

Interim Report on the Implementation of House Bill 137

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Acknowledgments

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I. Introduction

The Utah State Legislature passed House Bill 137, Pain Medication Management and Education, during the 2007 General Session. That bill established a two-year program in the Utah Department of Health to reduce deaths and other harm from prescription opiates utilized for chronic pain.

II. Executive Summary

The Pain Medication Management and Education Program has been established in the Utah Department of Health in collaboration with the Utah Attorney General Office, the Labor Commission, and the Division of Occupational and Professional Licensure (DOPL). A Steering Committee has been established to provide oversight of the program. In addition, an Advisory Committee with several active workgroups on specific issues has been established to help coordinate with related initiatives and programs. The Program goals are to:

- Improve understanding of occurrence of deaths related to prescription pain medications and understanding of prescribing patterns and other risk factors that increase risk of death.
- Prevent deaths due to prescribable pain medications by educating providers, patients, insurers, and the public.
- Provide recommendations regarding use of the CSDB to identify risks and potentially to prevent deaths due to prescription pain medications.

Matching funds were contributed by the University of Utah's Research Center for Excellence in Public Health Informatics and the Worker's Compensation Fund of Utah resulting in a first year budget of \$500,000.

Analysis of Controlled Substances Database (CSDB)

The Utah Department of Health has been working actively with the Department of Commerce to establish an agreement for use of the CSDB to meet the legislative direction of HB 137 while providing adequate assurance for the security of the CSDB data. We hope to have a signed MOU by the time this report is reviewed by the legislative interim committees. The results presented here (see tables) are from analyses of a previously provided dataset and refer to drug poisoning deaths from 1999-2004.

- Total number of deaths due to drug poisoning of accidental or underdetermined intent - 1,218
- A substantial proportion of these deaths occurred in close relation to a legally prescribed prescription for an opioid medication. The CSDB analysis indicated that 41% of decedents (opioid-related deaths of accidental or undetermined intent) had filled a prescription for an opioid that would have lasted to within 30 days of the date of death if taken as prescribed.

Recommendations for CSDB Development and Use:

UDOH and DOPL have worked actively to establish a partnership and technical environment to support the analyses needed to meet the legislative direction of HB 137 and provide adequate security for the sensitive data contained in the CSDB. A MOU should be signed by the middle of November and we hope that an adequate technical environment will be established by the end of calendar year 2007. Detailed recommendations on uses of the CSDB to identify and prevent misuse of opiates, inappropriate prescribing, and adverse outcomes that have been developed in collaboration with the DOPL will be presented in the 2008 report to the legislature.

Interventions to Prevent Diversion:

Based on input from the Steering Committee and Advisory Committee, plans have been developed and work begun on the following interventions that will be implemented during year one of this program.

- Interventions planned for health care providers will include quality care guidelines, academic detailing, print and web-based material.
- Interventions for patients will include print materials and web-based information.
- Interventions for insurers will include print materials and in-person discussions to improve coverage of pain control.
- Interventions for the general public will include messages delivered by productions agency through TV, radio, billboards, and website.
- Other interventions are being developed through an organized Steering Committee, Advisory Committee, and several Work Groups: Provider Behavior Change; Insurance/Policy/Incentives; Patient and Community Education; and Data, Research, and Evaluation.

Development of Guidelines:

A process has been implemented to produce scientifically based guidelines. The process for producing those guidelines will:

- Assess the quality of the literature using explicit criteria for the best practices in prescribing opioid analgesics;
- Provide guidance on assessing the risks and benefits of opioid use as a treatment modality for a given individual;
- Utilize the Oregon Evidence-Based Practice Center to conduct the in-depth literature review;
- Utilize Dr. Roger Chou, lead physician on the Oregon review board, to present the research findings to the Utah Guideline Development Panel in May 2008

The Guideline Development Panel will finalize Utah guidelines, assist in the development of appropriate practice tools and facilitate dispersion of the guideline by September 2008.

Other

The UDOH is developing a website where committee members, the general public, and other interested parties can find information about how to get involved, the committees, minutes to our meetings, and a calendar of upcoming events.

III. Progress Report on HB 137

Report on Analysis of Controlled Substances Database

HB 137: “Requires the Utah Department of Health...to investigate causes and risk factors and solutions for deaths and nonfatal complications of prescription opiate use and misuse in Utah by using the Utah Controlled Substance Database.”

Background information:

Unintentional fatalities due to prescription medications are an increasing problem in United States and Utah. Over the past few years, the Utah Medical Examiner noted an increase in the number of deaths occurring due to overdose of prescription opioid medications that are typically used for pain management. Epidemiologic studies of data collected by the Office of the Medical Examiner, as well as from emergency department encounters and controlled substances dispensing confirmed the increases and uncovered an alarming problem.

