

Department of Veterans Affairs Office of Inspector General

Healthcare Inspection

Review of Alleged Institutional Mistreatment, Department of Veterans Affairs Medical Centers Iowa City and Knoxville, Iowa

Report No. 04-03313-58

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Department of Veterans Affairs

Office of Inspector General Washington, DC 20420

TO: Director, Veterans Integrated Services Network 23 (10N23)

SUBJECT: Healthcare Inspection – Review of Alleged Institutional Mistreatment,

Department of Veterans Medical Centers Iowa City and Knoxville,

Iowa

1. Purpose

A complainant alleged to Senator Charles Grassley that a family member (the patient) received poor care at several Department of Veterans Affairs (VA) medical centers in the midwestern and western United States and that the VA retaliated against the complainant for raising concerns regarding the quality of his care. Senator Grassley requested a thorough and impartial assessment of the facts and circumstances related to the care and death of this veteran by VA's Office of Inspector General (OIG), Office of Healthcare Inspections (OHI). This review chronicles the facts of this veteran's care and determines whether evidence in the record supports the overall nature of the allegations.

2. Background

A complainant contacted Senator Charles Grassley and alleged:

• The VA has retaliated against [the complainant] because [the complainant] is a whistleblower who has complained to the VA about the poor treatment that [the complainant's] 86-year old [family member], received while he was a patient at several VA hospitals.... In response to [the complainant's] numerous complaints about the quality of [the patient's] care, [the complainant] says that among the ways the VA has retaliated against [the complainant] is by reporting [the complainant] to the [State of Iowa] Dependent Adult Abuse Registry...thereby effectively damaging [the complainant's] career and livelihood.... The VA hospital staff contended that [the patient], who was bedridden and confined to the VA Iowa City Medical Center, apparently had some bruising on parts of his body. The VA then points to [the complainant] as being the direct cause of this bruising; claiming that [the complainant] physically abused [the patient] while he was in the VA's care.

- [The complainant] continues to contend that [the patient's] bruising was the direct result of the improper and inadequate medical treatment he received while in the hands of the VA.
- [The complainant] also alleges that some of [the patient's] medical records have been revised with addenda, after-the-fact, by the VA in an effort to attempt to retroactively support the claims the VA is making against [the complainant].
- [The complainant] advises us that the hospital staff has warned some of [the complainant's] VA hospital coworkers about probable adverse consequences and repercussions that could befall them if any of [the complainant's] coworkers agree to provide written support for [the complainant].

The complainant, in the course of an OHI interview and in written communications, also promulgated additional allegations. Other issues included, but were not limited to, quality of care, diagnosis of Parkinson's disease, treatment for the patient's parkinsonism, housestaff supervision, physical therapy, end-of-life care, and alleged medical record alterations. The overarching theme was that of alleged institutional mistreatment of the patient. Overall, the complainant made several hundred allegations.

3. Scope and Methodology

OHI established a team ("the team") consisting of two senior physicians and a healthcare inspector. One of the physician team members serves as OHI's Director of Medical Consultation and Review and the other served as the Chief of Staff (COS) at a midwestern VA Medical Center (VAMC).

On November 13, 2004, the team interviewed the complainant to further understand and clarify the allegations concerning the patient's care. During November 17-19, 2004, and December 16-17, 2004, the team visited the lowa City VAMC. During December

www.michaeljfox.org/parkinsons/glossary.php.

www.indianpsychiatry.com/Glossary.htm.

www.macalester.edu/~psych/whathap/UBNRP/nightmares/Terms_Glossary.html.schizophrenia.atspace.org/glossary/.

A brain disorder due to dopamine depletion. Symptoms of Parkinson's disease include tremor (shaking); slowness of movement; rigidity (stiffness); difficulty with balance; small, cramped handwriting; stiff facial expression; shuffling walk; muffled speech, [and] depression."

http://www.parkinson.org/site/pp.asp?c=9dJFJLPwB&b=71125.

B The patient discussed in this report is described as having "Parkinson's disease" throughout his voluminous medical records. However, Parkinson's disease is, in the final analysis, a diagnosis that can only be made on autopsy, and that diagnosis was neither confirmed nor refuted at autopsy. Therefore, in this report, OHI uses the term "parkinsonism" to describe many of the patient's neurologic symptoms of muscular rigidity, tremor, impaired motor control, loss of movement, lack of facial expression, stiff gait, tremor, or stooped posture. While Parkinson's disease indeed is a cause of parkinsonism, other etiologies include certain drugs, frequent exposure to toxic chemicals, multiple system atrophy, progressive supranuclear palsy, head injury, encephalitis, syphilis, carbon monoxide poisoning, cerebral arteriosclerosis, use of MPTP (a synthetic narcotic), or other diseases or conditions. http://www.answers.com/topic/parkinsonism.

14-15, 2004, the team visited the Knoxville Division of the VA Central Iowa Health Care System. In the course of these site visits, we interviewed staff and obtained and reviewed the patient's medical and administrative records (electronic and paper). Non-VA medical records were often a part of the VA medical record. These, too, were reviewed. We interviewed VA employees involved in the care of the patient.

