TITLE: Stepwise Approach for the Prescription of Opiates for Non-Cancer Pain: A Review of Clinical Evidence and Guidelines

DATE: 12 May 2014

CONTEXT AND POLICY ISSUES

The terms opiate and opioid are often used interchangeably.[1] Opiates are medications derived from opium poppy such as morphine and codeine, while opioids refer to opium-like substances including endogenous substances such as endorphins, as well as exogenous synthetic drugs that interact with opioid receptors.[1] The generic term "Opioid" (including opiates and opioids) is therefore the preferred term for use throughout this report.

In Canada, the prescription of opioids for pain management increased by about 50% between 2000 and 2004.[2] The increase in prescribing of opioids has been associated with increase in misuse, abuse, diversion, and opioid-related overdoses that are accompanied by increasing emergency department visits, hospitalizations, and deaths.[3] In 2008, the prevalence of any use of opioid pain relievers in general population in Canada was 21.6%.[4] In 2011, the rate was decreased to 16.7%.[4] There was an almost 250% increase in the number of emergency visits in Ontario related to narcotics withdrawal, overdose, intoxication, harmful use and other related diagnoses from 2005-2006 to 2010-2011.[4]

Given the current rate of opioid overdose and harms associated with opioid use, stepwise approaches to prescribing, which progress from non-opioids to weak opioids and finally strong opioids such as hyrdomorphone if pain persists, have been proposed. As such, there is a growing need for clinical evidence and guidance for the use of stepwise approaches for the prescription of opioid for non-cancer pain management in the emergency department and in-hospital setting.

RESEARCH QUESTIONS

1. What is the clinical evidence regarding the use of a stepwise approach to the prescription of opiate analgesics for pain management in the emergency department or in-hospital setting?

2. What are the evidence-based guidelines regarding the use of a stepwise approach to the prescription of opiate analgesics for pain management in the emergency department or in-hospital setting?

KEY FINDINGS

No clinical evidence could be identified regarding the use of a stepwise approach (from lower to lower to higher potency) to the prescription of opioid analgesics for pain management in the emergency department or in-hospital setting. Guidelines for chronic pain or for pain management in the adult emergency department recommend the use of low dose and titrate cautiously, if opioids are indicated.

METHODS

Literature search strategy

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2014, Issue 3), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. Methodological filters were applied to limit retrieval to No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2009 and April 10, 2014.

Selection criteria and method

One reviewer screened the titles and abstracts of the retrieved publications and evaluated the full-text publications for the final article selection, according to the selection criteria presented in Table 1.

Table 1: Selection Criteria

Population	Patients in the emergency department or in-hospital who require opiates for pain management for non-cancer pain
Intervention	Stepwise approach to pain management (prescribing lower potency opiates [eg: morphine] before more potent opiates [eg: hydromorphone])
Comparator	No comparator or physician's discretion
Outcomes	Clinical evidence for stepwise approach, patient safety, guidelines for stepwise approach, best practice
Study designs	Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, and evidence-based guidelines

Exclusion criteria

Articles were excluded if they did not satisfy the selection criteria in Table 1, if they were published prior to 2009, duplicate publications of the same study, or included in a selected health technology assessment or systematic review.

Critical appraisal of individual studies

The AMSTAR checklist[5] was used for critical appraisal of systematic reviews (Appendix 1). AGREE II[6] was used for quality assessment of included guidelines (Appendix 2).

SUMMARY OF EVIDENCE

Quantity of research available

The literature search yielded 286 citations. Upon screening of titles and abstracts, 280 citations were excluded and six potentially relevant articles were retrieved for full-text review. An additional six potentially relevant reports were retrieved from grey literature and hand searching. Of the 12 potentially relevant reports 10 were excluded; six reports describing three guidelines which were included in the selected systematic review,[7-12] one was a summary of another and included guideline,[13] one examined an irrelevant intervention,[14] and two were incorrect study designs (a narrative review and a case report).[15,16] One systematic review of guidelines on opioid prescribing for chronic pain[17] and one guideline on prescribing opioids in the emergency department[18] were included in this review. Clinical evidence relating to stepwise opioid prescribing (Question 1) was not identified. The process of study selection is outlined in the PRISMA flowchart (Appendix 3).