During the years 1997–2004 deaths attributed to poisoning by drugs increased 128% in Utah from 174 to 397. Deaths of Utah residents from non-illicit drug poisoning (unintentional or intent not determined) have increased from about 50 deaths per year in 1999 to over 250 in 2006. The increase was mostly due to the higher number of deaths from prescription opiate pain medications, including methadone, oxycodone, hydrocodone, and fentanyl.

Methadone was the most common drug identified by the Utah medical examiner as causing or contributing to accidental deaths, accounting for a disproportionate number of deaths compared to its frequency of use. Methadone was the single drug most often associated with overdose death and had the highest prescription adjusted mortality rate (PAMR) with an average of 150 deaths for every 100,000 prescriptions during the study period (range: 89 deaths/100,000 prescriptions in 1998 to 224 deaths/100,000 prescriptions in 2004). From 1997–2004, population-adjusted methadone prescriptions increased 727%. This increase in the methadone prescription rate was for treatment of pain and not addiction therapy.

The numbers of prescriptions for four of the primary drugs of concern with respect to fatal drug overdose have increased at a greater rate than the growth of the Utah population. The population-adjusted relative increase in prescribing for methadone and fentanyl exceeded 700% while oxycodone nearly tripled.

For the years 1999–2003, unintentional deaths due to prescription medications were the fourth-leading cause of death in 25–54 year olds in Utah. Notably, while deaths of unintentional or undetermined intent caused by prescribable narcotics nearly tripled, cases of self-inflicted harm from narcotics remained stable from 1991–2003.

In 2006, methadone was implicated in 30% of non-illicit drug-related deaths, oxycodone in 21%, hydrocodone in 18%, and fentanyl in 9% of deaths associated with non-illicit drug overdose. The average age at death for deaths due to overdose of non-illicit drugs was 42 years old, with the ages ranging from 16 to 80 years old. Rates of death were slightly higher for males (51.3%) than females. At least one death occurred in 24 out of the 29 counties in Utah, suggesting that the problem spans both the urban and rural population.

Research combining Medical Examiner's data and data from the CSDB from 1997-2004 found that 50% of individuals who died of an overdose of methadone had a valid prescription at the time of death. This is informative in showing that there are two distinct populations: individuals with a valid prescription and individuals who found prescription opioids from some other source. To prevent future deaths of individuals with a valid prescription, the approach may be teaching proper use and warning against deviating from the directions given by their doctors, whereas to prevent deaths of individuals who are getting prescription drug from other sources, the approach may be to decrease availability of these drugs (for example, by educating others to lock up or dispose of their leftover medication).

A national report found that among young adults aged 18 to 25 who used prescription pain relievers non-medically in the past year, over half (53.0 percent) reported that they obtained the medication from a friend or relative for free. (National Survey on Drug Use and Health, 2006, retrieved on October 14, 2007 from <http://www.oas.samhsa.gov/2k6/getPain/getPain.htm>)

Recreational use of prescription drugs is increasing. In 2003, approximately 15 million Americans reported using a prescription drug for non-medical reasons at least once during the year. Approximately 6.3 million Americans reported current non-medical use of prescription drugs. (Office of Applied Studies, Substance Abuse and Mental Health Services Administration, National Survey on Drug Use and Health, 2004)

Abuse of prescription pain killers in the last year now ranks second, following marijuana, as the nation's most prevalent illegal drug problem. Even more foreboding is the fact that the number of new abusers of prescription drugs is equal to the number of new abusers of marijuana. Much of this abuse appears to be fueled by the relative ease of access to prescription drugs. Approximately 60 percent of people who abuse prescription pain killers indicate that they got their prescription drugs from a friend or relative for free. (Office of National Drug Control Policy, 2007, retrieved on October 17, 2007 from <http://www.whitehousedrugpolicy.gov/news/press07/022007.html>)

Preliminary results from the linked CSDB-Vital Statistics database analysis:

For the years 1999-2004, the CSDB includes 22,215,471 records of filled prescriptions. This represents 2,339,058 unique individuals that filled at least one controlled substance prescription. During the same time period, there were 1,920 drug poisoning deaths identified using death certificates. We analyzed the demographics of the decedents and

present summary results in Table 1. Intentionality status of the decedents is determined by the medical examiner or certifying official and is captured on the death certificate. Fatal drug overdose is a problem of middle-aged adults, with an average age of 38.8 years. The majority (67%) of drug poisoning where intent was accidental or undetermined were male. The greatest number of deaths occurred in the urban counties of the Wasatch Front where the largest proportion of the population lives, but when death rates are used to account for the population distribution (number of deaths per 100,000 population) this problem was seen to have affected frontier, rural and urban areas of the state similarly.

