Exhibit OO12.by

UNIVERSITY of VIRGINIA HEALTH SYSTEM

Clinical Staff Executive Committee

MEDICAL CENTER POLICY NO. 0239

A. SUBJECT: Pain Assessment and Management (Adult Patients)

B. EFFECTIVE DATE: April 1, 2014

This policy applies to all adult patient encounters at the University of Virginia Medical Center.

C. POLICY:

1. All caregivers at The University of Virginia Medical Center, within the scope of their individual practice, shall:

    a. Provide consistent and proficient screening, assessment, documentation, and treatment of pain while assessing for the risk associated with pain treatment and/or history of persistent pain;

    b. Collaborate and cooperate with the patient, care partner, and members of the patient's health care team, to optimize patient comfort. The common purpose is to safely and ethically optimize the patient's comfort and to improve activity tolerance, understanding that total absence of discomfort may not be a realistic goal.

2. Health care team members have an obligation to:

    a. Offer individualized pain relief interventions to patients consistent with their medical, psychological, and social history;

    b. Respect the individual's personal, cultural, and religious values in regard to the relief of pain and suffering;

    c. Acquire and maintain the knowledge and skills to assess and manage pain effectively using multimodal therapies;

    d. Utilize available resources for pain management.

3. Pain will be considered as the 5^{th} vital sign. Pain will be screened with routine vital signs.

4. The complexity and frequency of assessment, reassessment and monitoring for pain and treatment will be determined by factors such as:

    a. The patient setting (e.g., inpatient, outpatient clinics, procedural areas);

b. Patient's perception of efficacy of treatment;

c. Patient's physiologic condition that may affect the response to treatment (e.g. renal or liver function, compromised respiratory function, OSA);

d. The side-effects and risks associated with the treatment;

e. Concurrent use of potentiating medications.

Note: unless otherwise indicated, all hyperlinked materials in this policy are contained in the University of Virginia Health System Pain Resource Manual.

D. DEFINITIONS

See **Appendix A "**GLOSSARY OF PAIN-RELATED TERMS"

E. RESPONSIBILITIES

1. **Authorized Prescriber** (MD, DO, DDS, NP, PA, DPM; collectively referred to in this Policy as "Licensed Independent Practitioners" or "LIPs"), Outpatient and Inpatient:

   a. Perform pain assessment as indicated by patient report, pain screen or nursing assessment;

   b. Prescribe appropriate pain interventions as warranted by the patient's medical and psychological conditions;

   c. Consider referral to appropriate consultative service for complex pain management needs (CONSULTATION RESOURCES).

2. **Registered Nurse (RN)**

   a. Screen patients for pain on admission or clinic visits. If pain is present perform a pain assessment as outlined in Section F below ("PROCEDURE");

   b. Reassess pain, patient's satisfaction with pain interventions, and patient safety as outlined in Section F below (see Section F below, "PROCEDURE");

   c. Assure maximum comfort with minimal side-effects;

   d. Administer medications as ordered;

   e. Notify the LIP if adverse effects occur, or if pain intervention is ineffective;

   f. Educate patients about pain medication and treatment.

3. **Licensed Practical Nurse (LPN)**

   a. Screen patients for pain;

b. Implement patient education related to pain management as determined by RN;

c. Provide appropriate non-pharmacologic interventions;

d. Notify the RN/LIP if the patient would like pain addressed, or if he/she continues to report moderate to severe pain.

4. **Unlicensed Nursing Staff** (i.e., Patient Care Technicians and Patient Care Assistants, Certified Nurse Assistants, Medical Assistants).

a. Screen patients for pain with routine vital signs and document pain score. The patient must be able to self-report his/her pain rating;

b. Provide appropriate non-pharmacologic interventions;

c. Notify RN/LIP if the patient would like pain addressed, or continues to report moderate to severe pain.

5. **Clinical Pharmacist**

a. Review all new pain medication orders for potential drug interactions and elimination of duplicate therapies;

b. Provide recommendations for analgesic drug dosing and modifications of therapy as needed to achieve optimal pain relief while minimizing the occurrence of adverse events;

c. Monitor use of high risk analgesic medications (e.g., fentanyl, methadone, IV Patient Controlled Analgesia);

d. Consult with primary team on medication dosages and supportive medication for adverse effects of pharmacological pain management.