Summary of study characteristics

Systematic review

The characteristics of the systematic review of guidelines by Nuckols et al. (2014)[17] are presented in Appendix 4. Briefly, the systematic review conducted a comprehensive search of guidelines addressing the use of opioids in the treatment chronic pain in adults in general. Guidelines had to been published after 2006, and the search was last updated in July 2013. A total of 13 guidelines had been identified and evaluated. The review used AGREE II to assess the guideline quality and the AMSTAR checklist to assess the quality of systematic review supporting each guideline. The study was funded by the Commission on Health and Safety and Workers' Compensation (USA).

Guideline

A guideline published in 2012 and produced by the American College of Emergency Physicians, in consultation with the Centers for Disease Control and Prevention, was identified for inclusion. This guideline provided recommendations on issues related to the prescribing of opioids for adult patients treated in the emergency department. Recommendations were based on a search for relevant literature published between 2000 and 2011

Summary of critical appraisal

The methodological quality assessment of the systematic review by Nuckols et al. (2014)[17] met seven criteria of the AMSTAR checklist (Appendix 5). Two items relating to data pooling and assessment of publication bias were not applicable. Two items that appear to be limitations related to "a priori" design and grey literature search.

Overall, the ACEP guideline agrees with five out of six domains of AGREE II (Appendix 6). These were scope and purpose, stakeholder involvement, rigour of development, clarity of presentation, and editorial independence with few exceptions. Several limitations in those items were identified including seeking the views and preferences of target populations, description of the criteria for selecting the evidence and the strengths and limitations of the evidence, and the lack of a procedure for updating the guideline. The ACEP guideline has also shortcomings in the applicability regarding the lack of providing advice and/or tools on how the recommendations can be put into practice, as well as the monitoring and/or auditing criteria.

Summary of findings

Systematic review

The findings of the systematic review of guidelines are summarized in Appendix 7. Thirteen eligible guidelines published in 2009 or later were included. Of those guidelines, one was a Canadian guideline (Opioids for chronic noncancer pain: a new Canadian practice guideline, NOUGG). The systematic reviews supporting those guidelines were conducted in 2008 or later. Using AGREE II to assess the quality of guidelines, the guidelines by the American Pain Society – American Academic of Pain Medicine (APS-AAPM) and the National Opioid Use Guideline Group (NOUGG) were rated highest. Using AMSTAR to assess the quality of systematic reviews, the APS-AAPM review was of excellent to outstanding quality, the NOUGG was of good to excellent quality, the Veterans Affairs / Department of Defense (VA/DoD) review was of good quality, and the remaining 10 guideline reviews were of poor or fair quality.

Most guidelines recommend that physicians should be cautious in prescribing doses greater than 90 to 200 mg of morphine equivalents per day, having additional knowledge to prescribe methadone, recognizing risks associated with fentanyl patches, increasing doses slowly, and reducing doses by at least 25% to 50% when switching from one opioid to another. The guidelines also agree that opioid risk assessment tools, written treatment agreements, and urine drug testing can be helpful when opioids are prescribed for long-term use. Most of the recommendations are supported by lower-quality evidence or expert opinions.

Guideline

A summary of recommendations of the guidelines of the American College of Emergency Physicians (ACEP) are presented in Appendix 8. Most of the recommendations were of level C, which are supported by class III evidence (Appendix 9).

