VERMONT
DEPARTMENT OF HEALTH

VERMONT2013
Unified Pain Management System Advisory Council

February 25, 2013

Background

Practices for treating patients with conditions that cause chronic pain vary among the medical professions as much as the professionals themselves. Pain is subjective and treatment of pain can be complex. With increasing problems stemming from prescription drug misuse and abuse, the Unified Pain Management System Advisory Council was created on June 3, 2012 pursuant to 18 V.S.A § 5(3). The Council's purpose is to advise the Commissioner of Health (the Commissioner) on matters relating to the appropriate use of controlled substances in the treatment of chronic, non-cancer pain and addiction, and in preventing prescription drug abuse.

The Council was appointed by the Commissioner and approved by the Governor. The Council is composed of a variety of prescribers and dispensers who are committed to improving the care and management of patients with chronic, non-cancer pain. With staff support from the Vermont Department of Health, the Council met six times between September 2012 and February 2013. It also and created three subcommittees (System Improvement, Pain Management and Medical Affairs), each of which met several times to work on specific issues.

The following report presents advice and recommendations to the Commissioner in the four key areas discussed below. The recommendations cover a wide range of areas related to the Council's charge. While there was consensus on nearly all of the recommendations, there are instances where members had differing perspectives on substantive issues. The thoughtful input by Council members will inform and advance continued policy considerations related to safe and effective pain management.

Recommendations

The Council was charged with producing recommendations in four key areas:

1. **Unified Pain Management System**-Recommendations for guidelines for the appropriate use of controlled substances in treating chronic non-cancer pain and addiction and in preventing prescription drug abuse, including the development and recommendation of principles and components of a unified pain management system;

2. **Guidelines for the use of the Vermont Prescription Monitoring System (VPMS)**-Recommendations for the use of the VPMS by dispensers and healthcare providers including data thresholds for patient follow-up;

3. **Improvements to the VPMS** - Recommendations regarding ways to improve the utility of the VPMS and its data; and

4. **Evidence-Based Training Modules** -Recommendations for the continuing education of all licensed health care providers in the state who treat chronic pain or addiction or prescribe controlled substance in Schedule II, III or IV consistent with a unified pain management system.

Guidelines

For each of the four areas of recommendations, the Council has defined important action steps and guidelines. Some of these guidelines cluster into topics of common focus and are identified by a subtitle below. In some instances, the Council has distilled the most important guidelines into two tiers - namely "must do" and "should do" - based on common agreement regarding degree of clinical necessity. Where applicable, the two tiers are listed separately within each of the main areas of recommendation.

1. Guidelines for the Unified Pain Management System:

Management of Patients with Chronic Pain

Must do:

- As recommended by the Vermont Board of Medical Practice, the initial prescriber must document a thorough medical evaluation and physical examination as part of their medical record when prescribing controlled substances. In addition, documentation of the diagnosis that supports the use of controlled substances for pain relief must be included in the medical record.
- Prescribers must include an assessment of risk of substance abuse when considering a patient for chronic controlled substance treatment. For patients who are at high risk for misuse or addiction, the medical record should include a discussion of relative risks and benefits. There are several assessment tools commonly available such as:
  - The Screener and Opioid Assessment for Patients with Pain (SOAPP[1]).
- Prescribers must have patients sign an informed consent before starting controlled substances on a chronic basis. Several of these examples are available on the Vermont Board of Medical Practice website located here: **http://www.healthvermont.gov/hc/med_board/documents/pain_policy.pdf**
  - A statement will be included in the pain management guidelines about the possible lethality of using opiates in combination with benzodiazepines.
- The Vermont Board of Medical Practice should review its pain management guidelines and revise them to reflect current best practices and require all licensees who prescribe either in Vermont or for one or more patients who are Vermont residents to enroll in the VPMS and use it appropriately. At a minimum, appropriate use includes the first time that a controlled

[1] https://www.painedu.org/load_doc.asp?file=SOAPP_24.pdf

substance is prescribed to a patient, at appropriate intervals thereafter and whenever there are indications of possible abuse.

