Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Alleged Pain Management Deficiencies
VA Maryland Health Care System
Baltimore, Maryland

Report No. 11-00904-216 **July 8, 2011**

VA Office of Inspector General
Washington, DC 20420

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Contents

Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted a review to determine the validity of two allegations regarding hospice care at the Baltimore VA Rehabilitation and Extended Care Center (BRECC), which is part of the VA Maryland Health Care System (the system). The objectives of the review were to determine whether the care provided to four hospice patients adequately addressed end-of-life pain and whether the lack of "piped in" oxygen, suction, and air compromised hospice patients' safety and comfort.

Our review found that two patients did not have adequate pain management as defined by Veterans Health Administration (VHA) policy and hospice industry standards. We identified five factors that contributed to pain management deficiencies: (1) BRECC staff did not develop individualized and comprehensive pain management care plans, (2) patient pain reassessments were not appropriately documented, (3) clinical staff did not have sufficient training on the principles of pain management for hospice patients, (4) hospice interdisciplinary teams were not effectively used, and (5) clinical pharmacists were not actively involved in the pain management process.

We did not substantiate the allegation that the lack of "piped in" oxygen, suction, and air compromised hospice patient safety and comfort. We found that the BRECC provided appropriate oxygen, suction, and air.

To improve pain management for hospice patients, we recommended that the System Director: (1) implement procedures to ensure that BRECC staff comply with VHA and system policies regarding development and documentation of comprehensive and individualized care plans, documentation of nursing pain assessments, and hospice and pain management training; (2) review the effectiveness and oversight of the Nursing Inpatient Pain Subcommittee; (3) review and modify the interdisciplinary team structure and process to provide more effective team discussions and patient/family participation; and (4) ensure that sufficient qualified clinical pharmacists are assigned for participation in hospice and pain management consultation.

The Veterans Integrated Service Network and System Directors concurred with the findings and recommendations and provided acceptable action plans. We will follow up on the planned actions until they are completed.

DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington, DC 20420

TO: Director, VA Maryland Health Care System (10N5)

SUBJECT: Healthcare Inspection—Alleged Pain Management Deficiencies, VA Maryland Health Care System, Baltimore, Maryland

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to assess the merit of allegations made by a complainant concerning quality of care for hospice patients at the Baltimore VA Rehabilitation and Extended Care Center (BRECC), which is part of the VA Maryland Health Care System (the system), Baltimore, MD.

Background

VA Maryland Health Care System

The system is part of Veterans Integrated Service Network (VISN) 5 and comprises the Baltimore VA Medical Center, the Perry Point VA Medical Center, the BRECC, and nine community based outpatient clinics.

The 120-bed BRECC, also known as the Loch Raven VA Community Living and Rehabilitation Center, provides rehabilitation and post acute care for veterans. The BRECC also provides inpatient hospice and nursing home care. Hospice patients receive services from both hospice care staff and long-term care staff on the units. There are 10–12 hospice beds, which are presently located in different areas on one floor and vary in number based on need. Construction has started at the BRECC on a hospice unit that will be separate from the long-term care units.

The system has two teams that are involved in end-of-life care—a Palliative Care Consult Team (PCCT) comprised of a physician, social worker, chaplain, registered nurse, and other ancillary members, such as a pharmacist,[1] and the BRECC interdisciplinary team

[1] System Policy Memorandum 512-102/GLTC-023, *Palliative Care Consult Team,* June 2008.

that generally includes the same member disciplines as the PCCT.[2] The PCCT acts in a consulting capacity for the system's palliative care patients, advising on treatment plans and care planning. The BRECC interdisciplinary team has primary patient care responsibility and meets with hospice patients and their families to discuss and develop comprehensive and individualized hospice plans of care.[3]

Palliative care providers in the system include the Hospice/Palliative Care Medical Director, one hospice/palliative care physician (HCP), and a physician assistant (PA). All three providers are responsible for hospice and palliative care assessments and direct provider services in all system facilities.[4] However, the HCP and PA deliver the majority of provider care at the BRECC.

Allegations

On December 13, 2010, OIG's Hotline Division received allegations concerning the BRECC. Specifically, a complainant alleged that hospice patients were not receiving adequate pain management, resulting in "needless suffering" before their deaths. The complainant also reported that system managers moved hospice patients to a unit that did not have "piped in oxygen, suction, or air." The complainant expressed concern that this move was detrimental to patient safety and comfort.

Overview of Palliative and Hospice Care

Palliative care and end-of-life care provide comfort and support to patients with life-threatening diseases or conditions. The goal of care is to prevent or treat as early as possible the condition-related symptoms or treatment side effects.[5] The focus is to help patients by providing physical, emotional, and spiritual comfort. This assistance is not restricted to a patient's terminal phase of illness.

Hospice is specialized palliative care for patients who have life expectancies of months rather than years and no longer seek curative or aggressive treatment for their terminal illnesses. The goal is to provide a dignified pain-free death using a multidisciplinary team approach. Pain and symptom management and spiritual and emotional care are individually "tailored to the patient's needs and wishes."[6] Family and loved ones are included in the care plan process, and bereavement services are offered after the patient's death.

[2] System Policy Memorandum 512-11/COS-013, *End-Of-Life/Palliative Care Policy,* September 2010.
[3] System Operating Procedure No. 102/GLTC 010, *Developing a GLTC Interdisciplinary Team Therapy Treatment Plan,* October 2005.
[4] System Policy Memorandum 512-102/GLTC-023, *Palliative Care Consult Team,* June 2008.
[5] National Cancer Institute, "Comfort Care," http://www.cancer.gov/dictionary?CdrID=269449, accessed on February 15, 2011.
[6] National Hospice and Palliative Care Organization, "Hospice," http://caringinfo.org/i4a/pages/index.cfm?pageid=3356, accessed on February 15, 2011.