The guideline recommended that emergency physicians should use a prescription monitoring program (with a focus on state-based monitoring programs for certain controlled substances that are prescribed by licensed practitioners and dispensed by pharmacies) in identifying patients who are at high risk for opioid abuse, should consider non-opioid analgesics and non-pharmacologic therapies for initial low back pain management, and should prescribe the lowest practical dose for a limited duration (e.g., <1 week) if opioid is indicated, to prevent opioid misuse, abuse or diversion.

Limitations

The systematic review by Nuckols et al (2014)[17] had several limitations. It excluded non-English-language guidelines and relied on publicly available information. Because its purpose

was to evaluate guidelines that address the use of opioids for chronic pain in adults in general, guidelines focusing on specific conditions, populations, types of pain, or setting were excluded.

The recommendations of most of the guidelines including those of the ACEP guidelines[18] were supported by lower-quality evidence or expert opinions.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

Clinical evidence on stepwise approaches for opioid prescribing (from lower to higher potency) for non-cancer pain in the emergency department or in-hospital settings could not be identified in this review. There exist guidelines for opioid prescribing for non-cancer chronic pain and for pain management in emergency department. Although there are no recommendations related specifically to stepwise approaches to prescribing, most guidelines recommend physicians to start prescribing low doses of opioids for a limited duration, increasing the doses slowly and using upper dosing thresholds. Opioid risk assessment tools, written treatment agreements and urine drug testing were recommended to be in place when opioids are prescribed for long-term use. Of note, the recommendations should be interpreted with caution since they are supported by lower-quality evidence or expert opinions.

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APPENDIX 1: AMSTAR Checklist for the Quality Assessment of Systematic Reviews

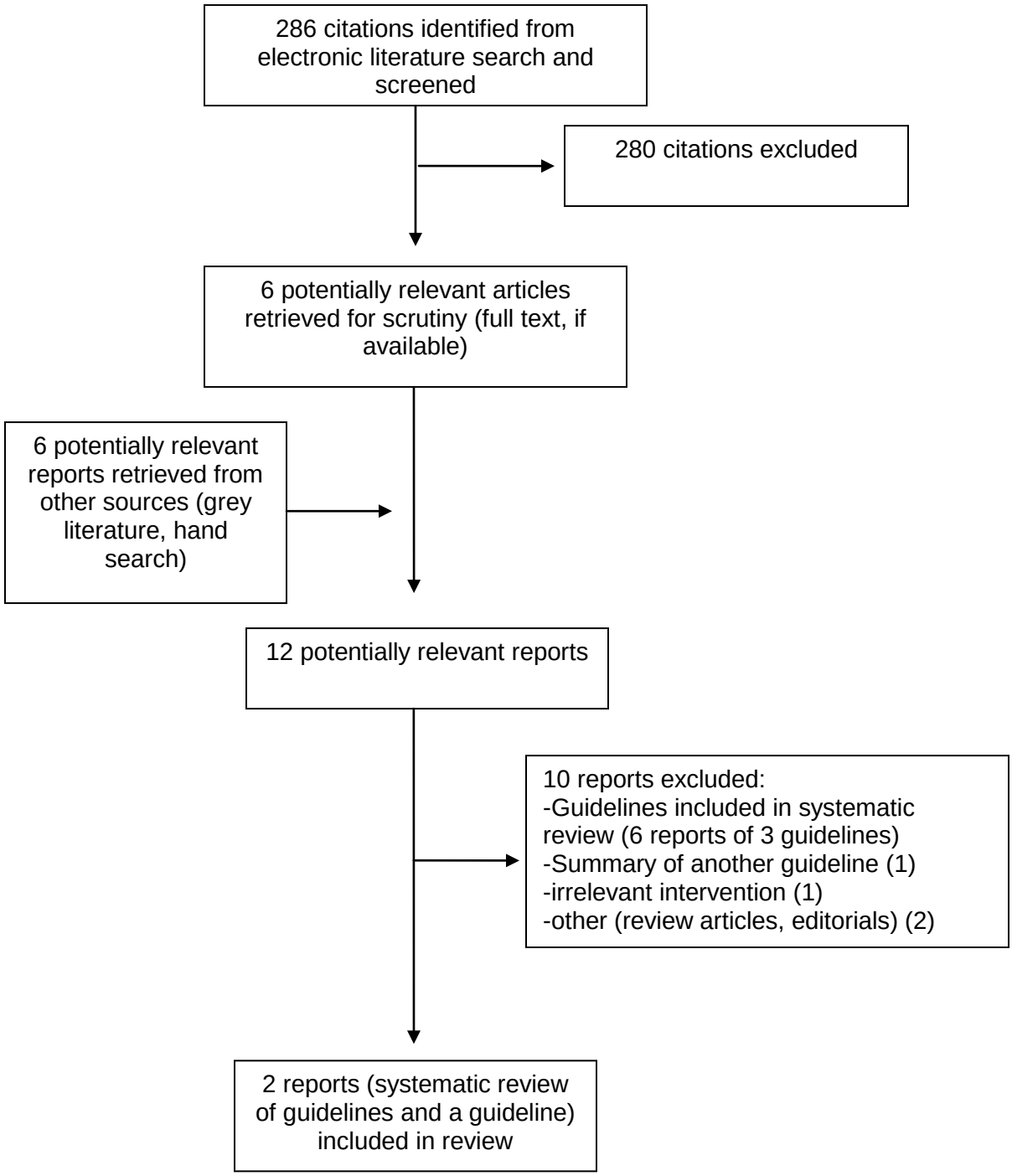
AMSTAR Checklist	***Check: Yes, No, Can't answer, or Not applicable***
1. Was an 'a priori' design provided?	
2. Was there duplicate study selection and data extraction?	
3. Was a comprehensive literature search performed?	
4. Was the status of publication (i.e. grey literature) used as an inclusion criterion?	
5. Was a list of studies (included and excluded) provided?	
6. Were the characteristics of the included studies provided?	
7. Was the scientific quality of the included studies assessed and documented?	
8. Was the scientific quality of the included studies used appropriately in formulating conclusions?	
9. Were the methods used to combine the findings of studies appropriate?	
10. Was the likelihood of publication bias assessed?	
11. Was the conflict of interest included?	