6. **Physical/Occupational Therapist/Speech Language Pathologist:**

a. Screen patients for pain prior to therapy;

b. Re-screen for pain after therapy;

c. Notify RN/LIP caring for the patient for pain that interferes with ability to participate with therapy.

7. **Respiratory Therapist:**

a. Screen patients for pain prior to and after completion of therapy or as indicated (therapy does not include basic oxygen therapy);

b. Notify RN/LIP if patient and caregivers would like pain addressed;

c. Notify RN/LIP caring for the patient for pain that interferes with ability to participate with therapy.

F. PROCEDURE

1. **Pain Screening** is the identification of the presence of pain. Screening will be performed on all patients (See Responsibilities Section E, above):

a. For Ambulatory setting, office visit or procedure encounters, patients are screened for presence of pain based on reason for visit or patient needs.

i. Responses to pain questions are documented in the electronic health record. Pain screening, scale and rating, may be documented by any member of the ambulatory staff.

ii. If no RN is present in ambulatory setting, the LIP performs assessment and reassessment as clinically indicated.

b. On all inpatients:

i. in the Admissions Assessment;
ii. with routine vital signs;
iii. at each Head-to-Toe Shift Assessment of Complex Assessment;
iv. when warranted based on patient needs.

2. **Pain Assessment** is an ongoing systematic process of identifying pain and its characteristics.

a. The RN will assess and document a comprehensive pain assessment when:

ii. pain is present on screening;

iii. patient reports a *new* complaint of pain;

b. The RN will assess the following pain characteristics as clinically indicated in the communicative patient:

i. Intensity
   1. Numeric Pain Score (Self Report)
   2. UVA Adult Standard Pain Rating Scale
   3. Verbal Analog Scale (VAS)

ii. Pain Type (e.g. Acute vs. chronic)
iii. Location of pain;
iv. Orientation (e.g., anterior, posterior etc.)
v. Descriptors (e.g., throbbing, sharp, dull, aching etc.)
vi. Pain onset (e.g., moving, breathing, turning, etc.)
vii. Clinical progression (e.g., worsening, improved, resolved)

viii. Patient satisfaction with comfort; *Note: The RN asks the communicative patient if the pain is satisfactorily (YES or NO response) controlled and will document if patient is satisfied with comfort*
ix. Multiple pain sites as appropriate.

c. The RN will use the following validated observation pain tools for **the non-communicative** adult patients using the following appropriate assessment tool:

i. Observation Cognitively Impaired Adult/ Procedural Assume Pain Present (APP);

ii. Critical Care Observation Tool (CPOT)*
** Note: Numbers used for observational tools do not reflect intensity of pain.*

3. **Reassessment** is the re-evaluation of the patient for pain intervention's effectiveness (including safety and side-effects).

a. The RN will reassess the patient for comfort prior to administering **pain interventions**.

b. When administering pain interventions, the RN will reassess pain or patient satisfaction with comfort within four (4) hours.

c. When administering **opioids,** the RN will reassess the patient for **opioid over-sedation** within 90 minutes following administration. Consideration must be given for the patient's expected response to the pain intervention.

d. The RN will use the following sedation tools:

i. Modified Pasero Opioid Sedation Scale **(POSS)** on adult Acute Care

ii. Richmond Agitation Sedation Scale **(RASS)** on ICU areas**.**

e. If patient meets **Over-Sedation Criteria**, the RN will assess respiratory status (rate and quality) and implement appropriate ACTION until opioid-induced sedation is resolved.