- A prescriber must have an informed consent and controlled substance agreement for a high-risk patient. Agreements may include urine testing, pill counts, and other appropriate conditions as determined by the prescriber.
- Best practice suggests that all patients being treated for chronic pain with controlled substances sign a controlled substance agreement.

Should do:

- Prescribers should include an assessment of the effectiveness of the prescribed regimen as part of routine follow-up. There are assessment tools commonly available such as the "Four A's" for assessing chronic pain management (analgesia, activities of daily living, adverse side effects, aberrant drug-taking behaviors).
- Prescribers should write the maximum daily dose on the prescription for the pharmacy or a "not to exceed" equivalent. The purpose of this is to resolve ambiguity in prescriptions that may be written with a range of doses on a PRN ("as needed") basis, e.g. 1-2 tabs TID (Three times a day) PRN. The implied maximum dose would be 6 pills in 24 hours (and by extension 42 tabs per week), but that may not be the intention of the prescriber.
- Language should be included in the Medical Practice Board Policy for the Use of Controlled Substance for the Treatment of Pain on how to interpret and utilize urine screens.

Provider Referrals

Prescribers must consider arranging for a consultation with an appropriate specialist when:

- The patient is not improving even with escalating dose of controlled substances for pain.
- The patient has been on pain medication for 3 months and is not improving.
- The patient is at high risk for substance abuse.

A consultation may involve the use of telemedicine[2] that may assist to eliminate distance barriers and improve access to specialty services.

Prescribers must consider referral for substance abuse evaluation for treatment when:

- The prescriber suspects or confirms that a patient is abusing opioids or other substances.
- The patient is seeing multiple prescribers and pharmacists.
- The patient is on multiple controlled substances.

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[2] Telemedicine: The use of medical information exchanged from one site to another via electronic communications for the health and education of the patient or healthcare provider and for the purpose of improving patient care. Telemedicine includes consultative, diagnostic, and treatment services.

- The patient is at high risk for substance abuse as determined by their history or a screening.

Verification of patient identification

- The dispensing pharmacists should check the patient's government-issued photographic ID and obtain a signature as proof of identity at the time the prescription is dispensed.
- If the patient is unable to pick up the controlled substance prescription, a designee (e.g. a family member or friend) may serve as a proxy to obtain the controlled substance for that patient; however, the designee must show a government-issued photographic ID and provide a signature.

Alternative Treatments

The Council supports advocacy for prescribers to use and insurance companies to cover evidence-based alternatives to opioid medications that include (but are not limited to):

- Biofeedback
- Acupuncture
- Chiropractic
- Massage
- Physical therapy
- Injections interventional pain
- Naturopathic physicians
- Hypnosis
- Neuropathic pain medications
- Non opioid pain medications/treatments

2. <u>Guidelines for the Use of the VPMS</u>

Use of VPMS by Prescribers

Must do:

- All Vermont licensed prescribers with a DEA number that prescribe controlled substances must register to use the VPMS when applying for their initial or the renewal of their Vermont license.
- The prescriber or their delegate must check the VPMS at least annually for patients who are on chronic opioid therapy.
- Medication Assisted Therapy (MAT) for opioid addiction treatment providers must have a policy where they review their patient's history in the VPMS at least quarterly.
    - The Division of Alcohol and Drug Abuse Programs (ADAP) will write this requirement into their treatment standards.

- A prescriber or their delegate must check the VPMS when starting a patient on a controlled substance for long term opioid therapy (defined as more than 90 days).

Should do:

- The VPMS registration should be linked to the online licensing process on the Medical Practice Board and the Office of Professional Regulation website for easy access for all prescribers to register for VPMS at time of re-licensure.
- Since the presence or absence of pain treatment agreements cannot be included in the VPMS data fields, it is recommended that prescribers communicate to the supervisory pharmacist that the patient is on an agreement by any of the following:
    - Request a signature to indicate the supervisory pharmacist's acknowledgement of the patient and the agreement.
    - Indicate on the prescription that the patient has an active treatment agreement. This could be written in the signature section or with a simple check box.
    - The prescriber should state that patient is a party to a controlled substance agreement in the e-prescribing field.