APPENDIX 2: Checklist for the Quality Assessment of Guidelines (AGREE II)

Item	Score*
Domain 1: Scope and Purpose	
1. The overall objective(s) of the guideline is (are) specifically described.	
2. The health question(s) covered by the guideline is (are) specifically described.	
3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described	
Domain 2: Stakeholder Involvement	
4. The guideline development group includes individuals from all relevant professional groups.	
5. The views and preferences of the target population (patients, public, etc.) have been sought.	
6. The target users of the guideline are clearly defined.	
Domain 3: Rigour of Development	
7. Systematic methods were used to search for evidence.	
8. The criteria for selecting the evidence are clearly described.	
9. The strengths and limitations of the body of evidence are clearly described.	
10. The methods for formulating the recommendations are clearly described.	
11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	
12. There is an explicit link between the recommendations and the supporting evidence.	
13. The guideline has been externally reviewed by experts prior to its publication.	
14. A procedure for updating the guideline is provided.	
Domain 4: Clarity of Presentation	
15. The recommendations are specific and unambiguous	
16. The different options for management of the condition or health issue are clearly presented.	
17. Key recommendations are easily identifiable.	
Domain 5: Applicability	
18. The guideline describes facilitators and barriers to its application.	
19. The guideline provides advice and/or tools on the recommendations can be put into practice.	
20. The potential source implications of applying the recommendations have been considered.	
21. The guideline presents monitoring and/or auditing criteria.	
Domain 6: Editorial Independence	
22. The views of the funding body have not influenced the content of the guideline.	
23. Competing interests of guideline development group members have been recorded and addressed	
Rate the overall quality of this guideline	
I would recommend this guideline for use (Yes; Yes, with modifications; No)	