VA Policy and Industry Standards

VA Policy. The Veterans' Health Care Eligibility Reform Act of 1996 made end-of-life care available to all veterans and promoted palliative and hospice care standards.[7] The Veterans Health Administration (VHA) provides hospice care at VHA facilities and through contracted community hospice programs. If a hospice patient is in a VHA community living center, VHA policy requires that a competent interdisciplinary team plan and direct services that are comfort oriented and supportive of the patient and family wishes.[8] Comprehensive, individualized care plans for management of pain and other symptoms are expected to be documented in the patient's medical record.

VHA policy also requires that each facility establish a PCCT to serve as expert consultants for hospice and palliative care patients.[9] The PCCT is comprised of medical professionals who have the credentials and skills to address the physical, psychosocial, emotional, and spiritual needs of palliative care patients and their families.[10] A facility may use the PCCT as its interdisciplinary management team rather than have two teams.

Industry Standards. The Centers for Medicare and Medicaid Services (CMS) originally set the regulatory standards for hospice care and services certification in the 1980s. It has continued since that time to define regulations for hospice programs throughout the country.[11] More recently, The Joint Commission (TJC) developed an accreditation program for hospices using the same principles as CMS certification. Both CMS and TJC require care that optimizes patient comfort and dignity and is consistent with patient needs and goals. Required services specified by both CMS and TJC include the availability of a 24-hour, 7 days per week pharmacy and hospice trained provider; a compounding pharmacy; hospice-trained staff; symptom management measures, such as pain control and oxygen; interdisciplinary team meetings every 2 weeks to discuss all patients on hospice services; and leadership that is specifically designated to manage and oversee the hospice program.[12] Although CMS and TJC provide the foundation for industry standards in hospice and palliative care, VHA end-of-life/palliative care programs are not required to be accredited by TJC or meet these standards.

[7] Title 38, Code of Federal Regulations, Section 17.38, "Medical benefits package."
[8] VHA Handbook 1142.01, *Criteria and Standards for VA Community Living Centers (CLC),* August 13, 2008.
[9] VHA Handbook 1142.01.
[10] VHA Directive 2008-066, *Palliative Care Consult Teams (PCCT),* October 23, 2008.
[11] 42 CFR 418, "Hospice Care."
[12] Joint Commission Perspectives®, *Accepted: Home Care Requirement Changes for Hospice Program,* 28: Issue 12 (December 2008):9.

Overview of Pain Management

The definition of pain is an "unpleasant sensory and emotional experience associated with actual or potential tissue damage,"[13] or more simply, "pain is whatever the experiencing person says it is."[14] Many hospice patients experience pain during the terminal phase of their disease which affects their quality of life.

- *Acute Pain* arises quickly and can be severe but last a relatively short time. It is generally due to an injury or tissue damage that will heal. The goal is to attain a quality of life that returns the patient to physical and psychosocial functioning.
- *Chronic Pain* progresses or persists over a long period and is often resistant to medical treatment. The goal is to improve symptom relief and quality of life, and restore independence with activities of daily living (ADLs).[15]
- *Hospice Pain* is associated with terminal stage cancer or other terminal stage diseases, such as AIDS, and is often persistent pain that can escalate quickly and dramatically. Treatment reflects a hospice care quality of life goal aimed at a pain free death rather than return to a previous functional status. Medications are used to prevent breakthrough pain, thereby ensuring that the patient remains comfortable.[16]

Pain management encompasses the process, procedures, and standards whereby pain is controlled and the patient experiences comfort. It is recognized as a patient right and is included in the Patient Bill of Rights in all medical facilities.[17]

VHA pain management standards address four key elements: (1) pain assessment, (2) pain treatment, (3) evaluation of pain management, and (4) clinical competence in pain management.[18]

Pain Assessment. Pain is recognized by VHA as the "5th vital sign," and pain indicators are expected to be assessed on admission and then routinely for all patients, whether they are able to communicate or not. Assessments use a range of methods, such as staff observation and patient and/or family input. Indicators include recent pain history, character, location, severity, duration, alleviating and exacerbating factors, and effectiveness of current pain treatment on the patient's quality of life. Patient response to pain medication is a key measure of treatment effectiveness and is part of routine

[13] American Pain Society, *Pain: Current Understanding of Assessment, Management and Treatment*, 2005, http://ampainsoc.org/ce/enduring/downloads/npc/npc.pdf, accessed on March 28, 2011.
[14] Caroline Bunker Rosdahl and Mary T. Kowalski, *Textbook of Basic Nursing*, (Philadelphia: Lippincott Williams and Wilkins, 2007), 704.
[15] ADLs are the basic tasks of life necessary for daily self care, including dressing, toileting, and feeding oneself.
[16] American Pain Society, *Pain: Current Understanding of Assessment, Management and Treatment*, 2005, http://ampainsoc.org/ce/enduring/downloads/npc/npc.pdf, accessed on March 28, 2011.
[17] Joint Commission, RI.01.01.01: The organization respects resident rights.
[18] VHA Directive 2009-053, *Pain Management*, October 28, 2009.

reassessments. Patients are asked to rate their pain on a scale using the numbers 0–10, with 0 signifying no pain and 10 indicating severe pain. If pain occurs before the next pain medication dose is due and is moderate or severe, pain medication is considered to be ineffective. Medication administration routes are also an important part of assessments and may change when a patient's condition deteriorates. Typical routes are by mouth (tablets or liquid), sublingual (liquids or tablets placed under the tongue), intramuscular (injection into the muscle), intravenous (injection into a vein), rectal, subcutaneous (injection under the skin), and topical.