We linked the Medical Examiner Database to the de-duplicated CSDB in order to determine what proportion of the poisoning decedents had ever filled a prescription for the implicated drug and what proportion had a valid prescription at the time of death or within certain time intervals of death (Tables 2 and 3). Among accidental drug poisoning deaths, 40% (101/251) of decedents had received an opioid prescription that would have lasted to within 30 days of death, and 74% (185/251) had ever received an opioid prescription. Among drug poisoning deaths of undetermined intent, 41% (393/967) of decedents had received an opioid prescription that would have lasted to within 30 days of death, and 75% (729/967) of decedents had ever received a prescription for an opioid drug. Decedents with undetermined intent, who had filled prescriptions tended to be older (38.6 years compared to 36.5 years; $p=0.0059$) than those for whom we found no evidence of prescription. A greater proportion of decedents of unknown intent from non-urban Utah counties had evidence of a prescription (83%) than decedents of unknown intent from urban Utah counties (73%; $p=0.0181$). No such differences were seen among decedents of accidental intent.

Recommendations for the Controlled Substances Database

HB 137: “Requires the department to report to the legislative Health and Human Services Interim Committee and the legislative Business and Labor Interim Committee...to present its recommendations on: the use of the Utah Controlled Substances Database to identify and prevent the misuse of opiates; inappropriate prescribing; and adverse outcomes of prescription opiate medications.”

The Utah Controlled Substance Database Program was legislatively created and put into effect on July 1, 1995. It is used to track and collect data on the dispensing of Schedule II-V drugs by all retail, institutional, and outpatient hospital pharmacies, and in-state/out-of-state mail order pharmacies. The data are disseminated to authorized individuals and used to identify potential cases of drug over-utilization, misuse, and over-prescribing of controlled substances throughout the state.

The Utah Department of Health has been actively working with the Department of Commerce to develop an agreement and implement a technical infrastructure to support use of the CSDB that will allow the analyses needed to meet the legislative direction in HB 137 and also assure appropriate protection of these highly sensitive data. UDOH has been able to make some limited progress as presented here using a database previously

provided under statutory changes enacted in 2006. The two agencies have made substantial progress and we hope to have a signed Memorandum of Understanding by the time this report is presented to the Interim committee on November 14 or shortly thereafter. We are hopeful that once that agreement has been established, we will be able to work rapidly with DOPL and DTS to implement the needed technical infrastructure to support these analyses.

Preliminary analyses of the previously provided database have suggested that improvements in the data and uses of the database are possible. We are beginning to work with DOPL staff to identify which of those improvements are possible using currently submitted data and resources and which would require changes in how the data are submitted, additional resources, or both. We are looking forward to working with staff in DOPL, with the assistance of informatics experts in the Research Center for Excellence in Public Health Informatics at the University of Utah to identify those potential improvements. We anticipate having detailed recommendations to present to the legislature by the time of the next required report in November of 2008.

In addition to improvements that are currently possible, developments in health care informatics such as Clinical Health Information Exchanges (e.g., the Utah Health Information Network) and electronic health records which are being implemented in many practices in Utah will offer new possibilities for the use of the CSDB to help prevent these adverse health outcomes. Some examples of these opportunities might include

1. Secure, real-time connections between pharmacies and the CSDB that could improve timeliness, completeness and accuracy of the information reported to the CSDB.
2. Automated alerts that might identify a patient at risk of an adverse event, a provider prescribing in a dangerous or questionable manner.
3. Secure, real-time connection between a physician's clinical information system and the CSDB providing ready access to information about prior prescriptions for a patient for a prescribing provider at the time the prescription is being prepared.

We are enthusiastic about partnering with the Department of Commerce and staff in DOPL to identify opportunities to use the CSDB to prevent adverse outcomes of these valuable but dangerous medications while providing appropriate protections for the privacy of individuals whose information is included in the CSDB.

Report on Interventions to Prevent Diversion

HB 137: "Requires the Utah Department of Health...to present its recommendations on: interventions to prevent the diversion of prescription opiate medications."

HB 137 requires the Utah Department of Health to "educate health care providers, patients, insurers, and the general public on the appropriate management of pain." We are in the process of developing interventions to educate these target populations.

Health Care Providers:

1. Guidelines will be developed by a panel of experts. The guidelines will provide direction for providers on the use of prescription pain medications, for purposes other than palliative care.
2. Professional Academic Detailing will be done in order to inform providers and insurers on recommended policies and procedures on the appropriate management of pain, including the effective use of medical treatments, non-pharmacological therapies, and care guidelines that are scientifically based and peer reviewed. Such consultation may occur by telephone, email, videoconferences, or other mutually acceptable forms of communication such as on-site visits.
3. Print and information on web-based materials will be delivered to physician's offices and other appropriate settings.
4. A Provider Behavior Change Work Group has been formed that will meet monthly to determine and develop other interventions.