Over-Sedation Criteria	ACTION
If Frequently drowsy, arouses, drifts off to sleep during conversation	*-Monitor respiratory status and sedation at **minimum every hour**, and do not give opioids until Acceptable.* *-Notify MD/LIP (notify APS prior to holding epidural infusion); SBAR communication appropriate.* *-Recommend MD/LIP to decrease opioid by 25-50% when patient returns to acceptable level.* *-For pain, consider offering a non-sedating non-opioid, such as acetaminophen or NSAID if ordered.*
If somnolent, minimal or no response to verbal and physical stimulation.	*-Stimulate the patient.* *-Assess airway.* *-Apply oxygen.* *-Observe respiratory rate & depth, and support respiration as indicated by patient status;* *-Stop opioid.* *-Call MET TEAM; notify GME Trainee and/or Acute Pain Service (APS) if receiving epidural analgesia;* *-Consider administering naloxone if clinically indicated (**RR <8 breaths per min. and***

	not responsive to stimulation). *-Stay with patient; continue to monitor respiratory status and sedation level closely until sedation level is stable and respiratory status is satisfactory.*

Note: Refer to specific guidelines pertaining to the Care of Patients receiving IV PCA, Epidural Analgesia, or IV Lidocaine infusion for *initial* assessment and documentation.

f. The RN will reassess if patient or care partner perceives that the patient is not satisfied with the response to the administered pain intervention.

4. **Interventions**

a. Pharmacologic

i. A placebo treatment is never substituted for analgesics unless being used as part of research and does not include deception, complies with all required consents, and receives approval by the University Investigational Review Board.

ii. When choosing an opioid by either IV push bolus or IV Patient-Controlled Analgesia (PCA) to treat continuous acute pain:

1. **HYDROmorphone should be considered as the first-line opioid analgesic;**

2. MORPHine should be considered second line except in patients with poor renal clearance or allergies;

3. FentANYL is generally reserved for pain during purposeful sedation, treatment of pain associated with procedural pain or in patients who cannot tolerate HYDROmorphone or MORPHine.

iii. Classes of medications used in pain management include:

1. Analgesic Adjuvant Medication Recommendations - Adults >40kg;
2. Non-opioid Analgesia Recommendations - Adults;
3. Opioid Analgesia Recommendations - Adults;

b. **Non-Pharmacologic Measures:** see Complementary Modalities For Pain Management. Use of non-pharmacologic measures shall be considered, optimized, and assessed as clinically indicated and as available.

c. **Multimodal analgesic techniques** are described as the combination of two or more analgesics and/or techniques, working through different mechanisms while providing more effective analgesia and should be:

i. Implemented when appropriate;

ii. Tailored towards the particular type of pain or surgery;

iii. Used to reduce the stress response associated with acute pain and decrease the adverse effects of opioid use as a single therapy.

d. **Special considerations and populations:**

i. Treating pain in the Older Adult

ii. Treating pain in patients with Active Substance Use Disorders (see Appendix B)

5. **Patient Education and Discharge**

a. Based on the patient's condition and assessed needs, the health care team will inform patients and care partners about any pain risks, the importance of effective pain management, measures that will be used to assess their pain, and options that may be used for treating pain.

b. The health care team will also:

i. provide the patient and family with standard discharge instructions and answer questions/concerns;

ii. communicate the current pain management plan to clinician(s) assuming care if patient is being discharged to home care, hospice or other facility.

6. **Education and Communication:** This policy will be communicated to the appropriate University of Virginia Medical Center personnel *via* the following channels:

a. Nursing: the nurse educators will be responsible for any education and training related to this policy;

b. Graduate Medical Education Trainees: education will occur during orientation and ongoing education through the Office of the Associate Dean for Graduate Medical Education and Grand Rounds;

c. All new care providers will be required to complete training related to the policy during clinical orientation;

d. Important aspects of this policy, as well as updates and revisions, will be communicated *via* clinical staff and nursing publications.

(SUBJECT: Pain Assessment and Management – Adult Patients)

SIGNATURE:

Robert S Gibson
Robert S. Gibson, MD, President, Clinical Staff

R. Edward Howell
R. Edward Howell, CEO, UVA Medical Center

DATE: 3/21/14

Medical Center Policy No. 0239 (R)
Approved October 15, 2002
Revised November 2003, March 2007, March 2010, June 2013, March 2014
Approved by Patient Care Committee
Approved by Clinical Staff Executive Committee

(SUBJECT: Pain Assessment and Management – Adult Patients)

Appendix A

Definitions

Acute pain generally refers to a normal response to injury or painful stimulus (nociception) from trauma or surgery, and can be somatic and/or visceral in nature. Acute pain is generally brief and subsides when the stimulus is removed and healing occurs. "A complex constellation of unpleasant sensory, perceptual and emotional experiences associated with autonomic, psychological, emotional, and behavioral responses." [1]

Adjuvant analgesic is a drug such as an anticonvulsant or antidepressant that is prescribed for a primary purpose other than pain relief, but can also be used as an analgesic for certain painful conditions.