Pain Treatment. Optimal pain management uses evidenced-based medical protocols and individualized and comprehensive treatment plans developed from patient assessments. As a patient's condition and pain deteriorates, providers anticipate changes and modify the treatment plan to reflect those changes. VHA recognizes the World Health Organization (WHO) Pain Management Ladder as an evidenced-based protocol when determining the type of medication needed for pain control. Originally developed to assist with treatment of cancer pain, the WHO ladder is now widely accepted as a pain treatment algorithm for other types of pain, especially at end of life. Once the severity of pain is determined, the treatment plan can reflect what type of medication from the WHO protocol is appropriate. A patient who has mild pain can use non-narcotic medications, but when pain is moderate to severe, treatment protocols call for more potent analgesics.

Treatment for moderate to severe pain focuses on providing narcotics that can relieve pain without recurrence. To accomplish this goal, providers use a two-pronged approach—baseline long acting narcotics and breakthrough short acting narcotics. Long acting narcotics are used to keep pain consistently controlled throughout the day and are routinely given around-the-clock. Providers use short acting narcotics if pain breaks through before the next dose of a long acting narcotic is due or if pain is expected to be of short duration, such as acute post-operative pain.

Evaluation of Pain Management. Facilities are expected to establish a multi-disciplinary committee to evaluate the quality of pain management. VHA requires facilities to monitor the quality of pain assessments and the effectiveness of pain management interventions.

Clinical Competence in Pain Management. VHA requires training that is relevant to the delineated responsibilities of clinicians providing pain management. Orientation and ongoing education must relate to the principles of pain assessment and management and reflect the specific needs of the patient population.

Hospice Pain Management

Hospice patients with moderate to severe pain are usually treated with long acting narcotics. Management can be difficult as end-of-life pain escalates. Best practice standards include increasing both the long acting and as needed breakthrough narcotics

when pain intensifies, with more frequent assessments to test effectiveness. Providers must decide if the patient requires an as needed breakthrough narcotic dose before the next dose of long acting medication is due, an occurrence known as end of dose failure. End of dose failures indicate that the long acting narcotic is ineffective and that the dosage should be increased or the interval between doses reduced.[19] Another standard for ineffectiveness is the use of more than three as needed breakthrough medications in 24 hours.[20]

Scope and Methodology

We visited the system on February 22, 2011, and interviewed the Hospice Medical Director, Hospice Nursing Manager, Extended Care Nursing Manager, Clinical Pharmacist, and several staff members who work with hospice patients. We reviewed four patient cases using records from the past 12 months. We also reviewed hospice and pain management standards and policies.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of Inspectors General on Integrity and Efficiency.

Case Summaries

Patient 1. The patient was a man in his fifties with metastatic melanoma, diabetes, coronary artery disease, congestive heart failure, and osteoarthritis. He was transferred from the VA hospital to a BRECC hospice bed in mid-February 2010.

The nursing admission assessment noted that the patient was oriented, at high risk for falls, and needed assistance with ADLs. The attending physician's admission note described "constant pressure in left axilla radiating to his left arm and neck, 10/10."[21] The patient's stated goals were to be pain free and have other symptoms, specifically hiccups, itching, and dyspnea,[22] managed by the hospice team.

While in the hospital, the patient received a long acting narcotic (sustained release oxycodone) twice daily along with an intravenous short acting narcotic (hydromorphone) given as needed. On admission to the BRECC, the PA and attending physician changed the patient's pain medication regimen to a different long acting narcotic (methadone) twice daily and a breakthrough narcotic (oxycodone) for use every hour as needed if the long acting medication was not sufficient. At that time, the patient had no difficulty swallowing, and the new medications were given as tablets. The PA added another as

[19] WHO Pain & Palliative Care Communication Program, *Breakthrough versus Baseline Pain in Cancer: An Interview with Dr. Sebastiano Mercadante,* http://whocancerpain.wisc.edu/index?q=node/104#inter, accessed on May 23,2011.
[20] System Policy Memorandum 512-127/NEU-004, *Pain Management,* October 2008.
[21] The term "axilla" refers to the armpit or underarm, and "10/10" means that on a pain scale of 0 to 10, with 10 being the worst, the patient rated his pain at 10.
[22] Dyspnea refers to breathlessness, shortness of breath, or difficulty breathing.

needed medication (haloperidol) to control hiccups. Nursing staff received orders to contact the physician if the patient required more than three doses of as needed breakthrough narcotics during a 24-hour period to control pain.

The patient had few complaints during his first 2 days at the BRECC. However, from hospital day(HD) 3 through HD 7 (5 days) the patient received 14 as needed narcotic doses for breakthrough pain, 8 of which were for end of dose failure. The breakthrough pain was reportedly severe, and assessments were made after as needed narcotics administration showed that the patient's pain continued to be moderate to severe. On HD 6, the patient complained of increasing pain. The HCP saw the patient on HD 6 and 7 and decided to wait to increase the pain medication. On HD 8, the long acting narcotic was increased.

For the next 5 days, HD 8–12) the patient required 15 as needed narcotics for breakthrough pain, 9 of which were for end of dose failure. Although the breakthrough narcotics provided some relief, the patient continued to report moderate to severe pain up to 6 times per day. Nursing staff documented that he was increasingly restless and confused. On HD 13, the day before his death, the patient again complained that the pain was increasing and medication was not providing relief. The PA evaluated the patient and determined that dyspnea was causing the patient's restlessness and discomfort. Although the PA changed the patient's medications to liquids for sublingual medication delivery, no other medication changes occurred. On that day, the patient received five as needed narcotics for breakthrough pain with two of those doses given for end of dose failure.

On HD 14, the patient complained of dyspnea. The PA evaluated the patient and noted that his "breathing looked comfortable" but that the nurse should give a muscle relaxant for a jerking movement that had developed. The nurse reported later that day that the medication gave the patient minimal relief. The patient received four as needed narcotic doses during the day for pain and dyspnea with only partial relief. The patient was calling out "help me" and trying to climb out of bed before he died that evening. There were no interdisciplinary team meetings documented in the patient's chart.

