

Interim Evaluation of the Washington State Interagency Guideline on Opioid Dosing for Chronic Non-Cancer Pain

8/31/2009

Executive Summary

Purpose of this report: Grant funding was provided by the Washington State Office of the Attorney General to complete this report. This report provides: 1) information about the purpose, development and dissemination of the ***Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain: an educational pilot to improve care and safety with opioid treatment***, (the Guideline), 2) current Washington State agency opioid utilization data and morbidity and mortality data associated with prescription opioid use, 3) results from an interim evaluation of the Guideline including a survey of primary care providers, and 4) recommendations for improving the Guideline based on the evaluation results.

Background: In the mid-1990s the use of potent prescription opioid medications, traditionally reserved for the treatment of cancer and acute pain, expanded to include treatment of chronic pain conditions not caused by cancer (chronic non-cancer pain or CNCP). This change resulted in part from advocacy centered on ethical concerns related the under-treatment of chronic pain. Directives and guidelines from state and national medical boards supported these changes and resulted in new policies that encouraged the use of opioids for long-term pain control.

Following this change, a dramatic increase in the volume of opioid medications and prescriptions increased throughout the US and in Washington State. Paralleling the increased distribution and use of these drugs for CNCP has been an increase in deaths and hospitalizations; observations of increasing deaths were reported soon after this policy shift occurred.

In Washington State, the Agency Medical Directors' Group (AMDG) responded to the increase in deaths by collaborating with community physicians with expertise in pain management to create an educational dosing guideline. The purpose of the Guideline is to assist primary care providers when treating patients with CNCP. The Guideline was published in April 2007 and includes two parts: Part 1 provides recommendations for initiating, transitioning and maintaining opioid treatment for patients with CNCP and includes a novel dosing threshold of 120 mg morphine equivalent dose (MED); Part 2 includes recommendations for optimizing treatment when opioid doses exceed a 'yellow flag' threshold dose of 120 mg morphine equivalent dose (MED).

Interim Guideline Evaluation Results: Since its publication, efforts to disseminate the Guideline have been substantial. The Guideline is recognized as an important educational resource for physicians.

State agency administrative data show use of the most potent opioids rapidly increased beginning in 1997. This upward trend appears to have peaked in 2006 and is relatively flat through 2008. Total average MED among those receiving long-acting opioids also increased in this period.

Unintentional deaths associated with prescription opioid use rose dramatically from 1998 through 2006 and may be moderating. Workers' compensation and Medicaid opioid-related death data, a subset of statewide data, show similar increases with possible moderation in the workers' compensation population.

Provider Survey Results: A web-based survey of selected provider groups was completed to assess the acceptability and usefulness of the Guideline and to identify areas for improvement or enhancement. Findings of the survey show that:

- Many providers (54%) have 'frequent concerns' about dependence, addiction, or diversion when prescribing opioids to treat CNCP.
- The Guideline is acceptable and useful to primary care providers.
- Dissemination of the Guideline is good; 45% report having read and applied the Guideline in practice.
- There is frequent reported use of some best practices including assessment of mental health and substance abuse history, and use of opioid agreements, but low reported use of tools to assess pain and function, or urinalysis.
- Many providers cite access or quality concerns related to use of pain specialists.

Recommendations: Evaluation findings support the following recommendations:

- Continue and improve dissemination of the Guideline: Providers familiar with the Guideline find it useful and a majority report 'frequent' concerns when treating CNCP with opioids.
- Evaluate and address potential access and quality concerns related to specialty pain consultations: Seventy-eight percent (78%) of providers surveyed reported success most of the time in getting specialty consultations for their patients, but 22% were not successful. The reported 'helpfulness' of consultations appears to be mixed.
- Develop or identify patient education or decision aid tools: Many providers surveyed noted use of the Guideline as a patient-education tool and a need for patient decision aids to help patients understand treatment choices for CNCP.
- Continue evaluation efforts: Given the rapid and dramatic impact policy changes have had on opioid prescribing for CNCP, future policies or guidelines to address these issues should be accompanied by prospective evaluation efforts.

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Purpose of this report

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Background

Chronic pain can result from a number of conditions, diseases or injuries and is generally considered pain lasting more than 3 months. Chronic non-cancer pain (CNCP) is considered chronic pain caused by or due to conditions other than cancer or pain at the end of life.

The use of opioids for the treatment of CNCP increased significantly beginning in the mid-1990s. Until then, the long-term use of opioid therapy for CNCP was essentially prohibited in most states. This prohibition was due to the addictive nature and illegal use of opioids at the beginning of the twentieth century. A change occurred when pain advocacy groups and groups of pain specialists successfully lobbied state medical boards and legislatures to change regulations and end the prohibition on opioid use for CNCP. Evidence at the time substantiated the use of opioids for acute pain, but there was, and remains, only very limited clinical data to support this use for CNCP.

Following the expansion of opioid use for CNCP, new guidelines were developed for providers nationally and in Washington State. These guidelines focused on ‘best practices’, including:

- Having one physician prescribe opioids,
- Use of a single pharmacy for a patient to fill his prescriptions,
- Use of opioid treatment agreements between the physician and patient to clearly define patient and physician responsibilities, and
- Assessment risks of developing addiction by conducting a thorough history including any history of substance abuse before starting treatment.

Within 2 years of the regulatory changes that expanded opioid use, deaths due to drug poisoning were observed to be increasing. Reports from workers’ compensation programs in Washington and Utah, and national data described increases in deaths and in the level of the average daily doses prescribed of the most potent (i.e., Schedule II) opioids¹. Paralleling the increase in deaths in the Washington State workers’ compensation system was a greater than 50% increase in daily morphine equivalent dose (MED) between 1997 and 2004.