Adverse drug reaction (ADR) is any noxious or unintended response to a drug occurring at normal doses used for prophylaxis, diagnosis, or treatment. Therapeutic failure and intentional overdoses are excluded. Reportable ADRs are those that result in:

1. a change or discontinuation of drug therapy;
2. treatment of the ADR;
3. an initial or prolonged hospital stay; or
4. Mortality.

*(From Adverse Drug Reaction Reporting Program, UVAHS)

Assume Pain Present (APP) is utilized when it is reasonable to conclude that the patient is likely to be experiencing pain. APP requires assessment. See Pain Scales 02

Basal infusion is a continuous infusion of a controlled substance delivered through a locked delivery system.

Breakthrough pain is defined as pain that the patient rates on a pain scale as ≥4, despite therapy. In the patient using patient controlled analgesia (PCA), breakthrough is defined as pain described as ≥4 while utilizing 75% of the PCA dose.

Clinician bolus describes an order for one or more additional doses to be administered by the clinician via the CADD SOLIS Pump. This dose is to be charted in the Medication Administration Record separately from total PCA doses. Reasons for clinician bolus to be

[1] Terman GW, Bonica JJ. (2003). Spinal mechanisms and their modulation. In Loeser JD, Butler SH, Chapman CR, Turk DC, eds.*Bonica's Management of Pain*. 3rd ed. Philadelphia, Pennsylvania, USA: Lippincott Williams and Wilkins. P. 73.

ordered may include additional breakthrough pain, procedural pain or interruption of PCA therapy requiring additional opioid analgesia.

Comfort goal is the level at which the patient identifies that the existing pain does not interfere with function or quality of life. The goal can be changed by the patient.

Chronic Pain is the abnormal processing sensory input. Chronic pain can be nociceptive or neuropathic in origin and may exist despite healing and regardless of physical cause. Its duration is generally unpredictable: "Pain that persists a month or more beyond the usual course of acute disease or a reasonable time for an injury to heal or that is associated with a chronic pathologic process that causes continuous pain or the pain recurs at intervals for months or years."

Opiate naive is a term used to describe the patient who does not regularly take opioids.[2]

Opiate tolerant is a term used in the patient who has consistently taken opioids daily for 3 months or longer.

Opioid ultra-tolerant is a setting on the CADD Pump Library indicating opioid tolerance to an extent requiring higher concentrations and doses of opioids (examples of possible candidates include palliative care or patients with refractory pain).

Pain is

1. an unpleasant sensory and emotional experience" arising from "actual or potential tissue damage or described in terms of such damage…. It is unquestionably a sensation in a part or parts of the body but it is also always unpleasant and therefore an emotional experience." [3]

2. Pain is whatever the experiencing person says it is, existing whenever the person says it does.

3. Pain may be categorized in the following ways for assessment and treatment: *Acute* pain, *Chronic* pain.

Pain Screen identifies the presence of pain. If patient reports pain, a valid pain rating scale is used.

Pain Assessment is an ongoing systematic process of identifying pain and its characteristics. An assessment includes the following:

---

[2] Turk, DC, Okifuji, A. (2003). Pain terms and taxonomies. In Loeser, JD.; Butler, SH.; Chapman, CR, Turk DC eds. *Bonica's management of pain* (3 ed.). USA Lippincott Williams & Wilkins. pp. 18–25.