Patients:

1. Print materials will be distributed to offices where prescription pain medication can be prescribed. This includes medical doctors, doctor of osteopathy, physician assistants, advanced practice nurses, dentists, podiatrists, certified nurse midwives, naturopathic physicians, and schedule VI and V optometrists.
2. Web-based materials will be advertised in the aforementioned offices.
3. Flyers will be distributed to providers delineating directions for proper use of prescription opioids as well as warnings and risks of misuse. We will encourage nurses, assistants, or providers to go over the contents of the flyer with the patient before a prescription is given to them for opioids. The disclosure will warn patients of the risks associated with taking pills more often than recommended by the doctor and combining pills with alcohol or sedatives. It will also include a warning to keep pills locked up and dispose of them once they are no longer needed.
4. We have identified a valuable partnership with state and local environmental agencies interested, for environmental reasons, in providing better options for safe disposal of medications.
5. A Patient & Community Education Work Group has been formed that meets monthly to do determine and develop interventions aimed at educating patients and the community.

Insurers:

1. We have begun to meet with insurers to better understand what areas of the system could be changed or adapted to improve outcomes of the insured individuals using prescription drugs. Specifically we are looking at coverage practices that may create incentives to prescribe more dangerous opioids based on price rather than based on need.
2. The Insurance, Incentives, and Policy Work Group meets monthly to develop ideas about how to best educate and coordinate with insurers to adapt or change coverage policies.

General Public:

1. A media campaign will be created to include public service announcements on television and radio, as well as billboards and web-based materials. The Request for Proposals is currently being prepared and a contract will be made with the selected agency by December 2007. By April, the media campaign will be fully implemented.
2. A website will be developed with information on risks of prescription pain medication, and the contact information for help hotlines and treatment facilities in Utah.
3. A Patient & Community Education Work Group has been formed that meets monthly to do determine and develop interventions aimed at educating patients and the community.

A Steering Committee has begun meeting on a monthly basis to discuss progress and help guide the direction for the program. The Steering Committee consists of eleven (11) individuals who have leadership roles and/or specialize in areas that are important as we consider prescription pain medication management. An Advisory Committee of over fifty (50) individuals from throughout the community has been convened. The Advisory Committee has been organized as a way to include and involve the large number of stakeholders in the community who work with or are concerned about prescription pain medications. Through this committee, we will coordinate our efforts with the efforts of others and also incorporate advice from others with expertise and knowledge in this area in order to achieve our objective of reducing deaths relating to prescription pain medication. The advisory committee has been further divided into four Work Groups: Provider Behavior Change; Insurance/Policy/Incentives; Patient & Community Education; Data, Research, & Evaluation. The purpose of the Work Groups is to identify and help to carry out additional interventions.

Each Work Group within the Advisory Committee meets monthly. They will each identify and develop specific interventions that will be part of the Prescription Pain Management and Education Program. These intervention ideas will contribute to the overall plan that will be implemented.

Report on Guideline Development

HB 137: “Requires the department to report to the legislative Health and Human Services Interim Committee and the legislative Business and Labor Interim Committee...to present its recommendations on: medical treatment and quality care guidelines.”

The guidelines will address best practices for prescribing opioid analgesics as well as provide guidance on assessing the risks and benefits of opioids for a given individual. An in-depth literature review has been conducted by the Oregon Evidence-Based Practice Center through the Oregon Health & Science University. This literature review has been organized around 35 practice questions posed by an interdisciplinary panel of practitioners (See Appendices D and E for list of questions and panel members). The review methodology for judging the literature is thorough and explicit. A draft report has been shared with staff and will be available for public use in May 2008. Dr. Roger Chou,

lead physician for the review has offered to come to Utah to present the project findings. Arrangements will be made to have Dr. Chou meet with the Utah evidence review panel chaired by Dr. Marc Babitz, Division Director of Health Systems Improvement, Utah Department of Health. Additional input will be sought from other pain management experts as needed and determined by the panel. Utah will base the development of implementation strategies and tools on the findings of this work. Additionally, the Division of Health Care Financing, Utah Department of Health has contracted with the Oregon Center for Evidence-based Policy to conduct additional literature review on the questions generated by the Utah panel.

Results from these two processes will be compared and synthesized for consistency and used in the guideline adoption and implementation. The final outcome for this component of the legislative charge will include recommendations on medical treatment and quality care guidelines. Dr. Babitz in consultation with Dr. Sharon Weinstein will synthesize the findings from both Oregon and the Health Care Financing contract. Differences between the findings will be discussed with the expert panel and resolutions will be incorporated. Once the expert panel has reached a consensus on adapting or adopting the guidelines, the guidelines will be reviewed by an Implementation Panel of practicing physicians. This panel will provide feedback on any difficulties or challenges in the clinical application of the guidelines. Based on feedback from both panels, tools will be developed as directed by the panel members.