Washington State data show a rapid rise in the number of hospitalizations and deaths associated with prescription opioids, beginning in the mid-1990s. From 1996 through 2007, unintentional prescription opioid

¹ Chapter 69.50 RCW, Uniform Controlled Substances Act, defines Schedule I-V drugs as controlled substances. Schedule II includes substances with accepted medical use, high potential for abuse, where abuse may lead to severe dependence. The State Agencies calculate MED using a subset of specific *long-acting* Schedule II opiates to better identify use for the treatment of CNCP.

involved overdose deaths increased by more than 1000% from 0.45 to 7.00 per 100,000. These increases parallel substantial increases in the volume and potency of prescription opioid medications distributed throughout the US and in Washington State.

Agency Medical Directors' Group Educational Guideline

In 2006, in response to the increase in deaths associated with the use of prescription opioids, the Interagency Workgroup on Practice Guidelines (Workgroup), sponsored by the Agency Medical Directors Group (AMDG), collaborated with pain management providers in Washington State to develop a guideline on opioid use for chronic pain. In April 2007, the Workgroup published the *Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain: an educational pilot to improve care and safety with opioid treatment* (The Guideline). The Guideline was developed as an educational tool for primary care providers and offers recommendations for managing patients with CNCP.

The Guideline is available online and in print. It is fourteen pages in length and provides accessible, best practice recommendations and information for primary care providers. The Guideline presents information in two parts: Part I addresses treatment of patients new to opioid treatment for CNCP. It focuses on careful monitoring opioid dosing for patients just developing chronic pain (i.e., their pain is lasting beyond 3 months). The key and novel recommendation in Part 1 is to request a specialty consultation for patients who have reached a 'yellow flag' dose, but have not had substantial improvement in their pain or function, or are experiencing adverse effects from the treatment.

The 'yellow flag' dose is unique to the Guideline. It establishes a threshold of 120 mg MED per day as a level where it recommends providers seek consultation from a pain specialist before proceeding. The threshold level was chosen by unanimous consensus of the Workgroup and is based primarily on the practice experience of the Workgroup members.

Additional elements in Part 1 include instructions on how to calculate MED, and a novel MED calculator using a spreadsheet template. This tool provides an online Excel-based form that can be used to quickly determine MED from a variety of different medications. The calculator can be saved by a user to their computer and can be used to print a result for a patient when needed.

Other information includes:

- Web links to tools for assessing pain and function,
- Information on urine drug toxicology screening to help verify that patients are taking the prescribed medications,
- Recommendations about specialty pain consultations and sources to help find pain management consultants including a non-exclusive list of pain specialists,
- Instructions for how to safely reduce or discontinue opioids in patients who are not benefiting.
- Information on recognizing and managing behavioral issues when reducing opioid doses.

Part 2 addresses optimization of treatment for patients with opioid doses above the 'yellow-flag' threshold. This section emphasizes assessment of changes in pain and function using the validated tools available in Part 1, and addresses methods for reducing doses. Part 2 also includes:

- Information and a web-link for referrals to the Directory of Certified Chemical Dependency Services in Washington State. This directory provides an updated list of chemical dependency resources approved by the Division of Alcohol and Substance Abuse (DASA),
- A web-link to the Collaborative Opioid Prescribing Education (COPE), a 90 minute online training provided through the University of Washington, School of Medicine. The goal of the COPE training is to provide providers with tools for “collaborative goal-setting” with their patients when starting opioid treatment.

In sum, the Guideline includes useful and accessible information in a brief and readable format. Similar to other recent guidelines on opioid use for CNCP, it includes recommendations for the use of validated best practice tools and resources including opioid contracts, tracking of pain and function to assess the effectiveness of treatment, and use of random urine screening. Unique to the Washington guideline is the inclusion of an explicit and modest MED threshold at which to seek expert consultation.

Publication of the Guideline

In April 2007, The Guideline was published to a website maintained by the AMDG². The website was specifically created to provide links to the Guideline, tools and resources, education and treatment programs referenced in it. Since its publication, two hours of free Category I continuing medical education credit (CME) have been accredited by the American College of Occupational and Environmental Medicine for physicians who participate in an online educational activity that includes reading the Guideline and completing a 15 item questionnaire; pharmacists can earn CE credits, approved by the Washington Board of Pharmacy, for this activity. The goal of the activity is to educate participants regarding:

- National trends in opioid-related overdose deaths,
- Use of tools and prevention strategies to address misuse and abuse of opioids,
- Key aspects of the AMDG dosing guideline,
- Use of the Guideline in a clinical setting,
- How to assess pain and function with standardized tools to improve opioid treatment.

Interim Guideline Evaluation

Data from website use reports (i.e., page views), completion of the CME module, and records of presentations given to professional groups were summarized to describe Guideline dissemination efforts and results. Data from the departments of Health, Labor and Industries, and Social and Health Services are included and describe statewide and agency-level morbidity, mortality and prescribing patterns related to prescription opioids. These data document changes in the volume of different opioids prescribed, the levels of average daily doses of long-acting opioids paid for by the state Medicaid and workers’ compensation programs, as well as statewide and agency program reporting of deaths, injuries and hospitalizations associated with prescription opioid.

To examine the provider familiarity, acceptability, usefulness and areas of potential improvement among select primary care providers, a cross-sectional survey was completed.

² www.agencymedicaldirectors.wa.gov

Dissemination of the Guideline

Substantial efforts to disseminate the Guideline in Washington have included or resulted in the following:

- Approximately 25 statewide CME talks to primary care provider groups. These presentations have reached more than 1000 providers in Washington and other locations.
- More than 6000 page views of the AMDG Guideline website occurred through of January 2008.
- Submission and publication to the National Guideline Clearinghouse in May 2008. In the 12 months following publication on this site more than 10,000 page views have been recorded.
- 107 healthcare providers completed the online CME training.

The Guideline has been recognized as an important tool in the efforts to address the national epidemic of death and injury associated with prescription opioid use. In September 2007, the Washington State Medical Association (WSMA) passed a resolution to publish a link to the Guideline from the WSMA resource page as a “best practice”. The Guideline was cited in Congressional testimony by Leonard Paulozzi MD, MPH, a Centers for Disease Control and Prevention injury epidemiologist, as an example of guidelines physicians might observe and principles that might be followed including the “120 milligrams of morphine per day” threshold for when to seek a consultation (Paulozzi 2008).