Patient 2. The patient was a man in his eighties with laryngeal cancer, pulmonary masses, hypertension, diabetes, and hepatitis C. The patient was transferred to the BRECC in mid-May, 2010, after being hospitalized and receiving treatment for hypercalcemia.[23]

At the time of transfer, the patient was extremely weak and frail and was incontinent of urine and feces, required total assistance for ADLs, had some difficulty swallowing, and was noted to have refused to take medications in the past. Medications for pain were a

[23] Hypercalcemia is an excessive amount of calcium in the blood, which may cause symptoms such as muscle weakness, nausea, and constipation.

routine short acting narcotic (oxycodone) and an as needed dose of the same short acting narcotic every hour if the patient had breakthrough pain or dyspnea. The patient also had medications for agitation, nausea, anxiety, and excess secretions to be given as needed. Admission orders included instructions for nursing staff to contact the physician if more than three as needed doses of breakthrough pain medication were required in any 24-hour period.

Until HD 5, the patient had good results from the pain regimen. During HD 6–7 , the patient became more restless, tried to take his clothes off, and refused nursing care. The HCP changed the patient's medication regimen to a long acting narcotic (methadone) to be given every 12 hours and increased the medication used for agitation. On HD 8, the patient complained of severe chest pain and required four as needed breakthrough narcotic doses, with two of those doses within 3 hours of the next long acting narcotic dose.

On HD 9, the PA increased the patient's long acting narcotic dose. From HD 10–15 , the patient received 19 as needed breakthrough narcotics; 8 of those doses were for end of dose failure. During this time, nursing staff noted that the patient continued to be uncooperative and restless and was moaning. When the patient was able to communicate, he reported moderate to severe pain. After he received as needed narcotics, his pain decreased to mild but would eventually escalate back to moderate to severe. Nursing staff noted that over the previous few days the patient had nothing to eat or drink and had increased dyspnea. On HD 16, staff felt that the patient was comfortable on his present pain medication regimen; however, later that day, the patient's pain medications and haloperidol dosages were increased to better control pain and restlessness.

During HD 17–28 , the patient received 38 as needed breakthrough narcotic doses. These doses were increased over time from one dose per day to seven doses on HD 29. During this time, 16 of the 38 as needed breakthrough narcotics were for end of dose failure. The PA evaluated the patient on HD HD 28 and, though aware of how many as needed narcotics the patient was receiving, documented that the patient appeared comfortable. On HD 29, the patient received 10 as needed breakthrough narcotics, and the Hospice Medical Director doubled all the patient's pain medications. Until his death 2 days later, the patient received two to three as needed breakthrough narcotics every day and reported moderate to severe pain. Nursing staff reported that he was not as restless. We found an interdisciplinary team meeting documented in the patient's record for late May.

Patient 3. The patient was a man in his sixties with metastatic lung cancer, schizophrenia, hypertension, diabetes, and anemia. The patient was transferred from the VA hospital to the BRECC for hospice care in late October, 2010.

The nursing admission assessment found that the patient had dyspnea and extreme weakness, required continuous oxygen and total assistance with ADLs, and was at high

risk for falls. The patient reported moderate pain, which was acceptable to him. He expressed the wish to have less dyspnea and be able to get out of bed.

When assessed by the HCP, the patient reported hallucinations at night. The HCP decided to "continue the patient's psychiatric medications as long as possible." In the hospital the patient had been receiving intravenous narcotics (morphine) on a continuous basis, with extra doses as needed for breakthrough discomfort. He was also receiving intravenous medication (lorazepam) for anxiety and dyspnea. At the BRECC, the HCP discontinued intravenous medications and started oral medications, including a long acting narcotic (methadone) at bedtime, a shorter acting narcotic (oxycodone) every 6 hours, and a breakthrough narcotic (oxycodone) every hour as needed. Within a few hours of that change, all the patient's pain medications were increased, as the patient became severely tachypneic[24] and uncomfortable. Other admission orders included a change to liquid medication if needed and for nursing staff to contact a physician if the patient received more than three doses of as needed breakthrough pain medications within a 24-hour period.

The patient received his regular medication for the first 3 days at the BRECC with occasional as needed breakthrough narcotics. On HD 3, the nurse discovered the patient face down on the floor with a nosebleed and several lacerations. Evaluation at a local hospital emergency room found that the patient had fractured bones in the nose and multiple lacerations requiring sutures. The patient returned to the BRECC later that day and received an as needed breakthrough narcotic that reduced his pain. There were no changes to his pain medications. The HCP evaluated the patient the next day and ordered all his medications changed to liquid, all psychiatric medications discontinued, and his long acting narcotic, as needed breakthrough narcotic, and medication for restlessness increased.

On HD 5, the patient received five as needed breakthrough narcotics, and he reported to the HCP that he was "miserable" but could not express why. At 8 a.m. on HD 6, the nurse found the patient on the floor beside his bed. He died approximately 20 minutes later. No interdisciplinary team notes were in the patient's record.

Patient 4. The patient was a man in his sixties who had prostate cancer. He had been admitted to the VA hospital with urosepsis[25] and respiratory failure and then transferred to the BRECC for hospice care in late December, 2010.

The nursing admission assessment found the patient unable to verbalize pain; he would occasionally moan or groan. He had dyspnea and required total assistance with ADLs. The HCP assessed the patient as unresponsive with periods of irregular and shallow breathing. In the VA hospital, the patient had received continuous intravenous morphine

[24] A patient who is tachypneic experiences abnormal rapid breathing.
[25] Urosepsis is a severe infection of the urinary tract and bloodstream often associated with low blood pressure and failure of multiple organs.

for pain management. Upon admission to the BRECC, the HCP changed the patient's pain regimen to a sublingual routine breakthrough narcotic (oxycodone), which was given every 4 hours with the same narcotic as an as needed dose every hour sublingually. Other admission orders included changing all the as needed medications from intravenous to sublingual liquids and for nursing staff to assess the patient's pain every shift and contact the physician if the patient received more than three as needed breakthrough doses of pain medication within 24 hours. When medications were changed from intravenous to sublingual, the HCP ordered an injection of morphine to prevent the patient from experiencing any pain during the transition.