* Score of 1 for lowest possible quality to 7 for highest possible quality

APPENDIX 3: Selection of Included Studies



APPENDIX 4: Characteristics of the Systematic Review of Guidelines by Nuckols et al. (2014)[17]

Data Sources and Searches	MEDLINE via PubMed, the National Guideline Clearinghouse, 12 Web sites of relevant specialty societies listed on the American Medical Association web site, web sites of selected states workers' compensation agencies, and 12 international search engines. The search was last updated in July 2013.
Guideline Selection	Guidelines had to have been published after 2006. Guidelines address the use of opioids for chronic pain in adults in general. Exclusion criteria included specific conditions, populations, type of pain or setting. Guidelines that derived entirely from another guideline and those did not provide details information on development were excluded. Two reviewers applied criteria independently and reached agreement; a third reviewer was available to resolve dispute.
Guideline Quality Assessment	Guideline quality was assessed using AGREE II. The quality of systematic review supporting each guideline was assessed using AMSTAR.
Guideline Synthesis and Analysis	Three appraisers abstracted recommendations from each guideline.
Role of funding source	The study was funded by the Commission on Health and Safety and Workers' Compensation. The funding source had no role in the design or execution of this evaluation.

APPENDIX 5: Summary of Critical Appraisal of Systematic Review by Nuckols et al. (2014)17 Using AMSTAR

Strengths	Limitations
• There was duplicate study selection and data extraction. • A comprehensive literature search was performed. • Lists of included and excluded studies were provided. • The characteristics of the included studies were provided. • The scientific quality of the included studies was assessed and documented. • The scientific quality of the included studies was used appropriately in formulating conclusions. • The conflict of interest was included.	• It was unclear if the research question and inclusion criteria had been established before the conduct of the review. • It was unclear if grey literature was included in the literature search.

APPENDIX 6: Summary of Critical Appraisal of ACEP Guidelines[18] Using AGREE II

Strengths	Limitations
• The overall aim of the guideline, the specific health questions, and the target populations were strongly agreed. • The guideline was developed by the appropriate stakeholders (i.e., professional groups and target users). • Five of eight items of the rigour of development were strongly agreed. • The language, structure and format of the guideline were appropriate. • The potential source implications of applying the recommendations have been considered. • The views of the funding body have not influenced the content of the guideline. • Competing interests of guideline development group members have been recorded and addressed.	• Seeking of the views and preferences of the target populations was unclear. • Criteria for selecting the evidence, and the strength and limitations of the body of evidence were not clearly described. • A procedure for updating the guideline was not provided. • The guideline did not clearly provide advice and/or tools on the recommendations can be put into practice. • The guideline did not clearly present monitoring and/or auditing criteria

APPENDIX 7: Summary of Findings of the Systematic Review of Guidelines by Nuckols et al. (2014)17