Dosing Patterns, Morbidity and Mortality in Washington State

Prescribing and dosing data: Administrative data from State Medicaid and workers’ compensation show increases in the total opioid prescriptions since the middle and late 1990s (Appendix A, Figures 1-2). Workers’ compensation data show a steady increase in the use of Schedule II opioids prescribed through about 2005; in 2008, Schedule II opioids accounted for 43% of the total opioids prescribed compared to 19% in 1996. Medicaid data indicate dramatic and steady increases in both Schedule II and III opioids that appears to continue through 2008. Implementation of Medicare Part D in 2005 affected the total volume of prescriptions since that year.

Similar patterns of increase and stabilization in average MED of long-acting Schedule II drugs occurred during this time period (Appendix A, Figures 3-4). Workers’ compensation data show a declining average MED since 2006. Medicaid data are similar, with a higher peak in average MED.

Morbidity and mortality data: Department of Health (DOH), Medicaid and workers’ compensation programs use similar definitions for classification of deaths associated with prescription opioids³. Statewide (DOH) and agency data show steady increases in deaths associated with prescription opioid use statewide and in the workers’ compensation population beginning around 1998 (Appendix A, Figures 5-8). Statewide, the death rate per 100,000 residents increased 1000% from 1997 to 2007. The patterns of increasing deaths are generally similar and parallel changes in prescribing patterns occurring in this period. Data from the Comprehensive Hospital Abstract Reporting System (CHARS) show a very similar pattern of increasing hospitalizations associated with prescription opioids (Appendix H).

Summary: State agency data show dramatic increases in the volume and potency of opioid prescriptions beginning in the late 1990s. Prescribing volume, MED and the number of deaths statewide and in workers’

³ L&I and Medicaid deaths are subsets of Statewide data from DOH.

compensation may have peaked in roughly 2006 though Medicaid experienced a higher number of deaths in 2007. A number of factors may be contributing to changes what has been a trend of increasing opioid utilization, morbidity and mortality associated with use of these drugs. These factors include increased awareness of opioid prescribing and abuse issues through increased media attention, medical professional society efforts, including practice guidelines, emphasizing use of best practices when treating CNCP with opioids, state agency efforts to control high-dose use of prescription opioids for CNCP, and the impact of the AMDG Interagency Guideline. It could also be that the number of deaths are reaching a steady-state based on the current utilization patterns.

Physician Use and Impact of the Guideline

A survey of primary care physicians was conducted to assess the acceptability and usefulness of the Guideline, as well as to identify ways to improve or enhance tools or recommendations in the Guideline. Data were collected through an anonymous, web-based questionnaire using the online service Survey Monkey⁴. Primary care providers in seven organizations were surveyed including: 2 multi-specialty clinics, 2 Centers of Occupational Health and Education (COHEs), 2 state professional societies, and the primary care division of a large regional health maintenance organization. Physician leaders in these organizations were asked to participate in the conduct of the survey by emailing web-links to the survey and encouraging participation.

A 21 item questionnaire was developed collaboratively by the AMDG and researchers at the University of Washington. Questions addressed practice and demographic information as well as the following areas:

1. Physicians' experience treating chronic non-cancer pain including:
 - Comfort level when prescribing opioids to treat CNCP
 - Use of best practices
 - Availability and helpfulness of specialty pain consultations
2. Acceptability and usefulness of the Guideline
 - Reasonableness of the 'yellow flag' threshold dose
 - Usefulness of key elements of the Guideline
 - Are providers using pain and functional assessment tools more?
 - of the effect on managing their CNCP patients, and patients' health
3. Ideas for improving the Guideline

Findings

Demographic and Practice Characteristics, and Familiarity with the Guideline

The survey was emailed to 3,353 providers; 655 responses were collected resulting in a 20% response rate. For this analysis results from providers identifying themselves as primary care or occupational medicine are included.

The majority of responses are from physicians (93%) and the remainder from ARNPS and Pas (7%) and most are located in urban areas (86%). Forty-five percent (45%) reported having read and applied the Guideline; an additional 17% reported having read the Guideline, but not applied it (Table 1).

⁴ SurveyMonkey.com, Portland, Oregon. Author Ryan Finley.

Table 1: Familiarity with the Guideline

Familiarity with the Guideline (n=441)	No. (%)
Not Familiar with the Guideline	38
Have read and applied in practice	45
Have read, but not applied in practice	17

1. Physicians’ experience treating chronic non-cancer pain

When asked “which statement most accurately reflects your experience”:

- 54% reported “frequent concerns” about development of psychological dependence, addiction, or diversion when prescribing opioids for CNCP, and
- 43% reported “occasional concerns”.
- 2% reported they treat most patients comfortably, without concerns about development of psychological dependence, addiction, or diversion when prescribing opioids for CNCP

Providers reported greater use of opioid agreements and review of patient histories, and less frequent use of patient education tools, tools for assessing pain and function, and use of random urine screening. Table 2 reports the use of best practices by physicians when treating CNCP.

Table 2: Use of Best Practices

When prescribing opioid medications for your patients with chronic, non-cancer pain, how often do you employ the following practices? (n=460)	Always or almost always %	Often %	Sometimes %	Never or almost never %
Prepare formal opioid agreement	49	20	22	10
Review patient’s history for past or current history of any substance abuse (alcohol, tobacco, illicit drugs).	81	15	3	1
Conduct an assessment of past or current history of mental health conditions	58	30	12	<1
Use random drug screening.	20	18	32	30
Use patient educational tools (handouts, etc.) regarding chronic, non-cancer pain.	9	19	38	34
Track pain using an assessment tool such as a Visual Analogue Scale.	15	15	31	40
Track physical function using a validated instrument such as the SF-36, QuickDash, and Oswestry Disability Index.	5	7	20	69

Among respondents familiar with the Guideline:

- 86% of those responding had tried to obtain a pain management consultant in the preceding 6 months,
- 78% reported they were successful in obtaining a consultation, though many responded that it is a challenge (33%), and
- 22% responded that they usually do not succeed.