At 7:00 p.m. that same day nursing staff noted that the patient had mottled feet and was gasping but had no apparent signs of pain. A nurse gave the patient an as needed breakthrough narcotic which helped alleviate gasping. The patient died approximately 4 hours later. No interdisciplinary team meeting notes were in the patient's record.

Inspection Results

Issue 1: Pain Management

For Patient 1 and Patient 2, we substantiated the allegation of inadequate pain management. Both patients experienced moderate to severe pain during their stays at the BRECC. Their care did not meet the hospice pain management standard to attain as much pain control as possible without breakthrough pain. These patients had significant end of dose failures that providers did not address and also had moderate to severe pain breaking through long acting narcotic regimens.

- **Patient 1.** During his 14-day stay at the BRECC hospice, the patient had 10 days of breakthrough pain and end of dose failure without pain medication changes. On HD 3, the PA identified that the patient's pain control was not optimal but deferred medication changes because methadone can take up to 5 days to become effective. As a result, the patient had pain which required end of dose failure and breakthrough pain medication for 5 days before medications were increased by the HCP on HD 8. From HD 9–13, the patient continued to receive from two to six as needed breakthrough pain medication per day. Subsequent patient assessments indicated that the patient had dyspnea but no pain, and no medication changes were made. On HD 13, the patient did complain of increased pain, but pain medications remained unchanged.
- **Patient 2.** The patient received hospice services at the BRECC for 31 days and experienced breakthrough and end of dose failure pain without medication changes on 18 of those days. The patient was confused and uncooperative but was sometimes able to verbalize that he was having pain. The PA or a PA student evaluated the patient 3–4 times per week on weekdays only. Documentation by the HCP was limited to acknowledgment of PA notes. The PA discussed changing the patient to a subcutaneous medication route because of agitation and

> restlessness but did not consider topical applications, and the PA felt the patient would pull out any needles required for the subcutaneous route. From HD 10–15, the patient experienced moderate to severe pain with end of dose failure. The PA doubled the long acting narcotic on HD 16. The patient and staff continued to report moderate to severe pain from HD 17–29, requiring as needed breakthrough narcotics. The Hospice Medical Director doubled the long acting narcotic on HD 29 after documentation of 12 days of moderate to severe breakthrough pain.

We are unable to confirm or refute the allegation that Patient 3 received inadequate pain management. We found that nursing notes for this patient often did not include an assessment of pain and that even when the patient received as needed breakthrough narcotics, the reason for the medications was not stated.

We did not substantiate the allegation that Patient 4 received inadequate pain management resulting in needless suffering before death. This patient died within 24 hours of admission and experienced pain and other symptoms, but we found no lapses in pain management.

Contributing Factors. Based on our reviews of the patient records, VHA policies, and industry standards and interviews with BRECC officials and staff, we identified five factors that contributed to the weaknesses in the BRECC's pain management program. The factors include: (1) BRECC staff did not develop individualized and comprehensive pain management care plans, (2) patient pain reassessments were not completed and documented according to VHA and local policy standards, (3) clinical staff involved in pain management did not have sufficient training on the principles of pain assessment and management for hospice patients, (4) hospice interdisciplinary teams were not effectively used, and (5) clinical pharmacists were not actively involved in the hospice pain management process.

Individualized and Comprehensive Pain Management Care Plans Not Developed. VHA policy requires that an interdisciplinary team develop and document in the patient medical record individualized care plans that address comprehensive treatments for pain management.[26] Furthermore, the hospice pain management standard for quality of life is to maintain patient comfort with as few breakthrough pain episodes as possible. To achieve patient comfort, providers must review all aspects of the patient's care to include patient, family, and staff input to determine what pain medications may be appropriate given the patient's unique circumstances.

At the BRECC, instead of developing individualized pain management care plans for each hospice patient and following VHA's new pain management directive, it appears that providers used a standardized approach to pain management by changing the majority of hospice patients from their admitting baseline narcotics to methadone. On

[26] VHA Directive 2009-053.

admission, nursing and providers interviewed patients about their pain and pain level, but we found no other indications in the records that clinical staff sought patient or family input concerning pain management. Our review of the four patient charts found that for three patients, providers changed their admitting narcotic medications to methadone. Although methadone is a useful hospice pain medication, it is not easily changed or increased.[27] Because of this difficulty, patients who use methadone and experience intense pain that is escalating quickly have a greater risk of breakthrough pain. There were no indications in the patients' records of whether the providers used the VHA quality of life measurement to determine if methadone would be the most effective intervention for these particular patients.[28]

In our interviews with clinical staff, they could not clearly explain why providers changed the majority of hospice patients to methadone other than it was available in a tablet and liquid form, which many other medications are as well, and there was some evidence that methadone is useful with neuropathic pain.[29] The standardized approach used by the BRECC and the lack of patient and family participation in care planning and ongoing care does not reflect VHA requirements or hospice pain management standards.