IV. Budget

A. Year One Program Revenues:

Item	Amount \$	Labor Commission Match Amount \$	Total \$
Legislative Appropriation	150,000	150,000	300,000
UofU Contribution, Research Center for Excellence in Public Health Informatics	23,000	23,000	46,000
Workers Compensation Fund of Utah	77,000	77,000	154,000
Total	250,000	250,000	500,000

B. Year One Budget Breakdown:

Item	Description	Amount \$
Project Director, Robert Rolfs, MD MPH	Responsible for overall direction of program and oversight of analytic investigation portions of project	In kind
Co-Project Director, Iona Thraen	Assist with supervision of project coordinator regarding education and guidelines portions of project	12,546
Lead Investigator: Christy Porucznik, PhD	Complete investigation of CSDB/ME/DC data; advise coalition on problem; design study	50,200
Project Coordinator, Erin Johnson, MPH	Coordinate education campaign and guidelines development processes, assist in investigation, coordinate coalition process, research and guide website development, liaison to partner/stakeholders	73,380
Research Consultant II	Transfer and analyze data from CSDB/ME/DC data; organize study design (hired December)	47,619*
Media Campaign	Estimate provided by UDOH Office of Public Information and Marketing, based on one year campaign to raise awareness of problem. Products would include produced media messages that could be reused if additional funding is available beyond the one year period.	200,000
Personnel associated costs	Phones, IT charges, OS&M. Based on 2.5 FTE and usual Bureau of Epidemiology costs	5,178
Contract for academic counter detailing	Estimate provided by HealthInsight: >\$200x200-300 visits; \$1,000 per lecture for hospital-based grand rounds, etc.	60,000
Contract to manage and support guidelines development	Literature reviews, physician leader to help develop draft guidelines, pain management content expertise, expertise in evidence-based guideline development.	10,000
UDOH IT improvements to support CSDB analysis	Dedicated server within DOPL architecture to facilitate analysis and database security, programming to set up ODBC access to database	20,000
Printing	Educational materials for physicians offices and to support public education campaign	8,000
Informatics consultation	Contract for informatics consultation	12,450
Total		499,272

*The future yearly amount for research consultant II will be \$95,236, but for FY'08 the research consultant II will be hired in December and so will only work for 6 months during this FY.

Appendix A

Table 1: Description of Decedents and Deaths Due to Narcotics, Psychodysleptics, or Other Unspecified Drugs, Utah, 1999-2004

Table 1. Description of decedents and deaths due to narcotics, psychodysleptics, or other unspecified drugs according to manner of death and selected demographic characteristics, Utah, 1999-2004

	All Decedents (N=76252)	Intentional Poisonings (N=201)	Accidental Poisonings (N=251)	Unknown Intent Poisonings (N=967)
Age categories, n (%)				
≤ 20	3040 (4.0%)	8 (4.0%)	10 (4.0%)	51 (5.3%)
≥ 21 and ≤ 40	4339 (5.7%)	83 (41.3%)	118 (47.0%)	494 (51.1%)
≥ 41 and ≤ 60	10356 (13.6%)	91 (45.3%)	109 (43.4%)	410 (42.4%)
≥ 61	58250 (76.4%)	18 (9.0%)	9 (3.6%)	10 (1.0%)
Missing	267 (0.4%)	1 (0.5%)	5 (2.0%)	2 (0.2%)
Gender, n (%)				
Male	38396 (50.4%)	95 (47.3%)	167 (66.5%)	649 (67.1%)
Marital Status, n (%)				
Single	7795 (10.2%)	49 (24.4%)	71 (28.3%)	333 (34.4%)
Married	32805 (43.0%)	77 (38.3%)	109 (43.4%)	317 (32.8%)
Divorced	8402 (11.0%)	62 (30.8%)	59 (23.5%)	278 (28.7%)
Widowed	27016 (35.4%)	12 (6.0%)	8 (3.2%)	21 (2.2%)
Other	32 (0.0%)			6 (0.6%)
Missing	202 (0.3%)	1 (0.5%)	4 (1.6%)	12 (1.2%)
Race, n (%)				
White	73888 (96.9%)	196 (97.5%)	237 (94.4%)	928 (96.0%)
Non-white	2364 (3.1%)	5 (2.5%)	14 (5.6%)	39 (4.0%)
Geography, n (%)				
Frontier	3523 (4.6%)	5 (2.5%)	11 (4.4%)	21 (2.2%)
Rural	10014 (13.1%)	18 (9.0%)	35 (13.9%)	79 (8.2%)
Urban	48745 (63.9%)	140 (69.7%)	168 (66.9%)	730 (75.5%)
Missing	13970 (18.3%)	38 (18.9%)	37 (14.7%)	137 (14.2%)