Results regarding the helpfulness of pain management consultations tended to center on ‘somewhat helpful’ for a variety of dimensions. Though for reducing patient’s dose or transfer-of-care consultations may be less than ‘somewhat helpful’ (Table 3).

Table 3: Experience with pain consultations

How helpful did you find the pain management consultation for the following: (n=182)	Very Helpful	Somewhat Helpful	Not Helpful at all	Don’t Recall
Reduce/stabilize my patient's opioid dose	9	46	45	<1
Clarify relevant medical issues	24	63	13	<1
Clarify relevant mental health/addiction issues	16	54	29	1
Clarify relevant pharmacological issues	19	61	19	1
Transfer the care of my patient to a specialist	10	24	61	5

2. Acceptability and usefulness of the guideline

Questions pertaining to specific elements of the Guideline were asked. With regard to managing patients, 91% reported the threshold dose to be ‘somewhat’ to ‘very useful’, and 10% reported it to be ‘not useful at all’. Seventy-five percent (75%) reported the threshold dose level (120 mg MED) to be reasonable, with 11% responding ‘too high’ and 14% ‘too low’. Usefulness of a number of elements are shown in Table 5.

Table 5: Usefulness of Guideline elements

How useful each has been for managing your patients with chronic, non-cancer pain: (n=264)	Very useful or useful	Somewhat useful	Not useful at all	Don’t recall
The 120 mg “yellow flag”	42	46	11	1
The opioid dosing calculator	46	41	9	4
Specific methods of weaning opioids in Part I	25	55	10	11
Specific validated functional assessment tools such as the SF-36, QuickDash, and Oswestry Disability Index	16	42	21	21
Specialty consultation for assessment and management of MH conditions	20	50	27	4

Reported effects on managing patients with CNCP

One question addressed change in use of validated pain assessment tools *“because of the Guideline”*:

- 30% reported more frequent use of the visual analog scale or other pain assessment tools, and
- 70% reported more frequent use of functional assessment tools (e.g., Oswestry disability index, SF-36 or Quickdash).

When asked *“because of the Guideline, I feel I can manage my patients:”*

- 62% responded more effectively,
- 35% responded the Guideline has had no impact, and
- 4% said less effectively.

When asked *“because of the Guideline, I feel that my patients’ health:”*

- 39% - has improved,
- 58% - The Guideline has had no impact,
- 3% - has worsened.

3. Ideas for Improving the Guideline

Which of the following methods would you find most helpful to manage your patients with chronic, non-cancer pain? (Check all that apply) (n=229)

- 70% responses for “patient decision aids” designed to help patients understand choices regarding treatment for chronic, non-cancer pain.
- 45% responses for web-based CME training.
- 42% responses for advanced training that would provide a certificate of special competence in the treatment of chronic, non-cancer pain.
- 35% responses to telemedicine (e.g., to obtain consultations with experts in chronic pain).
- 24% responses web-based interactive “ask the experts” sessions

Conclusion

Changes in opioid prescribing practices in the mid-1990s led to dramatic increases in the distribution and use of the most potent prescription opioids. Statewide and agency data demonstrate dramatic increases in the volume of prescriptions, average MED, death and hospitalization data subsequent to policy changes addressing the use of opioids to treat CNCP. It appears that the number of deaths may have peaked statewide and in the workers’ compensation population. The workers’ compensation utilization data (total prescriptions and average MED) have also moderated. Medicaid utilization data differ with what appears to be a continuing increase in the volume of Schedule II and III prescription as well as more reported deaths associated with prescription opioids. A number of factors may be contributing to the modest, but beneficial changes in these trends and include increased media attention on risks associated with prescription opioid use, medical professional society efforts to educate providers, state agency initiatives to improve controls on opioid prescribing and efforts on the part of individual healthcare providers and their practice organizations.

The Guideline may be contributing to changes in prescribing patterns and ultimately morbidity and mortality for state residents. At this point in time, it is not possible to determine to what extent the Guideline has impacted these trends in Washington. However, information from the provider survey supports continued use of the Guideline. Findings of the survey show that:

- Many providers (54%) have ‘frequent concerns’ about dependence, addiction, or diversion when prescribing opioids to treat CNCP.
- The Guideline is acceptable and useful to primary care providers.
- Dissemination of the Guideline is good; 45% reporting having read and applied the Guideline in practice.
- There is frequent reported use of some best practices including assessment of mental health and substance abuse history, and use of opioid agreements, but low reported use of tools to assess pain and function, or urinalysis.

- Many providers cite access or quality concerns related to use specialty consultations with pain specialists.

Recommendations: Areas to focus future efforts

- Dissemination: Improve diffusion of the Guideline through systematic public relations campaign targeted to primary care providers and others who prescribe opioids in Washington State. Many were not aware of it at all, many were aware but had not used it, and 45% had read and applied the Guideline.
- Specialty pain consultations- Access and Quality: Address access and quality issues related to specialty pain consultations. Survey responses indicate high levels of concern about the availability of consultants and the quality or usefulness of the consultations.
- Patient education tools: Develop additional patient education tools. Many providers reported use of the Guideline as a patient-education tool.
- Evaluation: The Guideline may be the most effective tool available to address a serious public health epidemic. Given the rapid and significant impact policy changes have had on opioid prescribing for CNCP, future efforts to address these issues should be accompanied by prospective evaluation efforts.