Patient Pain Reassessments Not Completed and Appropriately Documented. VHA pain management standards require pain assessments as a vital and fundamental piece of patient care plans. Accurate and timely documented reassessments are necessary to modify patient care plans appropriately. The system policy for documenting pain requires nursing staff to screen and document a patient pain assessment on admission and reassessments as part of the vital signs every shift for 3 days after admission, after a fall, every 30 days, and when a patient's condition changes.[30] Documentation for each assessment and reassessment should include the location, intensity, quality, relieving and trigger factors, and effectiveness of pain relief measures. Nursing staff should complete reassessments with new reports of pain and at appropriate intervals including before and after initiating pain relief measures and before, during, and after procedures known to cause pain.[31]

We found that documented nursing reassessments rarely included complete reassessment information. Often we found late entries, no note at all, or, if a patient received breakthrough narcotics for two symptoms, a one-word descriptor such as moaning, but no pain scale indicator. Whether for reported new pain or pain medication effectiveness, reassessments rarely incorporated other pain indicators, such as exacerbating factors. In

[27] VHA Pain Management, National Pain Management Strategies Coordinating Committee, Pharmacy Workgroup, *Methadone Dosing and Safety Information Paper,* http://www.va.gov/PAINMANAGEMENT/index.asp, accessed on February 15, 2011.
[28] VHA Directive 2009-053.
[29] Neuropathic pain is a type of pain that is caused by direct stimulation of nerve endings and is characterized by burning or tingling sensations (as opposed to pain felt by pressure on normal tissue such as visceral tumor growth).
[30] System Standard Operating Procedure 118-009, *Nursing Assessment/Reassessment of Pain in Geriatric Long Term Care Community Living Center,* March 2009.
[31] System Policy Memorandum 512-127/NEU-004.

addition, there were only a few notes documenting the nurses' contacts with providers to report escalating pain. During our interviews, nursing staff stated that because they generally spoke with providers during the weekdays, they did not document contacts. Providers and nursing staff seldom documented any contact with each other during nights and weekends.

We also found deficiencies in oversight of assessment and reassessment documentation. System policy requires that the Nursing Inpatient Pain Subcommittee meet regularly and review aggregated data and pain assessment monitors, including staff documentation. The committee uses this data to identify and correct issues and problems.[32] In reviewing the committee minutes, we found that data collected over the past 12 months for documentation of pain effectiveness for breakthrough as needed medications had been at only 70–80 percent compliance, well below the benchmark of 90 percent. Other pain monitors, such as reassessment documentation, were also inconsistent and at times below the 90 percent benchmark. Unfortunately, the committee collected these monitors for the entire system and not just the BRECC, but the aggregate data still demonstrated a system-wide issue with pain assessment documentation. Although the committee developed the plan of correction for the past 12 months to address issues below the benchmark, very little has changed in that plan to increase compliance.

Staff Training Not Sufficient. VHA requires that all clinical staff receive orientation and ongoing education related to the principles of pain assessment and management as it relates to the specific patient population.[33] This education includes the VHA standard that recognizes quality of life as a primary element to determine the effectiveness of pain treatment.[34] VHA also has a requirement that the hospice interdisciplinary team should have the knowledge and competency to plan and provide direct care to patients who receive hospice end-of-life care.[35]

Our interviews and medical record reviews found a general lack of understanding by many clinical staff members concerning pain management, especially the use of methadone and the application of an end of dose failure measurement. We also identified some confusion on the part of staff as to how to develop care plans that include quality of life goals for hospice patients who have pain management issues. These deficiencies may be due, in part, to the fact that hospice care represents only a small part of BRECC services. The primary focus of the BRECC is on *non-hospice* care, including long-term care, rehabilitation, and post-acute care, which involve different skill sets, competencies, and approaches to pain management. However, pain management is a mandate for all VHA facilities as well as education that enhances the competency of those providing pain management.

[32] System Policy Memorandum 512-127/NEU-004.
[33] VHA Directive 2009-053.
[34] VHA Directive 2009-053.
[35] VHA Handbook 1142.01.

Hospice Interdisciplinary Teams Not Effectively Used. VHA policy requires that a competent interdisciplinary team plan and direct services that are comfort oriented and supportive of patient and family wishes. Hospice programs use an interdisciplinary team approach to ensure the discussion of all patient needs and development of individualized care plans.[36] The basis of this approach is that different team members may be aware of separate factors and issues that impact a patient's treatment and quality of life. Equitable dialogue within a team meeting can add valuable information concerning a patient's care and feelings of well being.

Our review of patient records and local policies and interviews with staff found that only one of the four patient records had interdisciplinary team documentation and that the team does not discuss all hospice patients at weekly team meetings. As a result, a patient and/or family member may never participate in an interdisciplinary team discussion about the patient's hospice care, and team members may never have a chance to talk about specific patient's issues within the team meeting setting. The lack of patient and family participation and staff discussion during team meetings does not support VHA policy, local policy, or industry standards for an interdisciplinary approach to the development of an individualized hospice patient care plan.[37]

Clinical Pharmacists Not Actively Involved. VHA and industry standards recognize pharmacists as key participants on hospice interdisciplinary teams and as medication management consultants for providers. The active participation of a pharmacist in team meetings and as a consultant allows for an expanded discussion of appropriate medications that includes updated information about current and new medications and the potential risks and side effects that may occur. Although not required by VHA's end-of-life/palliative care policy, hospice industry standards require a pharmacist to be available for consulting for hospice patients 24 hours per day, 7 days per week, and, if there is a need for new medications or changes, the pharmacist must fill the order and provide the medication as soon as possible.[38] The pharmacists, like other staff who provide hospice care, should have the knowledge and competency to carry out their duties.

We found that the assigned BRECC hospice pharmacist works for the program 16 hours per week. Although the pharmacist does attend weekly patient interdisciplinary team meetings, our interviews and reviews of the charts and interdisciplinary team meeting notes found that she was not actively involved in consulting with the providers to determine appropriate pain management regimens for the hospice patients. Furthermore, when the pharmacist is not in the facility, the BRECC must contact an off-site pharmacy with any concerns. The off-site pharmacy is not required to operate "24/7" but may have

[36] VHA Directive 2009-053.
[37] VHA Handbook 1142.01.
[38] Joint Commission Perspectives®, *Accepted: Home Care Requirement Changes for Hospice Program,* 28: Issue 12 (December 2008): 9.

an on-call pharmacy representative to answer questions.[39] Filling orders or delivering medications must wait for the pharmacy to be open.