Use of VPMS by Pharmacists

Must do:

- All Vermont licensed pharmacists who dispense controlled substances must register to use the VPMS when applying for their initial or the renewal of their Vermont license.

Should do:

- Registration for the VPMS should be linked to the online licensing process on the Medical Practice Board and the Office of Professional Regulation website for easy access for all prescribers to register for VPMS at time of re-licensure.
- Pharmacists should be registered to use and be required to check the VPMS when dispensing controlled substances to new patients.
- Pharmacists should be required to check the VPMS for ongoing patients receiving controlled substances on a periodic basis and when abuse or diversion is suspected.
- Since the presence or absence of pain treatment agreements cannot be included in the VPMS data fields, it is recommended that prescribers communicate to the supervisory pharmacist that the patient is a party to an agreement and that the pharmacist acknowledge receipt of that information.

3. Improvements to the VPMS

- Change the interface so that the birth date can be entered in multiple formats.
- The VPMS should include pharmacists as recipients of threshold letters via fax and addressed to the "Pharmacy Manager/ Supervisory Pharmacist". The Supervisory Pharmacist should be required to fax back the threshold to VPMS as an acknowledgement of receipt.

- Interstate data sharing - The adoption of the Prescription Monitoring Information Exchange (PMIX) will give VPMS registered users the ability to know where their patients are picking up their controlled substance prescriptions, who the prescribers are and the prescribed medications regardless of the state where it occurred. This will result in an enhanced and more effective tool for health care providers and dispensers to prevent and detect prescription drug misuse through the VPMS.
- The VPMS does not capture small amounts of controlled substance prescriptions given from emergency departments. The Council suggested that the VPMS should consider a pilot project with a volunteer Emergency Department to see if it is feasible to include these prescriptions.
- Automate VPMS information by sending threshold alerts to prescribers' email addresses suggesting they look at the information in the VPMS.
- Population Based Reports - This enhancement would improve the quality of care by allowing prescribers to see all of their patients at one time and to see where their prescribing falls relative to their peers.
- Creation of a "Use Index" in the VPMS that would indicate how much each prescriber uses the system. This could be calculated as the proportion of patients that the prescriber has looked up on VPMS at least once per year. (i.e. number of patients looked up on VPMS divided by the number of patients prescribed for by that prescriber in a given year). In the ideal scenario a prescriber would have a VPMS Use Index of 1, and each patient would have been evaluated on VPMS at least annually.
- VPMS staff should perform more in-depth data analysis to determine if other thresholds are useful for understanding or improving prescribing, such as patients who are receiving:
    - Stimulants given by two or more doctors
    - Benzodiazepines given by two or more doctors
    - Opiates given by two or more doctors
- Look at top prescribers in VPMS and then sort by days supplied.
- Threshold for patients who are using more than two or more pharmacies in 30 days and have visited 2 or more prescribers.
    - Patients receiving controlled substances from three or more classes of Benzodiazepines, Opiates and Stimulants. (This can be completed in a six month time period, six months from now).

4. Suggestions for Evidence Based Training Modules

Education should include:

- How to taper medications if the patient is misusing.
- How to interpret urine screens and the appropriate use of their results in clinical practice.
- Guidance on patient abandonment issues.
- The Vermont Board of Medical Practice requires prescribers that prescribe controlled substances to complete a mandatory two, one hour CME training per each licensing cycle. The subcommittee recommended suggestions to these mandatory trainings:

- Educational modules should vary each two years giving prescribers an option of what they would like to spend their two hours learning about (chronic pain, palliative care, etc.).
- Combine CME credits with CE credits to have targeted pain and opioid conferences that include both prescribers and pharmacists.

Other prescribers and dispensers of controlled substances (those licensed by the Office of Professional Regulation including mid-level Practioners, dentists, doctors of Osteopathic medicine, Advanced Nurse Practioners) are not included in the requirement to complete mandatory CME trainings. The Pain Council strongly recommends that anyone who prescribes controlled substances shall be required to complete these trainings. Additionally, OPR licenses pharmacists and the council strongly recommends pharmacists be included in the mandatory trainings as well.