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Figure 1: Opioid Utilization Patterns in WA Workers' Compensation

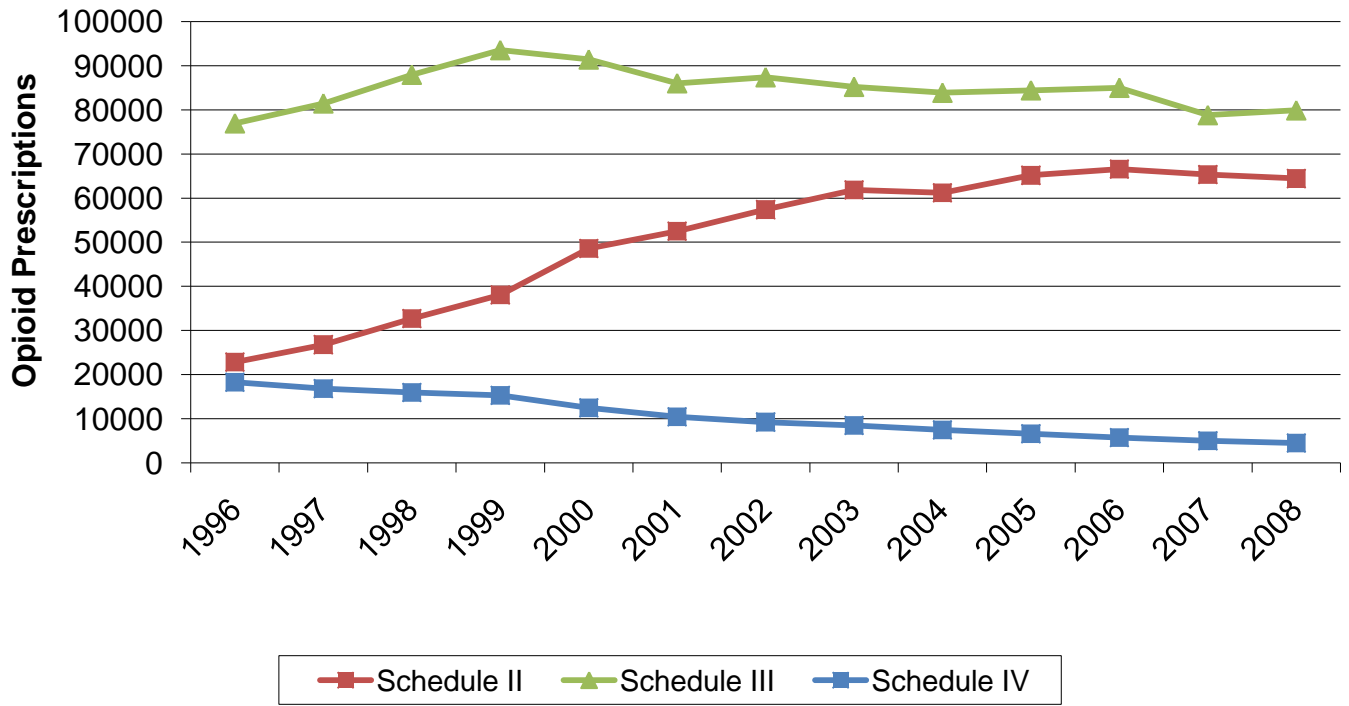
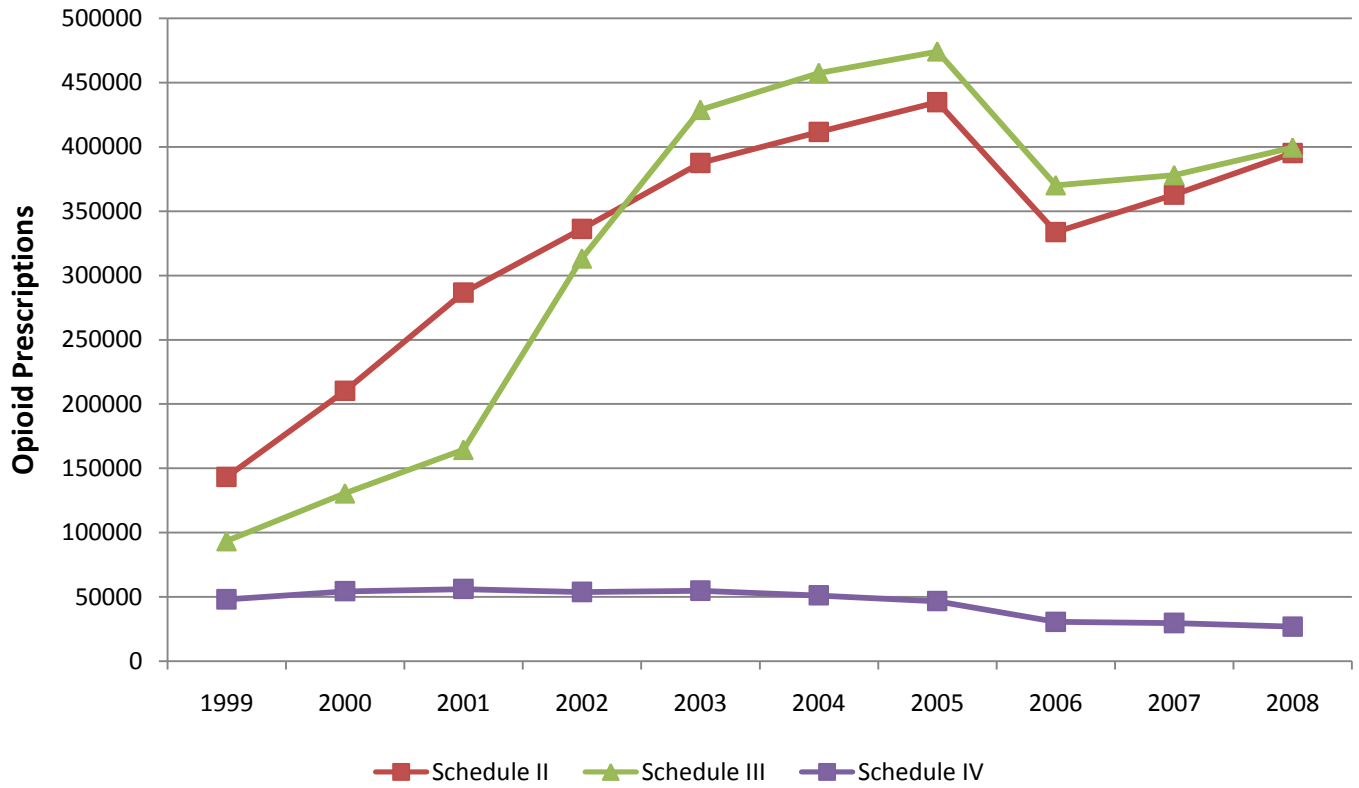
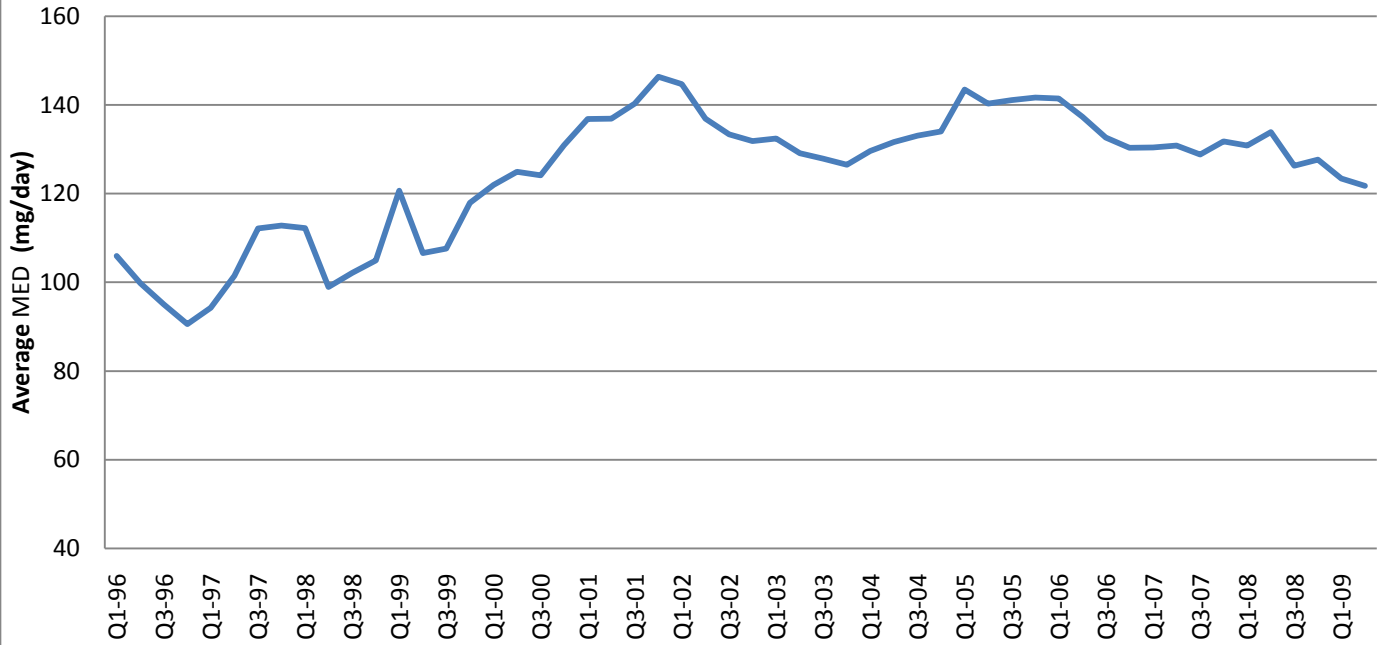