Appendix B

Table 2. Evidence of Prior Opioid Prescription among Drug Poisoning Decedents of Accidental or Unknown Intent, Utah, 1999-2004

Table 2. Evidence of Prior Opioid Prescription among Drug Poisoning Decedents of Accidental or Unknown Intent, Utah, 1999-2004

	Accidental Poisonings (n=251)		Unknown Intent Poisonings (n=967)	
	Evidence Opioid Rx (N=185)	No Evidence Opioid Rx (N=66)	Evidence Opioid Rx (N=729)	No Evidence Opioid Rx (N=238)
Age categories, n (%)				
≤ 20	5 (2.7%)	5 (7.6%)	36 (4.9%)	15 (6.3%)
≥ 21 and ≤ 40	92 (49.7%)	26 (39.4%)	359 (49.2%)	135 (56.7%)
≥ 41 and ≤ 60	83 (44.9%)	26 (39.4%)	325 (44.6%)	85 (35.7%)
≥ 61	5 (2.7%)	4 (6.1%)	9 (1.2%)	1 (0.4%)
Missing		5 (7.6%)		2 (0.8%)
Gender, n (%)				
Male	124 (67.0%)	43 (65.2%)	456 (62.6%)	193 (81.1%)
Marital Status, n (%)				
Single	50 (27.0%)	21 (31.8%)	225 (30.9%)	108 (45.4%)
Married	83 (44.9%)	26 (39.4%)	260 (35.7%)	57 (23.9%)
Divorced	46 (24.9%)	13 (19.7%)	220 (30.2%)	58 (24.4%)
Widowed	5 (2.7%)	3 (4.5%)	16 (2.2%)	5 (2.1%)
Other			2 (0.3%)	4 (1.7%)
Missing	1 (0.5%)	3 (4.5%)	6 (0.8%)	6 (2.5%)
Race, n (%)				
White	176 (95.1%)	61 (92.4%)	708 (97.1%)	220 (92.4%)
Non-white	9 (4.9%)	5 (7.6%)	21 (2.9%)	18 (7.6%)
Geography, n (%)				
Frontier	7 (3.8%)	4 (6.1%)	17 (2.3%)	4 (1.7%)
Rural	23 (12.4%)	12 (18.2%)	66 (9.1%)	13 (5.5%)
Urban	127 (68.6%)	41 (62.1%)	534 (73.3%)	196 (82.4%)
Missing	28 (15.1%)	9 (13.6%)	112 (15.4%)	25 (10.5%)

Appendix C

Table 3. Evidence for Opioid Prescription among Utah Drug Poisoning Decedents of Accidental and Unknown Intent According to Timing of Prescription in Relation to Death, 1999-2004

Table 3. Evidence for Opioid Prescription among Utah Drug Poisoning Decedents of Accidental and Unknown Intent According to Timing of Prescription in Relation to Death, 1999-2004