We inspected the Intensive Care Unit (ICU) of the Iowa City VAMC, where the patient primarily resided when at that medical center, and the Nursing Home Care Unit (NHCU) where the patient resided at the Knoxville Division.

We spoke with the Iowa State Medical Examiner who performed an autopsy on the patient.

Materials provided to us by the complainant were voluminous. Case records for this inspection totaled many thousands of pages, with materials from the complainant alone totaling over 1,000 pages. We categorized the complainant's allegations into major themes. A review of each one of the complainant's several hundred allegations was beyond the scope of this review and exceeded the resources available to OHI. However, analysis often revealed common and repetitive themes. Thus, each one of the complainant's several hundred allegations is not addressed. Instead, the allegations were grouped and addressed in the context of broad categories. Even employing this methodology, the number and scope of the complainant's allegations remained vast.

With regard to allegations of whistleblower reprisal, the complainant was referred to the U.S. Office of Special Counsel.^C

The inspection was conducted in accordance with the *Quality Standards for Inspections* published by the President's Council on Integrity and Efficiency.

4. Inspection Results

A. CASE HISTORY

The patient, an 86-year-old right-handed Caucasian male, born on March 20, 1917, was a World War II (WWII) veteran who served in the United States Army (USA) from August 5, 1941, to September 24, 1945. His service during WWII included duty in the Pacific area. During his period of active duty in the Pacific Theater, the patient developed several illnesses including dengue fever, malaria (first attack in June 1944), dysentery, jaundice (October 1943), "jungle rot," gastrointestinal ailments, and an anxiety disorder. At or about the time of discharge from active duty, he was adjudicated to be 10% service-connected for "anxiety state, moderate" and 0% for "duodenal ulcer"

^C http://www.osc.gov/.

A flu-like illness spread by the bite of an infected *Aedes* mosquito. http://www.astdhpphe.org/infect/dengue.html.

and malaria. After WWII, he spent most of his life in lowa, generally working in the automobile industry. His work included employment as a garage service manager and as an automotive salesperson. The patient was married and had two children. His wife died in 1985. After her death, he generally lived by himself until his later years when, afflicted with advanced parkinsonism and serious ophthalmological problems, he was no longer able to care for himself.

Throughout his life, the patient had many wide-ranging medical problems, for which he received extensive care at several VA medical centers.

Specifically, the patient's many medical issues included dermatologic conditions; gastrointestinal disorders; ophthalmologic issues; central nervous system disorders to include a progressive neurodegenerative disorder diagnosed as Parkinson's disease, a history of small cerebrovascular accidents/lacunar infarcts noted on computerized tomography (CT) scan, and a subdural hematoma with evacuation; cardiac problems; musculoskeletal disease; vitamin B₁₂ deficiency (with a normal Part I Schilling's Test); dental problems; podiatric problems; and several operations including appendectomy (1989), tonsillectomy (1938), left hernioplasty (1972), hemorrhoidectomy (1972), left pars plana vitrectomy, and a right Gamma nail to repair a hip fracture.

B. REMOTE MEDICAL HISTORY

We found no mention of significant medical problems prior to WWII service in the patient's VA medical records. During the patient's WWII service, he contracted several infectious diseases including dengue fever, malaria, dysentery, and "jungle rot." VA medical records document prescription of quinacrine^G and pamaquin (plasmochin)^H following WWII for treatment of malaria. VA medical records indicate that the patient's malarial episodes were infrequent from 1945–1947, with the disease apparently quiescent after 1947. There was no history or evidence of cerebral malaria. We also found no significant history of wartime exposure to heavy metals or neurotoxins. After WWII, the patient spent most of his life in lowa.

VA medical records from the 1950s and 1960s document that the patient had frequent complaints of dyspepsia, epigastric distress, and constipation. These symptoms were evaluated repeatedly with upper gastrointestinal (UGI) series radiographic tests and chest x-rays. Results were initially within normal limits. In April 1963, an UGI series revealed a small hiatus hernia, and subsequent UGI series revealed a small paraesophageal diaphragmatic hernia and Schatzki's Ring. In December 1963, the patient was evaluated privately for hematochezia (rectal bleeding). In 1964, the patient was evaluated for hematochezia and was diagnosed as having bleeding internal and

^E Service connection subsequently raised to 40 percent: 30% - (9400) Neurosis, Gen Anx Dis; 10% - (7305) Duodenal Ulcer; 0% - (6304) Malaria. VA Administrative Records.

F A microsurgical procedure to repair retinal disorders in which the initial step is usually the removal of the vitreous gel.

http://www.vrmny.com/vitrectomy.htm.

^G An antimalarial drug.

^H An antimalarial drug.

external hemorrhoids. The patient also was diagnosed with pruritis ani. Despite recurrent hemorrhoidal bleeding, he declined to undergo a hemorrhoidectomy at that time, although in 1972 he did undergo hemorrhoid surgery. In 1974, VA medical records record the patient as having "colitis," although no indication of inflammatory bowel disease was found in the patient's medical records. The term "colitis" appeared to be used by VA clinicians at that time to characterize the patient's well-documented gastrointestinal symptoms.