Figure 2: Opioid Utilization Patterns in WA Medicaid



**Figure 3: L&I Dosing Trend of Long-acting Opioids
(Morphine Equivalent Dose)**



**Figure 4 : Medicaid Dosing Trend of Long-acting Opioids
(Morphine Equivalent Dose)**

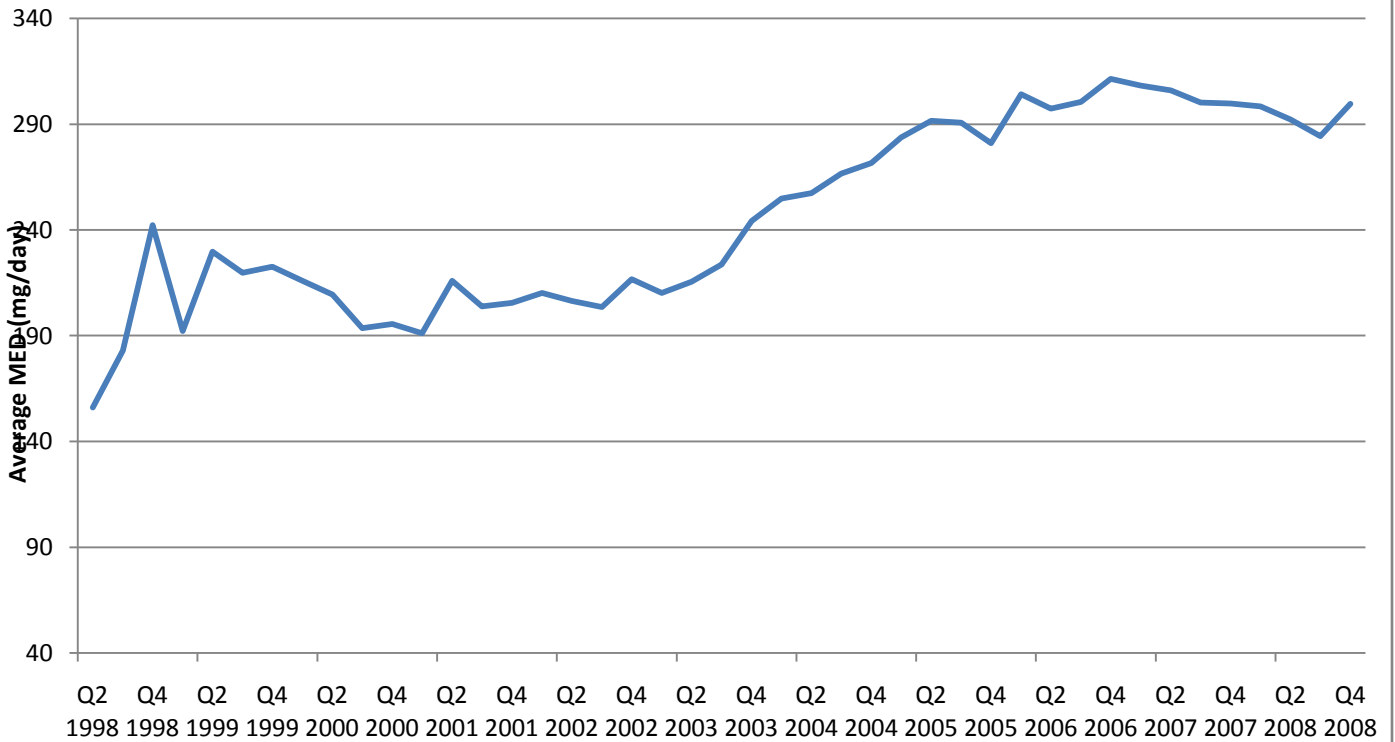


Figure 5: Unintentional Prescription Opioid Associated Deaths in Washington State