[3]The International Association for the Study of Pain (IASP) Taxonomy. (2011). http://www.iasp-pain.org/Content/NavigationMenu/GeneralResourceLinks/PainDefinitions/default.htm#Pain

1. Self-Report (Intensity) for the communicative patient or a valid observational tool for the non-communicative patient;

2. Location;

3. Frequency/Duration;

4. Descriptors;

5. Quality;

6. Acute vs. Chronic pain;

7. Precipitating & alleviating factors; and

8. Patient satisfaction with comfort level.

Pain Reassessment is the re-evaluation of the effectiveness (including safety and side-effects) of a pain intervention.

For opioid effectiveness/sedation, reassessment includes observation for sedation from opioid over-sedation using POSS (Adult Acute Care) or RASS (Critical Care), and occurs with reassessment following any opioid analgesic intervention.

Physical dependence indicates physical reliance on an opioid characterized by withdrawal symptoms when the opioid is suddenly discontinued or reversed with an antagonist.

Pseudoaddiction is an iatrogenic syndrome of abnormal behavior that develops as a consequence of inadequate pain management.

Substance use disorder *is a* problematic pattern of substance use in which two of the following are present: (DSM-5).

1. The substance is often taken in larger amounts or over a longer period than was intended;

2. There is a persistent desire or unsuccessful efforts to cut down or control substance use;

3. A great deal of time is spent in activities necessary to obtain the substance, use the substance, or recover from its effects;

4. Craving, or a strong desire or urge to use the substance;

5. Recurrent substance use resulting in a failure to fulfill major role obligations at work, school, or home;

6. Continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance;

7. Important social, occupational, or recreational activities are given up or reduced because of the substance;

8. Recurrent substance use in situations in which it is physically hazardous;

9. The substance is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by alcohol;

10. Tolerance, as defined by either of the following:
    a. A need for markedly increased amounts of alcohol or substance to achieve intoxication or desired effect; or

    b. A markedly diminished effect with continued use of the same amount of alcohol or substance.

11. Withdrawal, as manifested by either of the following:
    a. The characteristic withdrawal syndrome for the substance; or
    b. The substance is taken to relieve or avoid withdrawal symptoms.

Symptoms of tolerance and withdrawal occurring during appropriate medical treatment with prescribed medications (e.g., opioid analgesics, sedatives, stimulants) are specifically *not* counted when diagnosing a substance use disorder.

Tolerance is a physiologic adaptation to a medication resulting in a reduced effect following chronic use and requiring increasing dosage to maintain effectiveness over time. Tolerance rarely occurs with analgesic use if dosing is effective and pain levels remain stable.

(SUBJECT: Pain Assessment and Management – Adult Patients)

Appendix B:

Special Considerations and Populations: Substance Use Disorders

Patients with addictive disease and pain have the right to be treated with dignity, respect, and the same quality of pain assessment and management as all other patients.
University of Virginia 2014 Pain Sub-Committee
Providing care for patients with substance use disorders should address the potential for increased drug use or relapse associated with unrelieved pain (ASPMN, 2012).

A. DEFINITIONS:

1. SUBSTANCE USE DISORDERS: DSM-5 2013[1]

A problematic pattern of substance use in which two of the following are present:

- The substance is often taken in larger amounts or over a longer period than was intended.
- There is a persistent desire or unsuccessful efforts to cut down or control substance use.
- A great deal of time is spent in activities necessary to obtain the substance, use the substance, or recover from its effects.
- Craving, or a strong desire or urge to use the substance.
- Recurrent substance use resulting in a failure to fulfill major role obligations at work, school, or home.
- Continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance.
- Important social, occupational, or recreational activities are given up or reduced because of the substance.
- Recurrent substance use in situations in which it is physically hazardous.
- The substance is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by alcohol.
- Has the characteristic withdrawal syndrome for the substance. The substance is taken to relieve or avoid withdrawal symptoms.

(Symptoms of tolerance and withdrawal occurring during appropriate medical treatment with prescribed medications (e.g., opioid analgesics, sedatives, stimulants) are specifically not counted when diagnosing a substance use disorder).

2. ADDICTION/ADDICTIVE DISEASE

Addiction is a primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and

manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.