The patient had skin problems throughout his adult life. He had a history of contact dermatitis, rosacea, sebaceous hyperplasia on his nose and forehead, an erythematous atrophic plague on his back, and actinic keratoses. The patient's rosacea was treated with oral tetracycline and topical preparations. The patient also had a history of recurrent skin cancers that were treated at both VA and non-VA facilities. Lesions and treatments included an August 1971 excision of a basal carcinoma of the nose at Mercy Hospital in Des Moines; basal cell carcinoma on the back (1977); three July 24, 1980, biopsies of the tip of the nose performed at the Iowa Lutheran Hospital each showing basal cell carcinoma: radical clearance of basal cell carcinoma of his nose with frozen section control and cover of defect by full-thickness preauricular Wolfe graft (August 4, 1980); and biopsies of the lower lip and left cheek that revealed basal cell carcinoma (October 1982); a punch biopsy of a right cheek lesion (May 22, 1985) that showed basal cell carcinoma; a presumed basal cell carcinoma of the left scapula region (November 13, 1985); basal cell carcinoma of the right scapular region; basal cell carcinoma of the right temporal region (September 10, 1986); an erythematous back lesion showing basal cell carcinoma (April 1, 1987); and a forehead lesion showing basal cell carcinoma (September 16, 1987). The patient was also treated for squamous cell carcinoma. For example, on November 23, 1988, a hyperkeratotic exophytic lesion of the left ear was excised. This lesion showed squamous cell carcinoma in situ.

The patient had chronic anxiety symptoms. In the 1960s, meprobamate was prescribed. Librium® (chlorodiazepoxide HCl) and Dalmane® (flurazepam) were also prescribed.

In the mid-1960s, symptoms of joint pain were documented. Additionally, an August 1972 Des Moines VAMC note indicated that the patient complained of stiffness in his knees, elbows, and fingers which apparently had been worsening over several years. Early osteoarthritis was diagnosed. In the 1970s, limitation of movement of the right shoulder was also noted.

The patient had episodes of atypical chest pain. An electrocardiogram (EKG) obtained on November 18, 1981, indicated that the ordering physician's clinical impression was occasional angina. This EKG showed sinus bradycardia, left atrial enlargement, and first-degree atrioventricular (AV) block. In 1992, the patient had atypical chest pain and on March 12, 1992, a thallium dipyridamole study was performed. This test showed no abnormality and no further cardiac evaluation was felt to be required.

A type of chest pain that does not fit the usual or "classic" description of cardiac-related chest pain.

Other medical issues arising in the 1950–1980 time frame include identification in 1970 of a 2 x 2 x 2 centimeter left inguinal hernia followed by repair in 1972. The patient was hospitalized from November 1 to November 2, 1977, for a barium enema for evaluation of "attacks of colitis." In the 1980–2000 period, an early left eye cataract was diagnosed (June 16, 1986), followed by bilateral cataracts (1987). The patient had several podiatric problems including dystrophic nails, hyperkeratosis, calluses, intractable plantar keratosis, J and bilateral onychomycotic toenails. An April 6, 1990, progress note indicated that the patient had mild congestive heart failure (CHF). In the mid-1990s, the patient had surgery for chronic bilateral blepharitis. He had benign prostatic hypertrophy, a history of bilateral high frequency hearing loss, and a history of dental caries with exposed pulps. A stress thallium test performed on July 21, 1994, suggested a prior inferior myocardial infarction. In August 1995 the patient suffered a left eye retinal hemorrhage.

C. NEUROLOGICAL CONDITIONS

A December 12, 1975, Des Moines VAMC progress note records that the patient had lightheaded spells. As best we could ascertain, these were not evaluated in detail. On November 17, 1982, the patient was seen at the Des Moines VAMC stating that he needed "to see the doctor about a rash on my groin, lung condition and shaking in my left hand." On examination, the patient was noted to have a resting tremor in his left hand, monotonic speech, and mask-like facies. The examining clinician raised the possibility of "Parkinson's syndrome" and requested that the Neurology Service evaluate the patient. The Neurology Service saw the patient that same day. Its consultation note indicated that the patient had a mask-like face, drooling on his right side, prominent eyes, slight cogwheel rigidity greater in his left arm than right, slight stooping posture, and decreased coordinating movement in the left arm. There was no bradykinesia or dysphagia. The diagnostic impression was early Parkinson's disease and Symmetrel® (amantadine) at 100 milligrams (mg) daily was started.

July Intractable plantar keratosis (IPK) is a discrete focused callus, usually about 1 cm, on the plantar aspect of the forefoot. Typically IPKs occur beneath a metatarsal head or other area of pressure. http://www.emedicine.com/orthoped/topic159.htm.

Referring to the appearance or expression of the face. http://dictionary.reference.com/search?q=facies.

When rigidity of a muscle gives way in a series of little jerks upon being passively stretched, analogous to the ratcheting movement when a spring-loaded rod drops into the successive notches of a cog. http://www.morrisonfoundation.org/Parkinson's%20and%20Music.htm.

M Bradykinesia is the slowed ability to start and continue movements and impaired ability to adjust the body's position. Dysphagia is difficulty in swallowing. http://parkinsonindia.org/bradykinesia.htm.

http://dictionary.reference.com/search?q=dysphagia.