	Accidental Poisonings (Evidence of Opioid Rx)					Unknown Intent Poisonings (Evidence of Opioid Rx)				
	Opioid Rx (N=185)	Opioid Rx Time of Death (N=78)	Opioid Rx Time of Death 30 Days (N=101)	Opioid Rx Time of Death 60 Days (N=106)	Opioid Rx Time of Death 90 Days (N=114)	Opioid Rx (N=729)	Opioid Rx Time of Death (N=308)	Opioid Rx Time of Death (N=393)	Opioid Rx Time of Death (N=427)	Opioid Rx Time of Death (N=453)
Age categories, n (%)										
≤ 20	5 (2.7%)				1 (0.9%)	36 (4.9%)	7 (2.3%)	13 (3.3%)	13 (3.0%)	13 (2.9%)
≥ 21 and ≤ 40	92 (49.7%)	37 (47.4%)	49 (48.5%)	53 (50.0%)	57 (50.0%)	359 (49.2%)	133 (43.2%)	177 (45.0%)	198 (46.4%)	210 (46.4%)
≥ 41 and ≤ 60	83 (44.9%)	41 (52.6%)	50 (49.5%)	50 (47.2%)	53 (46.5%)	325 (44.6%)	163 (52.9%)	196 (49.9%)	209 (48.9%)	223 (49.2%)
≥ 61	5 (2.7%)		2 (2.0%)	3 (2.8%)	3 (2.6%)	9 (1.2%)	5 (1.6%)	7 (1.8%)	7 (1.6%)	7 (1.5%)
Gender, n (%)										
Male	124 (67.0%)	44 (56.4%)	59 (58.4%)	64 (60.4%)	70 (61.4%)	456 (62.6%)	158 (51.3%)	206 (52.4%)	223 (52.2%)	242 (53.4%)
Marital Status, n (%)										
Single	50 (27.0%)	15 (19.2%)	20 (19.8%)	21 (19.8%)	24 (21.1%)	225 (30.9%)	69 (22.4%)	91 (23.2%)	103 (24.1%)	113 (24.9%)
Married	83 (44.9%)	47 (60.3%)	55 (54.5%)	57 (53.8%)	61 (53.5%)	260 (35.7%)	138 (44.8%)	171 (43.5%)	176 (41.2%)	183 (40.4%)
Divorced	46 (24.9%)	15 (19.2%)	23 (22.8%)	25 (23.6%)	26 (22.8%)	220 (30.2%)	90 (29.2%)	117 (29.8%)	131 (30.7%)	140 (30.9%)
Widowed	5 (2.7%)	1 (1.3%)	3 (3.0%)	3 (2.8%)	3 (2.6%)	16 (2.2%)	10 (3.2%)	12 (3.1%)	13 (3.0%)	13 (2.9%)
Other						2 (0.3%)				
Missing	1 (0.5%)					6 (0.8%)	1 (0.3%)	2 (0.5%)	4 (0.9%)	4 (0.9%)
Race, n (%)										
White	176 (95.1%)	76 (97.4%)	98 (97.0%)	103 (97.2%)	111 (97.4%)	708 (97.1%)	302 (98.1%)	386 (98.2%)	419 (98.1%)	443 (97.8%)
Non-white	9 (4.9%)	2 (2.6%)	3 (3.0%)	3 (2.8%)	3 (2.6%)	21 (2.9%)	6 (1.9%)	7 (1.8%)	8 (1.9%)	10 (2.2%)
Geography, n (%)										
Frontier	7 (3.8%)	3 (3.8%)	4 (4.0%)	4 (3.8%)	5 (4.4%)	17 (2.3%)	6 (1.9%)	9 (2.3%)	11 (2.6%)	11 (2.4%)
Rural	23 (12.4%)	11 (14.1%)	14 (13.9%)	15 (14.2%)	16 (14.0%)	66 (9.1%)	39 (12.7%)	45 (11.5%)	46 (10.8%)	49 (10.8%)
Urban	127 (68.6%)	51 (65.4%)	67 (66.3%)	71 (67.0%)	77 (67.5%)	534 (73.3%)	200 (64.9%)	263 (66.9%)	289 (67.7%)	308 (68.0%)
Missing	28 (15.1%)	13 (16.7%)	16 (15.8%)	16 (15.1%)	16 (14.0%)	112 (15.4%)	63 (20.5%)	76 (19.3%)	81 (19.0%)	85 (18.8%)

Appendix D

Oregon Evidence-Based Practice Center's 35 Questions
Guiding Literature Review for Guidelines

Key Questions

The 35 Key Questions used to guide this evidence review were developed by a multidisciplinary expert panel convened by the American Pain Society and the American Academy of Pain Medicine.

Risk-Benefit

1. In patients being considered for opioids for chronic non-cancer pain, how accurate are patient features or characteristics for predicting:
 - a. Benefits of chronic opioid therapy?
 - b. Opioid-related harms?
 - c. Aberrant drug-related behaviors?
2. In patients being considered for opioids for chronic non-cancer pain, how accurate are formal screening instruments for predicting benefits of opioid therapy, harms, or aberrant drug-related behaviors?
3. In patients being considered for opioids for chronic non-cancer pain, how effective is risk assessment for:
 - a. Improving clinical outcomes?
 - b. Reducing risk of aberrant drug behaviors?

Benefits and harms

4. What are the benefits (including long-term benefits) of opioids for chronic non-cancer pain?
5. What are the harms (including long-term harms) of opioids for chronic non-cancer pain? In patients at higher risk for abuse or addiction?
6. What are the benefits and harms of opioids for non-cancer pain in patients with a history of substance abuse or addiction who are undergoing treatment for addiction?
7. What are the comparative benefits and harms of different opioids and different formulations of opioids for chronic non-cancer pain?
8. Do the comparative benefits and harms of opioids vary in subpopulations defined by demographics (e.g. age, gender, race), specific underlying pain conditions, or comorbidities (e.g. liver disease, renal disease, respiratory disease, heart disease, HIV, drug misuse, cancer survivors)?
9. How effective are different strategies for minimizing or treating opioid-related adverse events?
10. How does initial or chronic use of opioids impact driving or work safety?

Opioid dosing strategies

11. What are the benefits and harms of different methods for initiating and titrating opioids for chronic non-cancer pain?
12. What are the benefits and harms of round-the-clock versus as needed dosing of opioids, or round-the-clock with as needed dosing versus as needed dosing alone for chronic non-cancer pain?
13. What are the benefits and harms of regular intramuscular, subcutaneous, intranasal, buccal, or rectal versus oral or transdermal administration of opioids for chronic non-cancer pain?
14. What are the comparative benefits of different strategies for treating acute exacerbations of pain or a new acute pain problem in patients on chronic opioids for chronic non-cancer pain?
15. What are the benefits and harms of opioid rotation versus continued treatment or dose escalation with the same opioid in patients with chronic non-cancer pain?
16. How accurate are patient characteristics or features for predicting lack of response to high doses of opioids for chronic non-cancer pain?