Recommendations put forth but are not currently possible

- Look into possibility of linking VPMS with HIT - Health Information Technology (HIT) is not capable of linking with the VPMS at this point in time; the recommendation is for each hospital or health clinic to put an icon or pop-up link to the VPMS in order to promote the ease and utility of the VPMS. The VPMS training will now include requesting that a site work with the IT Department to include a pop-up link or icon for easy access to the VPMS.
- Include a treatment agreement flag into the VPMS. This was considered and tabled, as it does not appear that it will be the most helpful within the system as representing a living document in a statewide system has too many data management issues. However, contracts might be considered in education or guidelines discussions.
- Include Methadone dispensed from methadone clinic and marijuana registry information into the VPMS dataset. Information from the methadone treatment centers cannot be included into the VPMS database due to Federal law. Additionally, the VPMS only collects II-IV controlled substance medications so marijuana would not be included.
- Change reporting requirement from 7 days to 24-hour uploads - this is something to still be discussed to determine whether the more frequent reporting would yield substantial benefits.
- Prescribers should write future fill date on a prescription.
- Prescribers should specify the pharmacy the patient should go to on prescription itself.[3]

Conclusion

The goal of the Unified Pain Management System Advisory Council is to inform policy discussions aimed at creating a unified, comprehensive system of pain management care for all Vermont individuals and families. The recommendations in this report and any that will result from continued work of the Council through June, 2013, are intended to advance these discussions.

[3] It must be determined how this information can be tracked.

Screener and Opioid Assessment for Patients with Pain (SOAPP)® Version 1.0

The Screener and Opioid Assessment for Patients with Pain (SOAPP)® Version 1.0 is a tool for clinicians to help determine how much monitoring a patient on long-term opioid therapy might require. Physicians remain reluctant to prescribe opioid medication because of concerns about addiction, misuse, and other aberrant medication-related behaviors, as well as liability and censure concerns. Despite recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems, physicians often express a lack of confidence in their ability to distinguish patients likely to have few problems on long-term opioid therapy from those requiring more monitoring.

SOAPP® version 1.0 is a quick and easy-to-use questionnaire designed to help providers evaluate the patients' relative risk for developing problems when placed on long-term opioid therapy. Version 1.0 is:

- A brief paper and pencil questionnaire
- Developed based on expert consensus regarding important concepts likely to predict which patients will require more or less monitoring on long-term opioid therapy (content and face valid)
- Preliminary reliability data (coefficient α) from 175 patients chronic pain patients
- Preliminary validity data from 100 patients (predictive validity)
- Simple scoring procedures
- 24 items
- 5 point scale
- <10 minutes to complete
- Ideal for documenting decisions about the level of monitoring planned for a particular patient or justifying referrals to specialty pain clinic.
- The SOAPP® is for clinician use only. The tool is not meant for commercial distribution.
- The SOAPP® is **NOT** a lie detector. Patients determined to misrepresent themselves will still do so. Other clinical information should be used with SOAPP® scores to decide on a particular patient's treatment.
- The SOAPP® is **NOT** intended for all patients. The SOAPP® should be completed by chronic pain patients being considered for opioid therapy.
- It is important to remember that all chronic pain patients deserve treatment of their pain. Providers who are not comfortable treating certain patients should refer those patients to a specialist.

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SOAPP® Version 1.0

Name: ____ Date: _______________

The following are some questions given to all patients at the Pain Management Center who are on or being considered for opioids for their pain. Please answer each question as honestly as possible. This information is for our records and will remain confidential. Your answers alone will not determine your treatment. Thank you.