N Amantadine is an anti-influenza drug that modulates brain neurotransmitter responses and has been used to treat parkinsonian symptoms. http://www.biopsychiatry.com/amantadine.htm.

We note that several later VA notes state an earlier diagnosis of Parkinson's (e.g., 1977, 1978). However, our review of the documentary materials available to OHI indicates the diagnosis was first made in 1982.

The Des Moines VAMC Neurology Service followed-up on the patient 7 weeks later (January 4, 1983). A neurologist noted that the patient presented "essentially unchanged" from his visit of November 17, 1982. The patient had mask-like facies, prominent eyes with a diminished blink, cogwheel rigidity greater on the left than the right, decreased left arm swing upon walking, and some left-sided disintegration of rapid alternating movements. The patient had no dysarthria or bradykinesia, and his gait was normal. The diagnostic impression continued to be early Parkinson's disease. The patient had not been taking his prescribed amantadine regularly. At that time, the advice to the patient was for the patient to take amantadine at the dose already prescribed (100 mg daily).

The patient began regular follow-up with the Des Moines VAMC Neurology Clinic. A note of April 19, 1983, indicated that, in general, the patient was able to get along well. He was continuing to work. At times, while at rest, he was able to suppress his tremor. He continued to have decreased left arm swing, and he had a "pill rolling" tremor of his left hand when he walked. However, his actual gait remained normal. Amantadine was continued at 100 mg daily.

An August 23, 1983, Des Moines VAMC Neurology Clinic note documented a slight increase in the patient's left hand and arm tremor, and on walking there was a decrease in left arm swing. The patient was also observed to have mask-like facies, decreased eye blink, and a staring quality to his facial expression. A slight generalized bradykinesia was noted. It was felt that the patient was experiencing a slow progression of his Parkinson's disease, and amantadine was increased to 100 mg twice a day. Of additional note, at this time the patient was documented as having a bruise over the back of his left hand, "which appears to be related to age and vascular fragility."

An April 11, 1984, Des Moines VAMC Neurology Service note states that the patient was seen complaining of increased tremor of his left hand. This complaint was confirmed upon physical examination, and the neurologist added Sinemet® (carbidopa/levodopa)^P 10/100 mg three times daily to the patient's antiparkinsonian medication regimen. When seen a week later in follow-up in the Neurology Clinic, the patient felt somewhat better, and he was experiencing less movement of his left arm. There was a minimal decrease in spontaneous pill rolling of his left hand, and there was no evidence of right arm tremor or cogwheeling. The clinical assessment was, "Parkinson's disease with tremor, bradykinesia & mask [-] like facies," and the plan was to continue the patient on a medication regimen of amantadine and carbidopa/levodopa. The patient tolerated the carbidopa/levodopa and had decreased lightheadedness. In October 1984 the patient complained of increased left arm shaking; his neurologist increased the carbidopa/levodopa dosage from three times daily to four times daily, with

http://www.ninds.nih.gov/disorders/parkinsons_disease/parkinsons_disease.htm.

^P Carbidopa/levodopa is the mainstay of pharmacologic treatment for Parkinson's disease. Carbidopa delays the conversion of levodopa into dopamine until it reaches the brain, and levodopa is converted to dopamine, the desired (and diminished) neurotransmitter.

the amantadine dosage left unchanged at 100 mg twice daily. The patient stated that he had been depressed because his wife had inoperable metastatic cancer.

During this period, the same Des Moines VAMC neurologist followed the patient. Over a period of some years he saw the patient over 12 times. On January 15, 1986, upon evaluating the patient and reviewing his medications, the neurologist elected to increase the patient's carbidopa/levodopa dose in an effort to better control the patient's left hand shaking. This made the patient's antiparkinsonian medication regimen carbidopa/levodopa 10/100 mg three times daily, carbidopa/levodopa 25/100 mg once daily, and amantadine 100 mg twice a day. A May 7, 1986, Neurology note calls for the patient to take carbidopa/levodopa 10/100 mg at four times daily and to discontinue the carbidopa/levodopa 25/100 mg dosage. The reason for this was not clearly noted.

The medical record notes that the patient was doing well when seen in the Des Moines VAMC Neurology Clinic on August 6, 1986. However, he stated that while his left hand remained relatively unchanged, his right hand had begun to shake. His neurologist concluded that the patient's Parkinson's disease was moderately well controlled and increased the carbidopa/levodopa dose to 10/100 mg five times a day. In a November 6, 1986, visit to Neurology, he had increased tremor and his carbidopa/levodopa 10/100 mg dosing was further adjusted to two tablets three times daily.

During this period (approximately 1987–1989), different neurologists saw the patient at the Des Moines VAMC. They, too, concluded that the patient had Parkinson's disease. The patient was initially maintained on the same dosages of amantadine and carbidopa/levodopa, although on August 4, 1988, the Neurology Service added Vitamin E to the patient's antiparkinsonian regimen. Also, at some point in late 1988 or early 1989, the patient's amantadine dose was increased to 200 mg twice a day.