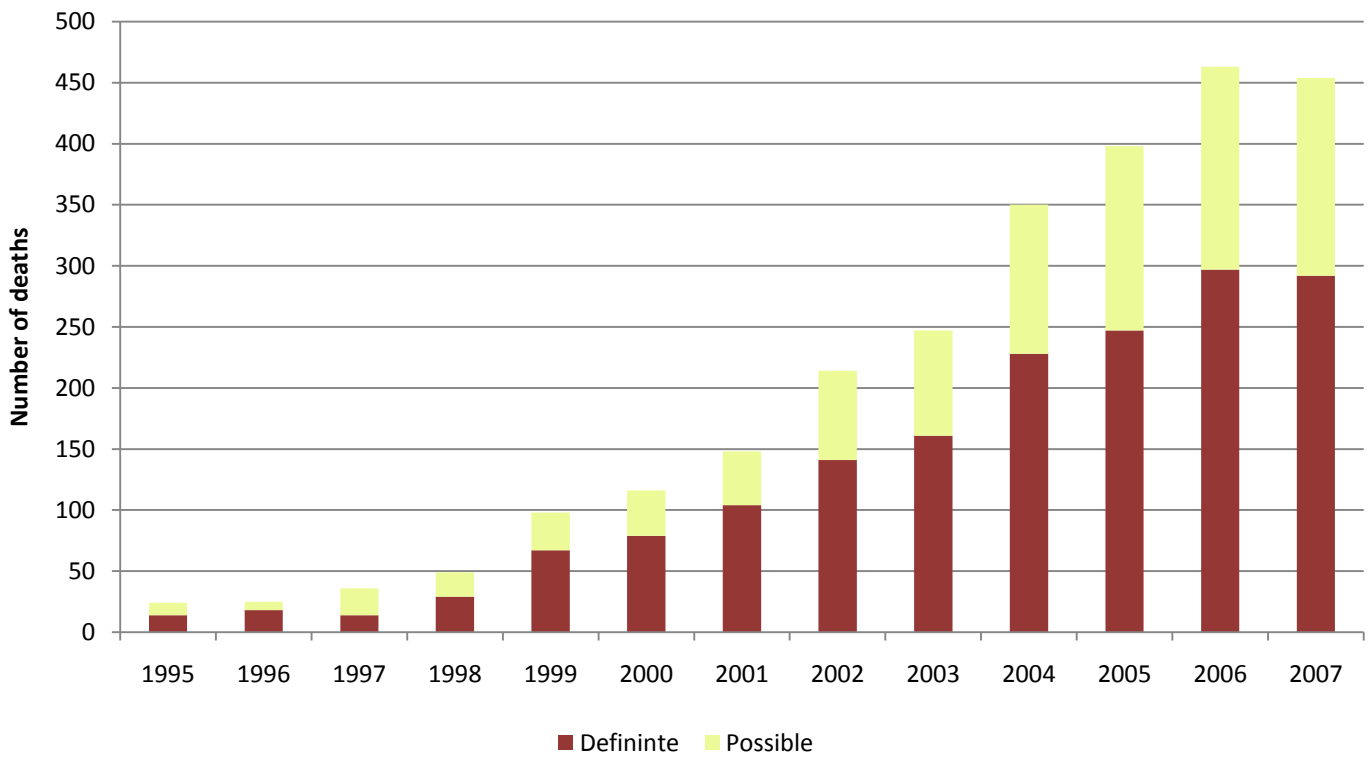


Figure 6: WA Workers' Compensation Opioid-related Deaths 1995-2007

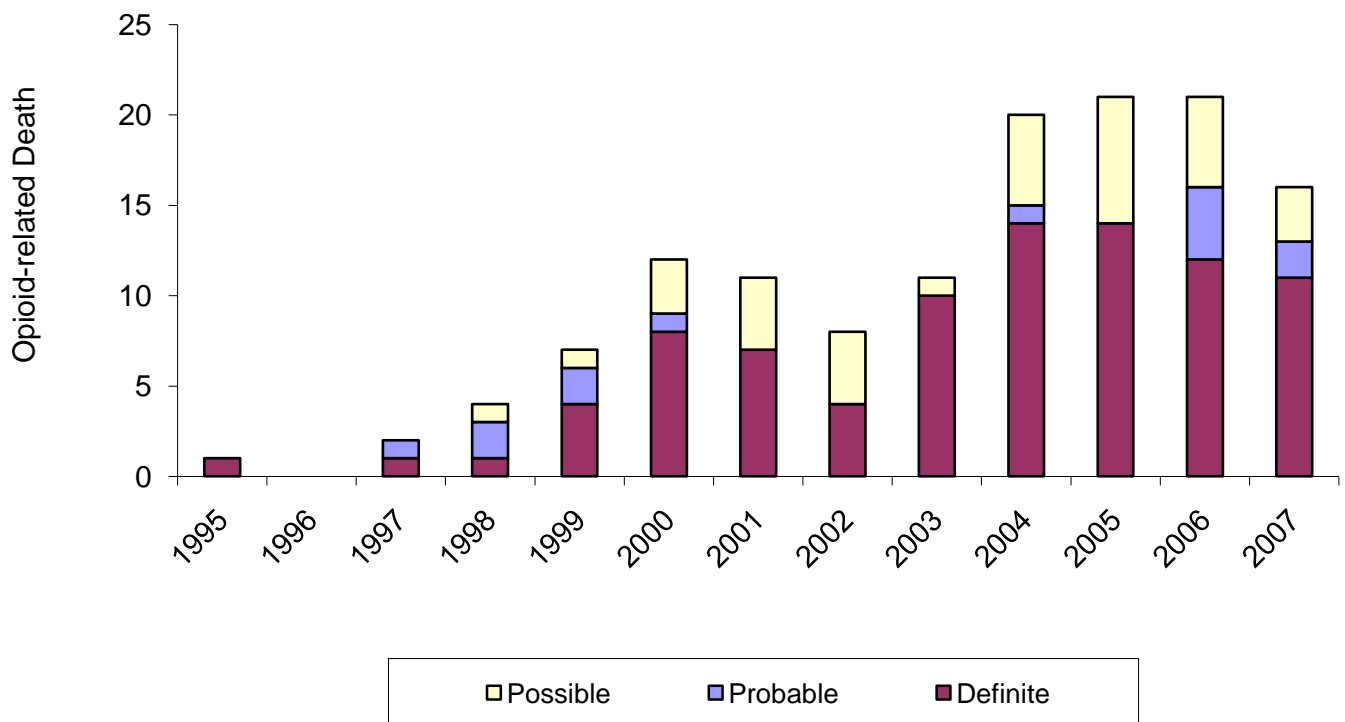