Data Sources	**13 eligible guidelines published in 2009 or later. Systematic reviews were conducted in 2008 or later.**
Guideline Development Group for Included Guidelines	• American College of Occupational and Environmental Medicine (ACOEM) – Guidelines for Chronic Use of Opioids • American Geriatrics Society (AGS) – The Management of Persistent Pain in Older Persons • American Pain Society – American Academy of Pain Medicine (APS-AAPM) • American Society of Anesthesiologists (ASA) – Practice Guidelines for Chronic Pain Management • American Society of Interventional Pain Physicians (ASIPP) – Guidelines for Responsible Opioid Prescribing in Chronic Non-cancer Pain • National Opioid Use Guideline Group (NOUGG) – Opioids for Chronic Noncancer Pain: A new Canadian Practice Guideline • Colorado Division of Workers' Compensation (Colorado DWC) – Chronic Pain Disorder Medical Treatment Guidelines • Fine et al (2009) – Ad Hoc Expert Panel on Evidence Review and Guidelines for Opioid Rotation • Institute for Clinical Systems Improvement (ICSI) – Assessment and Management of Chronic Pain • University of Michigan Health System (UMHS) – Managing Chronic Non-Terminal Pain in Adults, Including Prescribing Controlled substances • Utah Department of Health (UDOH) – Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain • Veterans affairs / Department of Defense (VA/DoD) – Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain • Work Loss Data Institute (WLDI) – Pain (Chronic)
Guideline Quality Assessment	***AGREE II*** APS-AAPM and NOUGG were rated highest. More than 50% appraisers voted to use without modifications. Most appraisers recommended against using 4 guidelines (Colorado DWC, UMHS, ASA, Fine et al) ***AMSTAR*** The APS-AAPM review was of excellent to outstanding quality. The NOUGG review was of good to excellent quality The VA/DoD review was of good quality Systematic reviews within remaining 10 guidelines were of poor or fair quality
Guideline synthesis and Analysis	***Recommendation*** Most of the recommendations are supported by lower-quality evidence or expert opinions. • **Dose that warrants scrutiny, *mg of morphine equivalent per day*** – Eight guidelines concur that higher doses (≥200 mg/day) require caution (Colorado DWC, UMHS, VA/DoD, ICSI, UDOH, APS-AAPM, ASIPP, NOUGG). The ASIPP guideline recommends staying below 90 mg unless pain is intractable. The UMHS guideline advises that patients receiving more than 100 mg be treated with pain specialists. • **Medications and formulations** – Ten guidelines agree that methadone poses risks for dose-related QTc prolongation and respiration suppression due to long half-life and unique pharmacokinetics (ACOEM, AGS, APS-AAPM, ASIPP, NOUGG, Colorado DWC, ICSI, UMHS, UDOH, Va/DoD). Eight guidelines recommend caution with fentanyl patch, including limiting use to opioid-tolerant patients and being aware that unpredictable absorption can occur with fever, exercise, or exposure to heat (Colorado DWC, UMHS, Va/DoD, ICSI, ASIPP, UDOH, ACOEM, NOUGG).

	• **Initiation and titration of dose** – Ten guidelines make variable consensus-based statements about initiating and titrating opioids, such as using a trial period, individualizing therapy, engaging multidisplinary pain management teams, increasing doses slowly, and scheduling regular follow-up visits (ACOEM, AGS, APS-AAPM, ASIPP, NOUGG, Colorado DWC, ICSI, UMHS, UDOH, Va/DoD). • **Switching between opioids** – Seven guidelines agree that reducing doses by at least 25% to 50% is necessary to avoid inadvertent overdose, when switching from one opioid to another (APS-AAPM, VA/DoD, ICSI, UDOH, Fine et al, ACOEM, NOUGG). • **Drug-drug interactions** – Ten guidelines concur that benzodiazepines and opioids are a high risk combination, particularly in elderly adults (APS-AAPM, Colorado DWC, UMHS, VA/DoD, ICSI, UDOH, AGS, ACOEM, ASIPP, NOUGG) • **Drug-disease interactions** – Six guidelines mention that accumulation of active, toxic metabolites of morphine among patients with kidney disease (Colorado DWC, VA/DoD, ICSI, ASIPP, UDOH, NOUGG). Ten guidelines considered the leading risk factors for overdose or misuse as having a personal or family history of substance abuse and having psychiatric issues (ACOEM, AGS, APS-AAPM, ASIPP, NOUGG, Colorado DWC, ICSI, UMHS, UDOH, Va/DoD). Seven guidelines identify obstructive respiratory disorders as risk factors for overdose (Colorado DWC, APS-AAPM, UMHS, VA/DoD, UDOH, NOUGG, ASIPP) • **Risk assessment tools and treatment agreements** – Nine guidelines recommend considering or using opioid risk assessment tools and treatment agreements (APS-AAPM, UMHS, VA/DoD, ICSI, UDOH, AGS, ACOEM, ASIPP, NOUGG) • **Urine drug testing** – Nine guidelines find urine drug testing to be helpful, but recommendations vary (APS-AAPM, Colorado DWC, UMHS, VA/DoD, ICSI, UDOH, ACOEM, ASIPP, NOUGG)