During an October 19, 1989, Neurology Clinic visit the patient complained of shaking in both of his hands that bothered him a great deal. At that time Cogentin® (benztropine)^R 0.5 mg twice a day was prescribed. However, the patient was apparently reluctant to take this medication for reasons that are not clearly documented in the medical record, and it appears that it was discontinued.

A February 28, 1990, progress note indicates that the patient was referred to Occupational Therapy (OT)^S for "activities of daily living" (ADL)^T assessment, a general

^Q There has been some suggestion that Vitamin E may slow progression or, or delay onset of Parkinson's disease

http://www.umm.edu/altmed/ConsConditions/ParkinsonsDiseasecc.html http://www.ninds.nih.gov/disorders/parkinsons disease/detail parkinsons disease.htm.

R Benztropine is prescribed to prevent or control movement-related side effects of antipsychotic medicines and to treat symptoms of parkinsonism unknown causes. http://www.drugdigest.org/DD/DVH/Uses/0,3915,72%7CCogentin,00.html.

S Occupational Therapy attempts to restore useful physical functionality following disabling accidents and sickness.

http://www.sigafoospt.com/Education/Occupational%20Therapy.htm.

Daily living activities such as feeding, bathing, dressing, grooming, work, homemaking, and leisure. http://www.medterms.com/script/main/art.asp?articlekey=2152.

conditioning program, and to work on modifying a hip protector to aid in prevention of hip fracture. Subsequent OT progress notes indicated that the patient attended that program regularly. He felt it was benefiting him in terms of increasing his neck range of motion and decreasing upper extremity joint stiffness. At this time, when the patient was over 70 years old, he was still working half-days as a car salesman.

In a Des Moines VAMC Neurology Service note of July 31, 1990, the patient complained of his hands shaking while resting, and this was partially interfering with his driving. His shaking was worse with stress. The neurologist noted, "Now having difficulty with resting tremors. Would try anticholinergic. SE [side effects] have been explained." Artane® (trihexyphenidyl)^U was prescribed.

While the primary medical issue during this period appears to have been the patient's neurologic condition, he also had other medical issues such as various skin lesions. For example, he had scalp and upper body lesions that raised concern of further basal cell carcinomas. VA medical records suggest that many such lesions were excised at private medical facilities. An April 6, 1990, Des Moines VAMC progress note indicated the patient had mild CHF with 4+ pitting leg edema. However, no cardiomegaly (enlargement of the heart) was seen on chest x-ray. Treatment modalities consisted of support hose, recommendation of less dietary salt intake, and diuretics. On August 9, 1990, the Des Moines VAMC Cardiology Service performed a detailed evaluation of the patient with regard to his diagnosis of mild CHF. The patient was found to have a normal echocardiogram and good left ventricular function. His lungs were clear, and no edema was noted. His EKG continued to show a long-standing first-degree AV block and no acute changes. No further cardiac workup was felt to be indicated at that time.

A Des Moines VAMC Neurology Service note of September 25, 1990, notes that the patient's resting tremors improved with the addition of trihexyphenidyl, although he still had tremors when excited or nervous. Its dosage was increased from 1 mg to 2 mg twice a day. A December 11, 1990, Neurology Service note further documents the patient's improved tremors. The patient lived alone at that time and was described as "functional." However, both the patient and his family were concerned about occasional confusion, and the patient's trihexyphenidyl dose was decreased to 2 mg daily. During a March 12, 1991, visit to the Neurology Service, the patient complained of forgetfulness. However, overall his Parkinson's disease symptoms appeared stable. A May 28, 1991, Neurology Service note indicates the patient had stopped working. He had been having trouble with increasing resting tremor and slowness of speech. However, he was still driving and able to perform daily activities to meet his living needs. A January 2, 1992, Neurology Service note indicated that the patient felt he was a little worse in the past few months, in that his gait was slower and he was having increased shakiness. His family reported an episode of bladder incontinence. On examination, the patient was noted to have a resting tremor of his left hand, buccal v

^U An anticholinergic antiparkinsonian agent.

V Relating to the cheek, particularly the inside of the cheek.

dyskinesia, was a slow shuffling gait, and mild bradykinesia. The assessment remained that the patient had Parkinson's disease, which at the time of this visit was felt to be "slowly progressive." His amantadine, carbidopa/levodopa, and benztropine were continued. Deprenyl (selegiline) at 5 mg twice a day was started. A June 16, 1992, Neurology Service note continues to refer to the patient's "slowly progressive" Parkinson's disease, and recommends increasing his carbidopa/levodopa dose to 10/100 mg each morning and then 50/200 mg three times daily, and discontinuing trihexyphenidyl. This latter medication was apparently stopped because it caused frequent urination and blurred vision. However, a November 12, 1992, Neurology Service note refers to adding trihexyphenidyl at 2 mg daily.

On or about March 10, 1992, the patient had an episode of atypical chest pain. A dipyridamole thallium test was performed and was negative. On June 26, 1993, the patient had an excision of basal cell carcinomas from his right chest and left neck. On October 12, 1993, the patient had an excision of several basal cell carcinomas from his head and neck, and 3 days later, basal cell carcinomas were excised from his back and nose. A stress thallium test performed on July 21, 1994, showed a "Fixed defect in the inferoseptal wall, most suggestive of a prior inferior myocardial infarction with minimal peri-infarct ischemia."