17. How do dose-related responses for opioids change at different dose ranges or with long-term use?
18. What are the benefits and harms of high (>200 mg/day of morphine or equivalent) versus lower doses of opioids for chronic non-cancer pain?
19. Are high doses of opioids associated with different or unique harms compared to lower doses?

Co-interventions and adjunctive interventions

20. How effective are patient education methods or clinician advice for improving outcomes associated with chronic opioid therapy?
21. How effective is co-prescription with other pain-attenuating medications or combining opioids for improving pain control or decreasing adverse events associated with opioid analgesics?
22. What is the effect of concomitant use of drugs with CNS effects on adverse events associated with opioids for chronic non-cancer pain?
23. What are the benefits associated with behavioral therapy, multidisciplinary rehabilitation, and/or functional restoration/work hardening in addition to or instead of opioids for chronic non-cancer pain?

Methods for monitoring opioid use and detecting aberrant drug-related behaviors

24. How effective are opioid agreements/contracts for improving clinical benefits and reducing harms, including abuse, addiction, or other aberrant drug-related behaviors associated with opioids for chronic non-cancer pain?
25. In patients receiving opioids for chronic non-cancer pain, what is the diagnostic accuracy of urine drug screening and different urine drug screening methods for:
 - a. Detecting illicit drug use?
 - b. Identifying the presence or absence of prescribed and non-prescribed opioids and estimating doses of opioids?
26. In patients receiving opioids for chronic non-cancer pain, how effective is urine drug screening and different urine drug screen methods for reducing abuse, addiction, and other aberrant drug-related behaviors, or increasing adherence to taking opioids as prescribed?
27. In patients receiving opioids for chronic non-cancer pain, how effective are other methods (pill counts, limited prescriptions, monitoring blood levels) for detecting or reducing abuse, addiction, other aberrant drug-related behaviors, or whether patients are taking opioids as prescribed?
28. Is re-evaluation of patients on chronic opioid therapy at different intervals associated with different outcomes?
29. What are the benefits and harms associated with different methods for evaluating outcomes in patients receiving opioids for chronic non-cancer pain?
30. In patients receiving opioids for chronic non-cancer pain, what is the accuracy of tools for differentiating pseudoaddiction from true aberrant drug-related behaviors?
31. In patients receiving opioids for chronic non-cancer pain, what is the effect of diagnosing pseudoaddiction on clinical outcomes?

Discontinuing opioids

32. What patient features or characteristics predict improved outcomes with discontinuation of long-term opioids versus continued treatment?
33. What are the benefits and harms of different methods for discontinuing opioids?

Pregnancy

34. What are the benefits and harms of continuing opioids versus switching to alternative analgesics in women with chronic non-cancer pain who become pregnant or are planning to become pregnant?

Opioid prescribing policies

35. What are the benefits and harms of opioid prescribing policies on clinical outcomes?

Appendix E

List of Practitioners on Guideline Development Panel

Co-chairs

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Dartmouth-Hitchcock Medical Center

Dept of Anesthesiology, Pain Management Center

Perry G. Fine, MD – Anesthesiology/Palliative care

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Christine Miaskowski, RN, PhD – Oncology/Pain management

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Panel

Jeremy A. Adler, MS, PA-C

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Jane Carol Ballantyne, MD – Pain Medicine/Palliative care

Harvard Medical School

Massachusetts General Hospital

Pamela Davies, MS, ARNP – NP Nursing

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Marilee I Donovan, PhD, RN - RN Nursing/HMO

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David Fishbain, MD, FAPA - Psychiatry

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Kathy Foley, MD - Pain Medicine/Palliative care

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Jeffrey Fudin, BS, PharmD, RPh, DAAPM – Clinical pharmacist

S. Stratton Dept. of VA Medical Center

Aaron Gilson, PhD - Policy

University of Wisconsin

Alex Kelter, MD – Public Health

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Alex Mauskop, MD - Headache

*SUNY, Downstate Medical Center; Beth Israel Medical Center
New York Headache Center*

Patrick O'Connor, MD, MPH – Primary care-Internal medicine

Yale-New Haven Hospital

Steve Passik, PhD, MA – Psychology/Addiction

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Department of Psychiatry and Behavioral Sciences*

Gavril W. Pasternak, MD, PhD - Pharmacology

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Russ Portenoy, MD - Pain Medicine/Palliative care

Beth Israel Medical Center

Ben Rich, JD, PhD – Law/ Ethics

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