Please answer the questions below using the following scale:

0 = Never, 1 = Seldom, 2 = Sometimes, 3 = Often, 4 = Very Often

1. How often do you feel that your pain is "out of control?" 0 1 2 3 4
2. How often do you have mood swings? 0 1 2 3 4
3. How often do you do things that you later regret? 0 1 2 3 4
4. How often has your family been supportive and encouraging? 0 1 2 3 4
5. How often have others told you that you have a bad temper? 0 1 2 3 4
6. Compared with other people, how often have you been in a car accident? 0 1 2 3 4
7. How often do you smoke a cigarette within an hour after you wake up? 0 1 2 3 4
8. How often have you felt a need for higher doses of medication to treat your pain? 0 1 2 3 4
9. How often do you take more medication than you are supposed to? 0 1 2 3 4
10. How often have any of your family members, including parents and grandparents, had a problem with alcohol or drugs? 0 1 2 3 4
11. How often have any of your close friends had a problem with alcohol or drugs? 0 1 2 3 4

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0 = Never, 1 = Seldom, 2 = Sometimes, 3 = Often, 4 = Very Often

12. How often have others suggested that you have a drug or alcohol problem? 0 1 2 3 4

13. How often have you attended an AA or NA meeting? 0 1 2 3 4

14. How often have you had a problem getting along with the doctors who prescribed your medicines? 0 1 2 3 4

15. How often have you taken medication other than the way that it was prescribed? 0 1 2 3 4

16. How often have you been seen by a psychiatrist or a mental health counselor? 0 1 2 3 4

17. How often have you been treated for an alcohol or drug problem? 0 1 2 3 4

18. How often have your medications been lost or stolen? 0 1 2 3 4

19. How often have others expressed concern over your use of medication? 0 1 2 3 4

20. How often have you felt a craving for medication? 0 1 2 3 4

21. How often has more than one doctor prescribed pain medication for you at the same time? 0 1 2 3 4

22. How often have you been asked to give a urine screen for substance abuse? 0 1 2 3 4

23. How often have you used illegal drugs (for example, marijuana, cocaine, etc.) in the past five years? 0 1 2 3 4

24. How often, in your lifetime, have you had legal problems or been arrested? 0 1 2 3 4

Please include any additional information you wish about the above answers. Thank you.

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Scoring Instructions for the SOAPP® version 1.0.

Of the 24 questions contained in the SOAPP® version 1.0, 16 have been empirically identified as predicting aberrant medication-related behavior six months after initial testing.

To score the SOAPP®, add the ratings of the following questions:

2, 7, 10, 11, 12, 13, 15, 17, 18, 19, 20, 22, 23, 24

A score of 7 or higher is considered positive.

Sum of Questions 2, 7, 10, 11, 12, 13, 15, 17, 18, 19, 20, 22, 23, and 24	SOAPP® Indication
> or = 7	+
< 7	**-**

What does the Cutoff Score Mean?

For any screening test, the results depend on what cutoff score is chosen. A score that is good at detecting patients at-risk will necessarily include a number of patients that are not really at risk. A score that is good at identifying those at low risk will, in turn, miss a number of patients at risk. A screening measure like the SOAPP® generally endeavors to minimize the chances of missing high-risk patients. This means that patients who are truly at low risk may still get a score above the cutoff. The table below presents several statistics that describe how effective the SOAPP® is at different cutoff values. These values suggest that the SOAPP® is a sensitive test. This confirms that the SOAPP® is better at identifying who is at high risk than identifying who is at low risk. Clinically, a score of 7 or higher will identify 91% of those who actually turn out to be at high risk. The Negative Predictive Values for a cutoff score of 7 is .90, which means that most people who have a negative SOAPP® are likely at low-risk. Finally, the Positive likelihood ratio suggests that a positive SOAPP® score (at a cutoff of 7) is nearly 3 times (2.94 times) as likely to come from someone who is actually at high risk (note that, of these statistics, the likelihood ratio is least affected by prevalence rates). All this implies that by using a cutoff score of 7 will ensure that the provider is least likely to miss someone who is really at high risk. However, one should remember that the SOAPP® is less good at identifying who is not at-risk. That is, in our sample, about 30% of the patients who scored a 7 or higher on the SOAPP®, did **not** go on to show detectable aberrant behavior. This proportion could be improved, but only at the risk of missing more of those who actually did show aberrant behavior.

SOAPP® Cutoff Score	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ration
Score 7 or above	.91	.69	.71	.90	2.94	.13
Score 8 or above	.86	.73	.75	.86	3.19	.19
Score 9 or above	.77	.80	.77	.80	3.90	.28

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