On December 3, 1994, the patient was brought to the Des Moines VAMC Emergency Room (ER) after he was found wandering in a confused and disoriented state. He was admitted with a "probable diagnosis of confusion secondary to medication," although other diagnostic considerations included confusion secondary to underlying Parkinson's disease and confusion secondary to dementia such as Alzheimer's disease. neurological examination, the patient was confused and disoriented to place and time. Resting tremors were observed in both hands, cogwheel rigidity was noted in the upper extremities, and the patient had a shuffling gait. A head CT showed cerebral and cerebellar atrophy, but no acute processes were identified. Des Moines VAMC clinicians concluded the patient's confusion was most likely due to his many medications. The patient's medication doses were adjusted. In the ensuing days, he responded well to medication minimization and dosage adjustment. He soon was alert and oriented. However, by the time of this medical center admission, a Neurology consultation note characterized his Parkinson's disease as "advanced." On December 15, the patient was discharged to the Grand Island, NE VAMC for continued care. By discharge, the patient's antiparkinsonian regimen had been simplified carbidopa/levodopa 50/200 mg twice daily.

The patient was hospitalized at the Grand Island VAMC from December 15, 1994, through September 25, 1995. Confusion continued to be a concern at the Grand Island VAMC. The patient was seen by neurological consultants at both the Grand Island and Omaha, NE VAMCs. The neurologist at the Grand Island VAMC felt the patient's

W Difficulty or distortion in performing voluntary movements. http://www.medterms.com/script/main/art.asp?articlekey=11214.

X A selective MAO-B inhibitor that has utility in symptomatic treatment of early Parkinson's disease. http://www.selegiline.com/.

picture to be that of advanced disease with medication induced confusional states. He adjusted his carbidopa/levodopa dose and suggested the possibility of trying several other medications as tolerated. Thus, in addition to varying dosages of carbidopa/levodopa, the patient was started or restarted on pergolide, selegiline, and amantadine. Overall, his medications were continually adjusted during his stay.

At the Grand Island VAMC, the patient had extensive Physical Therapy (PT) and also was seen in OT. He was seen at the Omaha and Des Moines VAMCs for dermatological care, and also seen by an ophthalmologist who found the patient to have chronic blepharitis and to be in need of cataract surgery and lid hygiene surgery. The latter was performed privately. Prior to having his cataracts addressed, the patient had a left central vein occlusion. A June 12, 1995, Ophthalmology Clinic note from the Grand Island VAMC states, "This patient is being seen on an emergency consultation The patient states that he has lost the upper half of his vision since approximately five days ago...Impression: 1. Central vein occlusion, left." The patient was seen by a private physician at the Retina Center of Nebraska who, on August 5, 1995, wrote that the patient had, "Marked [left eve] retinal hemorrhage and edema is present throughout the superior hemisphere including the macula. There appears to be early neovascularization over the disc...severe macular edema due to his superior hemispheric branch retinal vein occlusion...[with] marked retinal ischemia." therapy was recommended and initiated.

The patient's care was subsequently transferred to the Ft. Lyon, CO VAMC in conjunction with his family's move to that location. On September 18, 1995, the patient left the Grand Island VAMC on pass with his family. On September 22, 1995, he called the medical center and stated he was not returning and that he was going to be discharged to the Ft. Lyons community center. With regard to his parkinsonism, his medication regimen at the time of discharge was amantadine 100 mg twice daily, carbidopa/levodopa 50/200 mg three times daily, selegiline 2.5 mg twice daily, and Vitamin E 1 capsule daily.

From September 26–October 6, 1995, the patient was hospitalized at the Ft. Lyon VAMC in what appears to have been a medical ward. A brief history noted, "This patient has had Parkinson's disease since 1978 [sic], which has been quite labile, requiring strict adherence to his medication regimen; otherwise the patient will become either toxic or develop severe symptoms of Parkinson's disease with immobility."

The patient's two-week inpatient stay at this location of the Ft. Lyon VAMC was generally unremarkable with the exception of an episode of left eye conjunctivitis. On October 6, 1995, the patient was transferred to the Ft. Lyon VAMC Nursing Home Care Unit (NHCU). The plan at that time was to continue the patient on his antiparkinsonian medications to include amantadine 100 mg twice daily, carbidopa/levodopa 10/100 mg twice daily, selegiline 2.5 mg twice daily, and Vitamin E 400 units daily.

The patient had two stays at the Ft. Lyon VAMC NHCU, the first lasting four and one-half years, from October 6, 1995–March 30, 2000. During this stay, the medical record indicates that while occasionally confused, the patient was oriented and generally

ambulatory. He could perform some ADLs independently. He participated in PT, OT, and recreational activities, and would take long walks with his family. However, his vision continued to deteriorate as his proliferative retinopathy resulted in a dense vitreous hemorrhage in the left eye. Despite multiple sessions of panretinal laser photocoagulation therapy, the vitreous hemorrhage remained chronic and the patient's left eye vision loss was severe. A left pars plana vitrectomy was recommended. This operation was performed at the Denver VAMC on July 17, 1997. The medical record reflects some aspects of improvement, but also residual vitreous hemorrhage as well as a repeat vitreous hemorrhage. The patient's ophthalmologic problems were compounded by cataracts, glaucoma, and infections. The patient received extensive eye care from the Denver VAMC, as well as optometric care locally at the Ft. Lyon VAMC.