3. PHYSICAL DEPENDENCY

An expected consequence of the long-term use of opioids and a variety of other medications such as clonidine, prednisone and tricyclicantidepressants. It reflects a state of physical adaptation manifested by withdrawal symptoms produced by abrupt cessation, rapid dose reduction, or decreasing blood levels of the medication and/or the administration of an antagonist. Physical dependency does not indicate addiction or directly relate to the development of abuse or addiction.

4. TOLERANCE

Tolerance, is defined by either:
A need for markedly increased amounts of alcohol or substance to achieve intoxication or desired effect; or

Has a markedly diminished effect with continued use of the same amount of alcohol or substance.

Tolerance is a state of adaptation in which exposure to a medication induces changes that result in a decrease in one or more of the drug's effects over time. Tolerance to the analgesic effects of opioids is variable in occurrence but is never absolute; therefore there is no established upper opioid dosage limit. Tolerance may occur to some side effects, most commonly, nausea, sedation and respiratory depression.

5. PSEUDO-ADDICTION

An iatrogenic syndrome created by the under treatment of pain, characterized by behaviors such as anger and escalating demands for more or different medications, distinguished from true addiction in that behaviors resolve when pain is effectively treated.

B. GENERAL PRINCIPLES:

1. In the setting of acute pain caused by injury or disease, pain medications should not be withheld from patients with suspected or actual addictive disease. In the setting:

   a. Talk with the patient and reassure the patient that his/her pain will be managed and withdrawal symptoms minimized.

   b. The same principles that guide pain management in the general patient population should be used for patients with addictive disease.

   c. Assess for and treat symptoms of withdrawal from alcohol and other drugs. Patient may be able to identify signs of withdrawal and be asked to notify the staff should they occur.

d. Be prepared to titrate opioid analgesics and benzodiazepines to doses higher than usual. The patient may have developed tolerance to some medications, or drug use may have caused increased sensitivity to pain.

2. When patients are using opioid medications:

a. The most appropriate route should be used (oral or PCA.)

b. Avoid the use of PRN dosing of opioids in patients who are addicted as this may simulate the process of getting "high" and may create a secondary gain in their pain management. PCA gives the patient more control and may reduce potentially confrontational interactions with staff. Monitor and adjust PCA pump parameters because active addicts may require and safely receive larger doses than opioid naive patients.

c. Avoid titrating methadone for the management of acute pain given its long half-life and the multi-week withdrawal period necessary to taper the patient off the medication. Consider consulting Chronic Pain Services.

f. Converting to a buprenorphine taper once the patient's acute pain has been resolved.

3. Benzodiazepine, phenothiazine or other sedating medication that do not relieve pain should not be used as substitutes for analgesics.

4. If the patient is physically dependent on opioids, or requires opioids for pain control, do not treat pain with agonist/ antagonist opioids such as nalbuphine, butorphanol, buprenorphine, or pentazocine, because it will precipitate withdrawal.

5. For patients recovering from addiction, respect their right to decide whether or not to take opioid analgesics,

6. When opioids are no longer needed for analgesia, taper them very slowly to minimize the emergence of withdrawal symptoms.

7. Consider nonpharmacologic methods

C. PATIENTS ON METHADONE MAINTENANCE TREATMENT (MMT)

1. Patients on MMT should receive analgesics in addition to their regular methadone dosage for managing pain

2. The following guiding principles are recommended for prescribing medications to MMT patients:

a. Morphine or other opioids may be administered to control pain. The dosage may have to be slowly increased because of tolerance induced by methadone.

b. A fixed schedule of administration is preferable to a variable schedule.

c. Avoid medications with antagonistic properties, such as naltrexone and agonist/antagonist opioids such as pentazocine and buprenorphine.

d. Monitor for QTC Electrocardiogram changes.

3. Numerous medications interact with Methadone, including but not limited to, HIV medications and anticonvulsants.

   Consult with the Pharmacy for drug interactions and pharmacological management along with The Chronic Pain Services.

   Contact and consult with the previous prescriber or addiction treatment for Methadone Maintenance prior to adjusting doses and prior to discharge. Confirm a follow-up appointment prior to discharge

---

1. American Psychiatric Association. (2013). *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.). Arlington, VA, American Psychiatric Publishing.