Figure 7: WA Medicaid Opioid-Related Deaths 2004-2007

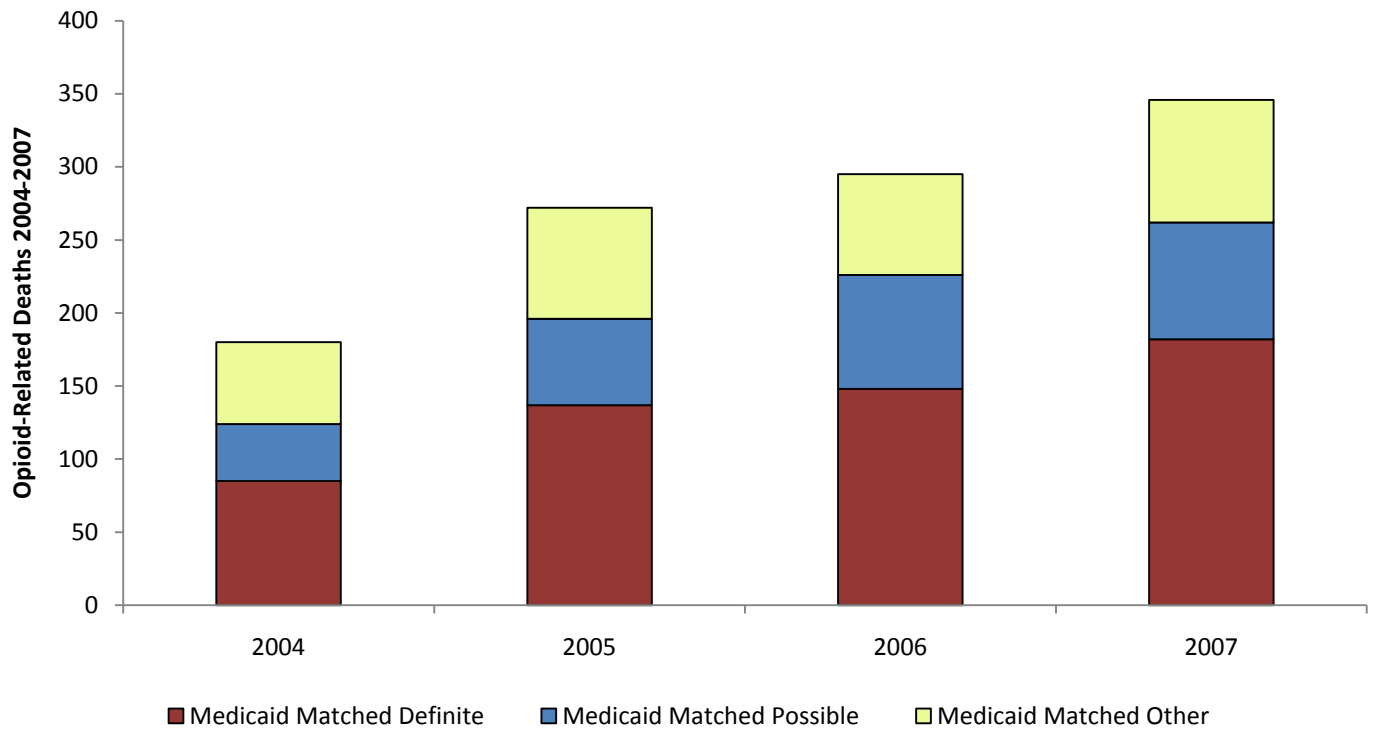


Figure 8: Hospitalizations with Rx Opiate Toxicity in Primary Diagnosis (CHARS)