APPENDIX 8: Summary of Recommendations of the Guidelines of the American College of Emergency Physicians (ACEP) by Cantrill et al. (2012)18

Questions	Recommendations
1. In the adult Emergency Department (ED) patient with noncancer pain for whom opioid prescriptions are considered, what is the utility of state prescription drug monitoring programs in identifying patients who are at high risk for opioid abuse?	*"The use of state prescription monitoring program may help identify patients who are at high risk for prescription opioid diversion or doctor shopping."* ***(Level C)***, p.502
2. In adult ED patient with acute low back pain, are prescriptions for opioids more effective during the acute phase than other medications?	• *"For patients being discharged from ED with acute low back pain, the emergency physician should ascertain whether nonopioid analgesics and nonpharmacologic therapies will be adequate for initial pain management."* ***(Level C)***, p.504 • *"Given a lack of demonstrated evidence of the superior efficacy of either opioid or nonopioid analgesics and the individual and community risks associated with opioid use, misuse, and abuse, opioids should be reserved for more severe pain or pain refractory to other analgesics rather than routinely prescribed."* ***(Level C)***, p.504 • *"If opioid is indicated, the prescription should be for the lowest practical dose for a limited duration (e.g., <1 week), and the prescriber should consider the patient's risk for opioid misuse, abuse, or diversion."* ***(Level C)***, p.504
3. In the adult ED patient for whom opioid prescription is considered appropriate for the treatment of new-onset acute pain, are short-acting schedule II opioids more effective than short –acting schedule III opioids?	• *"For short-term relief of acute musculoskeletal pain, emergency physicians may prescribe short-acting opioids such as oxycodone or hydrocodone products while considering the benefits and risks for the individual patient."* ***(Level B)***, p.505, 506 • *"Research evidence to support superior pain relief for short-acting schedule II over schedule III opioids is inadequate."* ***(Level C)***, p.506
4. In the adult ED patient with acute exacerbation of noncancer chronic pain, do the benefits of prescribing opioids on discharge from the ED outweigh the potential harms?	• *"Physicians should avoid the routine prescribing of outpatient opioids for a patient with acute exacerbation of chronic noncancer pain seen in the ED."* ***(Level C)***, p.506 • *"If opioids are prescribed on discharge, the prescription should be for the lowest practical dose for a limited duration (e.g., <1 week), and the prescriber should consider the patient's risk for opioid misuse, abuse or diversion."* ***(Level C)***, p.506 • *"The clinician, should, if practical, honor existing patient-physician pain contracts/ treatment agreements and consider past prescription patterns from information sources such as prescription drug monitoring programs."* ***(Level C)***, p.506, 507

APPENDIX 9: Grading of Recommendations and Levels of Evidence

Guideline	Strength of Evidence for Therapy	Strength of Recommendations
ACEP Guidelines	**Class I**: Randomized, controlled trial or meta-analysis of randomized trials	**Level A**: Generally accepted principles for patient management that reflect a high degree of clinical certainty (i.e., based on strength of evidence Class I or overwhelming evidence from strength of evidence Class II studies that directly address all of the issues).
	Class II: Non-randomized trial	**Level B**: Recommendations for patient management that may identify a particular strategy or range of management strategies that reflect moderate clinical certainty (i.e., based on strength of evidence Class II studies that directly address the issue, decision analysis that directly address the issue, or strong consensus of evidence Class III studies).
	Class III: Case series, case reports, other (e.g., consensus, review)	**Level C**: Other strategies for patient management that are based on Class III studies, or in the absence of any published literature, based on panel consensus.