In addition to his visual problems, the patient's parkinsonism progressively worsened over his more than 4 year stay at the Ft. Lyon VAMC. He was initially prescribed an antiparkinsonian medication regimen similar to that of the Grand Island and Des Moines VAMCs. But nursing notes documented falls occurring on January 23, 1996; April 12, 1996; and May 29, 1996. The last fall occurred while the patient was with family on a pass from the facility. During this time, the patient received one hour of aquatic therapy twice weekly and other therapeutic modalities three times a week. Initially, the staff made only minor medication adjustments. For example, on or about July 2, 1996, the dose of selegiline was increased to 5 mg twice daily. By August 3, 1996, a progress note reflects that the patient's flexibility varied on a daily basis but that he could ambulate without assistance.

On or about December 1, 1996, the patient's carbidopa/levodopa was reduced. Another medication dose adjustment was attempted on or about December 20, 1996, in an attempt to decrease the patient's confusion. Further adjustment of the patient's carbidopa/levodopa dose and his selegiline is noted on January 8, 1997. The facility initiated procedures for leaving a light on in the bathroom and shutting the door leading into the hallway to help him locate the restroom at night. By January 1998, the patient's physical therapy regimen included exercise bicycling, exercise groups, outdoor recreation, and Nautilus®. The patient fell in August 1998, resulting in abrasions of the skin. Interventions described in a note of November 24, 1998, included assisting the patient when ambulating outdoors, assisting the patient with ambulation if he was shuffling excessively, providing for rest periods when ambulating moderate distances, and continuing with physical therapy and balancing exercises.

In November 1998, the patient's family requested that the patient be started on Tasmar® (tolcapone). Tolcapone was prescribed to replace selegiline, but it was soon discontinued due to confusion and increasing tremors. The patient's amantadine dose

YA microsurgical procedure to repair retinal disorders in which the initial step is usually the removal of the vitreous gel.

http://www.vrmny.com/vitrectomy.htm.

A catechol-O-methyltransferase (COMT) inhibitor that has shown efficacy in the treatment of Parkinson's disease. *J Clin Psychopharmacol.* 1999 Aug; 19(4):329-35. http://www.biopsychiatry.com/tolcapone.htm.

was increased, and on February 9, 1999, the patient had an increase in his carbidopa/levodopa dosage. The patient's family requested Mirapex® (pramipexole);^{AA} this drug was started on March 1, 1999. Pramipexole was initially started at 0.125 mg three times daily and on March 17, 1999, increased to 0.25 mg three times daily.

After pramipexole was initiated, the patient had some improvement in his gait. However, he also remained confused and incontinent. There was again concern about drug side effects to include hallucinations, tremors, weakness, and incontinence. The patient fell on January 15, 1999, and February 9, 1999. The patient had some dyspnea and, on January 29, 1999, chest x-rays showed bronchial changes. A staff meeting with the family on March 2, 1999, focused on the patient's incontinence. Additional falls occurred on June 28, 1999, and July 9, 1999.

In January 2000, the patient saw a neurologist at the Denver, CO VAMC. That consultation resulted in several recommendations for medication changes, but the medical record indicates that the patient's family did not approve of these changes, and therefore they were not made. This appears to have created substantial concern at the Ft. Lyon VAMC, and a special staff meeting was held to clarify roles and decision-making prerogatives regarding the patient's medical care. The Denver VAMC neurologist recommended discontinuation of amantadine, and this was done on January 20, 2000, after a slow taper; the patient's pramipexole was increased to a dose of 0.375 mg three times daily. The medical record documents Ft. Lyon VAMC staff concern that the patient was gradually declining, "but [the family was] not willing to accept this fact."

A family conference on February 1, 2000, reflected family concerns about the patient's increased tremors, medication issues, confusion, conjunctivitis, and overall status. On February 29, 2000, the patient fell in the hallway and was subsequently unable to bear weight on his right hip. An x-ray revealed an intertrochanteric fracture of the right proximal femur; the patient was transferred via ambulance to the Denver VAMC, where he was hospitalized from February 29, 2000, through May 9, 2000. On March 2, 2000, the Denver VAMC Orthopedic Service performed a right Gamma nail. Medical records note that the patient had significant mental status problems attributable to his parkinsonism. This impeded rehabilitation, and on March 5, 2000, the patient was transferred to the Inpatient Medicine Team at the Denver VAMC until nursing home placement could be made.

The medical record stated that the Neurology Service worked diligently with the patient's family to arrive at a mutually acceptable treatment strategy. The family was noted to be frustrated at the patient's "on and off" status, BB which was felt by the Medical and Neurology Services to be typical of the patient's advanced Parkinson's disease.