While we recognize that VHA policy does not require "24/7" availability for the hospice pharmacist, expanding the role of clinical pharmacists in interdisciplinary team meetings and pain management consulting would be beneficial to better address pain management issues for hospice patients.

Issue 2: Relocation of Hospice Patients

We did not substantiate the allegation that relocating hospice patients to a unit without "piped in" oxygen, suction, or air compromised their comfort and safety.

VHA policy describes end-of-life care planning that emphasizes comfort, relief from pain, symptom management, and quality of life.[40] However, there are no specific standards or procedures defining how providers should treat symptoms or requiring "piped in" oxygen, suction, or air. The National Hospice and Palliative Care Organization standards also promote the provision of oxygen as a symptom management and comfort measure but do not define how facilities should provide that service. The only provision is that patients should determine what comfort measure is appropriate and helpful.

At present, BRECC hospice and palliative care patients are on one unit but in different areas. The unit does not have "piped in" oxygen, suction, or air; therefore, the BRECC provides access to oxygen concentrators, suction machines, and fans. In the future, hospice patients will move to a designated hospice unit with oxygen concentrators and suction machines available in each room whether or not patients use or need those measures. The unit will also have fans placed in the ceiling to circulate air.

Based on our interviews with staff and review of VHA and BRECC policies, we found that the BRECC provided patients with oxygen, suction, and air as comfort measures and properly evaluated management of those measures based upon patient wishes and comfort. Therefore, we made no recommendations.

Conclusions

Veterans admitted to the BRECC for hospice and palliative care expect to receive superior services that focus on end-of-life care. Their expectations and goals are to experience deaths that are dignified and as pain free as possible. Indeed, VHA directives and policies support an aggressive approach to pain management as well as comprehensive and individualized care planning that address quality of life standards. Our interviews and medical records reviews found that although staff is committed to

[39] VHA Handbook 1108.07, *Pharmacy General Requirements*, April 17, 2008.
[40] VHA Handbook 1142.01.

providing effective hospice and pain management, there appeared to be hesitancy when treating patients with escalating pain and symptoms, which increased the risk of patients suffering. Lack of education added to the staff's confusion. As a result, BRECC staff did not adequately manage pain for at least two of the four hospice patients we reviewed.

Both patients had blocks of time ranging from 5 to 12 days where breakthrough pain occurred up to 6 times per day and end of dose failure once a day. Admission assessments done by providers did not seem to delineate any difference between patients in regard to pain management. On admission, or shortly thereafter, providers changed three of the four patients to methadone, a medication that is difficult to change quickly and did not appear to address the patients' complaints of increased pain. Nursing staff frequently reassessed the patients for pain, but many reassessments were not completed or documented. During the weekdays, providers visited patients and attended team meetings and rounds; however, providers appeared to base clinical pain management decisions on the individual visit to the patient rather than the totality of documented information or discussion with the patient and staff. Furthermore, the providers did not address one of the more common indicators of ineffective pain control—end of dose failure.

The system has recognized that hospice is an important service for veterans and has taken steps to enhance the education and orientation program for the BRECC and system. Construction has begun on a separate hospice unit that will provide hospice services in an environment that supports the individual attention that patients require. By addressing the contributing factors that resulted in inadequate pain management for at least two veterans and continuing to enhance the program changes, the system has the opportunity to create a model hospice unit with exceptional care and pain management that addresses the specific needs of veterans requiring hospice care.

Recommendations

Recommendation 1. We recommended that the System Director implement procedures to ensure that BRECC staff comply with VHA and system policies regarding development and documentation of comprehensive and individualized care plans, documentation of nursing pain assessments and reassessments, and hospice and pain management training.

Recommendation 2. We recommended that the System Director review the effectiveness and oversight of the Nursing Inpatient Pain Subcommittee.

Recommendation 3. We recommended that the System Director review and modify the interdisciplinary team structure and process to provide more effective team discussion and patient/family participation.

Recommendation 4. We recommended that the System Director assign sufficient qualified clinical pharmacists to act as hospice and pain management consultants.

Comments

The VISN and System Directors agreed with the findings and recommendation and provided acceptable action plans. (See Appendixes A and B, pages 18–23, for the Directors' comments.) We will follow up on the planned actions until they are completed.

(original signed by:)

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Appendix A

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: June 15, 2011

From: Director, VA Capital Health Care Network (10N5)

Subject: **Healthcare Inspection—Alleged Pain Management Deficiencies, VA Maryland Health Care System, Baltimore, Maryland**

To: Director, Bedford Office of Healthcare Inspections (54BN)

Thru: Director, Management Review Service (10A4A4)

1. Attached is the response to the OIG Draft Report: Healthcare Inspection: Alleged Pain Management Deficiencies, VA Maryland Health Care System, Baltimore, Maryland.

2. I have received the comments provided by the Medical Center Director, VA Maryland Health Care System and concur with the attachment memorandum response.

3. Please refer questions to Dr. Raymond Chung, VISN 5 Chief Medical Officer.

(o*riginal signed by Pedro Garcia for*:)
Fernando O. Rivera, FACHE
Director, VA Capital Health Care Network (10N5)

Appendix B

System Director Comments

Department of Veterans Affairs **Memorandum**

Date: June 9, 2011

From: Director, VA Maryland Health Care System (512/00)

Subject: **Healthcare Inspection—Alleged Pain Management Deficiencies, VA Maryland Health Care System, Baltimore, Maryland**

To: Director, VA Capital Health Care Network (10N5)

1. Attached please find the VAMHCS responses and relevant action plans for the four (4) recommendations from the Office of the Inspector General Healthcare Inspection conducted February 22, 2011.

