminophen (e.g. Darvocet, Wygesic)				
Schedule III	□	□	□	□
Codeine/Codeine combination products (e.g. Tylenol #2, #3, #4)				
Hydrocodone combination products (e.g. Vicodin, Lortab)				
Schedule II	□	□	□	□
Fentanyl (e.g. Actiq, Fentora, Duragesic)				
Hydromorphone (e.g. Dilaudid)				
Meperidine (e.g. Demerol)				
Methadone (e.g. Dolophine)				
Morphine (e.g. Avinza, Kadian, MSContin, Oramorph, Roxanol)				
Oxycodone or Oxycodone combination products (e.g. Oxycontin, Percocet, Percodan, Roxicet, Roxicodone)				

Part II. Please take a few moments to answer questions about topics related to chronic pain, opioids and prescription of opioids.

Q13 If, in your clinical judgment, you believe that a patient with chronic pain has developed tolerance to the analgesic effects of the current opioid therapy, what would be your next course of action?

- □ Increase dose of the current opioid
- □ Maintain dose of the current opioid and evaluate patient for potential misuse or abuse.
- □ Reduce dose of the current opioid
- □ Rotate to another opioid
- □ None of the above

Q14 Research and clinical experience reveal that patients generally **do not** develop tolerance to which of the following side effects of opioid therapy? Check all that apply:

- □ Nausea and vomiting
- □ Respiratory depression
- □ Constipation
- □ Sedation
- □ None of the above

Q15 Which of the following characteristics indicates that an individual is addicted to an opioid pain medication? Check all that apply:

- □ Physical dependence/withdrawal symptoms
- □ Tolerance
- □ Compulsive use despite harm
- □ None of the above
- □ Not sure

Q16 In your individual clinical practice experience with patients with **chronic pain**, has opioid treatment, used either alone or as part of a interdisciplinary care plan:

	Yes	No	Not sure
Provided sufficient pain relief (i.e. at least 30% reduction in pain scores)?	□	□	□
Improved physical function (e.g. ability to engage in activities of daily living, resume exercise, or return to work)?	□	□	□
Improved patient quality of life?	□	□	□

Q17 In your opinion, is patient **diversion** of prescribed opioid medication a problem in Montana?

- □ Not a problem
- □ Minor problem
- □ Moderate problem
- □ Serious problem

Q18 In your opinion, is patient **abuse** of prescribed opioid medication a problem in Montana?
- □ Not a problem
- □ Minor problem
- □ Moderate problem
- □ Serious problem

Q19 To the best of your knowledge, are the following prescribing practices legal in Montana:

	Yes	No	Not sure
A prescriber can, in an emergency, call in a prescription to a pharmacy for 72 hours of a schedule II opioid and then follow up with a hard-copy within 7 days.	□	□	□
A prescriber can fax a schedule II opioid prescription to a pharmacy only for a Hospice or Long Term Care facility patient.	□	□	□
A prescriber can prescribe more than a 30-day supply of a schedule II opioid at one time but cannot write for refills.	□	□	□
A prescriber can prescribe methadone for pain relief.	□	□	□

Q21 Because of **concern about possible investigation** by a regulatory agency, how frequently in your overall practice do you change your opioid prescribing practices for chronic pain by doing the following?

	Never	Occasionally	Often	Always
Prescribe a lower dose	□	□	□	□
Prescribe a smaller quantity	□	□	□	□
Limit the frequency of refills	□	□	□	□
Prescribe a Schedule III or IV opioid rather than a Schedule II opioid	□	□	□	□
Choose not to prescribe a Schedule II opioid	□	□	□	□
Prescribe a shorter acting opioid rather than a longer acting formulation such as Oxycontin or MSContin.	□	□	□	□

Q22 Because of **concern about possible abuse or diversion** of opioids by the patient, how frequently in your overall practice do you change your opioid prescribing practices for chronic pain by doing the following?

	Never	Occasionally	Often	Always
Prescribe a lower dose	□	□	□	□
Prescribe a smaller quantity	□	□	□	□
Limit the frequency of refills	□	□	□	□
Prescribe a Schedule III or IV opioid rather than a Schedule II opioid	□	□	□	□
Choose not to prescribe a Schedule II opioid	□	□	□	□
Prescribe a shorter acting opioid rather than a longer acting formulation such as Oxycontin or MSContin.	□	□	□	□

Q23 Consider what circumstances may serve as **barriers** to pharmacological chronic pain management in your practice. (Check one box for each item.)

	Not a Barrier	Minor Barrier	Barrier	Major Barrier
Inadequate knowledge of pharmacotherapy for chronic pain	□	□	□	□
Inadequate or inconsistent pain assessment methods	□	□	□	□
Complex nature of chronic pain and chronic pain patients	□	□	□	□
Lack of adequate patient insurance or medication coverage	□	□	□	□
Inadequate access to chronic pain specialist consult	□	□	□	□
Discomfort with long-term use of opioid medication	□	□	□	□
Concerns of addiction to opioid pain medication	□	□	□	□
Concerns of drug diversion or misuse	□	□	□	□
Concerns regarding medication side effects	□	□	□	□
Patient non-compliance with medication regimen	□	□	□	□
Lack of a clear physiological cause for the pain	□	□	□	□
Inadequate understanding of controlled substance policy	□	□	□	□
Concerns of investigation for prescribing practices	□	□	□	□
Discomfort using opioids for patients with a history of substance abuse	□	□	□	□

Q24 Consider what would **facilitate or help** you to address pharmacological chronic pain management in your practice. (Check one box for each item)

	Less Helpful	Helpful	More Helpful	Uncertain
Access to chronic pain consultation service	□	□	□	□
Access to pharmacist knowledgeable in chronic pain management	□	□	□	□
Information on opioid pharmacotherapy for chronic pain	□	□	□	□
Information on non-opioid pharmacotherapy for chronic pain	□	□	□	□
Information on pain medication agreements/contracts	□	□	□	□
Information on controlled substance policy and regulation	□	□	□	□
Information specific to opioid use for patients who have a history of substance abuse or co-morbid psychiatric disorders	□	□	□	□
Information on non-pharmacological pain management	□	□	□	□
State-wide electronic prescription drug monitoring program	□	□	□	□