2. We appreciate the professionalism demonstrated by your team and the consultative attitude during this review process.

3. If you have any questions regarding this report, please contact Dorothy A. Snow, M.D., MPH, VAMHCS Chief of Staff at 410-605-7004.

(o*riginal signed by*:)
DENNIS H. SMITH
Director, VA Maryland Health Care System (512/00)

Director's Comments to Office of Inspector General's Report

The following Director's comments are submitted in response to the recommendations in the Office of Inspector General's report:

OIG Recommendations

Recommendation 1. We recommended that the System Director implement procedures to ensure that BRECC staff comply with VHA and system policies regarding development and documentation of comprehensive and individualized care plans, documentation of nursing pain assessments and reassessments, and hospice and pain management training.

Concur

System's Response:

The Director of GEC [Geriatrics and Extended Care] and Loch Raven Associate Chief Nurse will be responsible for the implementation of procedures, including education and monitoring to ensure that BRECC staff comply with all VHA/facility policies related to pain management and pain management in a Hospice setting.

Education

The Director of GEC and Loch Raven Associate Chief Nurse will establish/maintain educational segments at monthly staff meetings and other venues reinforcing to all staff the critical elements of comprehensive and individualized care plans that must be developed and documented related to the pain management care plans. The elements will include, but are not limited to:

- Ongoing Care of Hospice Patients
- Pain Management Training
  - Pharmacologic interventions
  - Prescribing opioid analgesics for regular use
  - Non-pharmacologic interventions, including:
    1. Educational interventions to improve self-management;
    2. Psychological interventions;
    3. Family interventions and community supports;
    4. Rehabilitation therapies;

5. Complementary therapies as available; and
6. Pain medicine specialty procedures, such as injections, nerve blocks, ablations, and neuromodulation.

- Required documentation
  - Components of Care Plan
  - Nursing Pain Assessment/Re-assessment:
    1. Pain Assessment/re-assessment training (review of VAMHCS policy) provided to all Hospice Nursing staff initiated in March 2011 and **completed** April 2011.
    2. Review of Pain Inventory Template documentation with all RNs and LPNs in Hospice completed April 2011.
    3. All of the LR-1 Nursing Assistant staff **completed** the Hospice and Palliative Nurse's Association training course including a module on Pain Management, Jan-2010 - April 2011
    4. Pain Management 101 training for all nursing staff scheduled.
    5. End of Life Nursing Education Consortium (ELNEC) training scheduled for June 15, 2011 in Martinsburg VA.

Target Completion Date: July 1, 2011

Monitoring

VAMHCS GEC Director and Associate Chief Nurse will have the LTC PI [Long Term Care Performance Improvement] SubCouncil monitor the following for the three (3) month period (July to September) or until compliance of at least 90% is achieved.

- Hospice Care Plans for comprehension and individualization.
- Nursing Pain Assessments and Reassessments for inclusion of required components according to VHA/facility policy.

Target Completion Date: October 1, 2011

Status: In Process

Recommendation 2. We recommended that the System Director review the effectiveness and oversight of the Nursing Inpatient Pain Subcommittee.

Concur

System's Response:

The Chief Nurse Executive will review the effectiveness of the Nursing Inpatient Pain Subcommittee through review of minutes, discussions with Subcommittee Chairpersons related identification/implementation of improvement interventions (action plan), and data monitoring. This oversight will continue for 3 months and scheduled oversight will be evaluated to a longer time frame if criteria are not met.

Target Completion Date: October 1, 2011

The Nursing Inpatient Pain Subcommittee will submit the use of prn pain medications, effectiveness and other monitors with analysis to the Executive Performance Improvement Council on a monthly basis for six (6) months or until the threshold (90%) is sustained.

Target Completion Date: January 1, 2012

Status: In Process

Recommendation 3. We recommended that the System Director review and modify the interdisciplinary team structure and process to provide more effective team discussion and patient/family participation.

Concur

System's Response:

Interdisciplinary Team Structure

The Director of GEC and the Director of Hospice will review/define/modify and stipulate that the interdisciplinary team must include: providers, nurses, pharmacist, social workers, counselors, chaplains, and therapists. The Directors will review the current process and determine when the first meeting of the team must occur for each newly admitted patient to the Program. Further they will review the discussion of all patients at the weekly team meeting. All assessments and conclusions will be documented in the patient's record. The process will be reviewed to determine how and when to include patient/family participation. At a minimum if patient/family are unable to participate at the designated times, a designated team member will be available upon patient or family request to answer questions or address concerns. Team members will be notified of the new process.

Target Completion Date: July 15, 2011

Monitoring

The Director of GEC or designee will audit all charts monthly for three (3) months to ensure compliance after team decides initial meeting date of team and weekly documentation.

Target Completion Date: October 1, 2011

Status: In Process

Recommendation 4. We recommended that the System Director assign sufficient qualified clinical pharmacists to act as hospice and pain management consultants.

Concur

System's Response:

The Chief, Pharmacy Service and Associate Chief of Pharmacy for Clinical Pharmacy Practice reviewed the Loch Raven Community Living Center staffing and determined that the current clinical pharmacist staffing is sufficient to meet the clinical pharmacist participation needs of the hospice program. To demonstrate participation with the team and consultative recommendations for the providers, the participating pharmacist will add an addendum to the interdisciplinary team note documenting the medication treatment recommendations made during the meeting for each patient presented.

Target Completion Date: June 6, 2011

To determine ongoing compliance, the Chief, Pharmacy Service or designee will monitor random hospice interdisciplinary team notes (at least one week per month) for three (3) months. Results and analysis will be sent to GLTC PI SubCouncil on a monthly basis for three months or until 90% compliance sustained.

Target Completion Date: October 1, 2011

Status: In Process

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
Acknowledgments	Elaine Kahigian, RN, JD, Team Leader Jerome Herbers, MD Sonia Whig, LD

Appendix D

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