The patient slowly regained function and was able to work with PT. Due to the patient's slow mental status recovery, on March 6, 2000, the Neurology Service ordered a head

^{AA} A dopamine agonist used in the treatment of Parkinson's disease. *Expert Opin Pharmacother*. 2002 Feb;3(2):197-210.

http://www.biopsychiatry.com/pramipexole.htm.

BB Refers to periods of fluctuation in Parkinson's disease signs and symptoms.

CT scan. It showed an old right corona radiate infarct but no acute findings. The issue of pulmonary fibrosis was raised at the Denver VAMC. A high-resolution CT scan of the chest showed no evidence of pulmonary fibrosis. The medical record also notes that the patient had a sacral decubitus ulcer that was treated with zinc oxide cream. On March 29, 2000, the patient was discharged from the Denver VAMC internal medicine ward and transferred to the Denver VAMC NHCU. At discharge, the patient's antiparkinsonian discharge medications included amantadine 100 mg daily, carbidopa/levodopa 50/200 mg four times daily, selegiline 5 mg daily, and Vitamin E 400 units daily. It was planned that the Neurology, Physical Therapy, and Occupational Therapy Services would continue to work with the patient while he resided in the NHCU.

The patient resided at the Denver VAMC NHCU from March 29–May 9, 2000. He had extensive PT and OT during his stay at the NHCU. At the time of discharge, his antiparkinsonian medication regimen had been modified to include amantadine 100 mg daily, carbidopa/levodopa 25/100 mg every morning, carbidopa/levodopa 50/200 mg three times daily, entacapone 200 mg three time daily, CC and selegiline 5 mg daily. The director of the NHCU noted that the patient used a wheelchair and described the patient as having end-stage Parkinson's disease.

The patient was readmitted to the Ft. Lyon VAMC on May 9, 2000. At the end of June, he had a low-grade temperature with cough; on June 29, he was transferred to the Arkansas Valley Regional Medical Center. He was diagnosed as having pneumonia and returned to the Ft. Lyon VAMC for completion of his treatment. The medical record states, "On July 1, 2000, [the patient's family] came to see [the patient] and decided he needed immediate transfer to Denver for his Parkinson's Disease...[and] arranged to have the Medical Officer of the Day agree to a transfer to [the] Denver VAMC...."

The patient was readmitted to the Denver VAMC for the period of July 1–23, 2000, due to aspiration pneumonia. Denver VAMC medical records note, "A full course of fourteen days Augmentin^{DD} was continued and the patient remained stable throughout this hospital course." During this hospitalization, the patient's family expressed concerns that the patient's Parkinson's disease had progressed. The Neurology Service was consulted but concluded that since the patient was recovering from pneumonia, it would not manipulate the patient's medications at that time. The record notes that the patient had outpatient follow-up planned with a Parkinson's disease specialist. In view of the aspiration pneumonia, the Speech Therapy Service at the Denver VAMC evaluated the issue of dysphagia. It concluded that the patient's swallowing mechanism was likely "submaximal," but it recommended against further intervention at that time.

On July 24, 2000, the patient was admitted to the Cheyenne VAMC Intermediate Medicine Service. He was hospitalized at the Cheyenne VAMC through August 3, 2000. The admission history and physical examination noted that the patient saw a Parkinson's disease specialist in Denver who raised the issue of placing a percutaneous

^{CC} An adjunct to carbidopa/levodopa therapy for patients with idiopathic Parkinson's disease who experience the signs and symptoms of end-of-dose "wearing-off." http://www.rxlist.com/cgi/generic3/entac_ids.htm.

DD Amoxicillin and clavulanate potassium.

endoscopic gastrostomy (PEG) feeding tube to bypass the patient's swallowing difficulties. During his 2-week Cheyenne VAMC hospitalization, the patient experienced progressive worsening of his mental status, somnolence, and left-sided weakness. On or about August 2, 2000, a head CT scan was performed which revealed a large chronic right sided subdural hematoma with acute changes. The patient was transferred back to the Denver VAMC on August 3, 2000.

On August 3, a craniotomy for evacuation of a subdural hematoma was performed at the Denver VAMC. Two cranial burr holes were made and a subdural drain was placed. There were no complications from this operation. The medical record noted that after the operation, the patient regained some strength in his left side, but made little progress with speech, swallowing, or ambulation. The patient had a urinary tract infection during this hospitalization which was treated with Cipro® (ciprofloxin). He was transferred back to an acute bed at the Cheyenne VAMC on August 17, 2000, and on September 8, 2000, he was admitted to the Extended Care Unit (ECU) at that same facility.

During this Chevenne VAMC hospitalization, the patient had a PEG tube placed on August 21. The patient had good days and bad days related to his parkinsonism. On some days, he was confused, while on other days, he was noted to be more oriented. On some days, the patient could walk better than on other days. Some days he had far more noticeable facial movements and tremors than others. Medical records reflected that as well as day-to-day variation in the patient's parkinsonism, there could also be variation throughout a single day. Additionally, Cheyenne VAMC records document that the patient was not always able to communicate with the staff about his needs. At the Cheyenne VAMC, the patient received a course of PT. However, ultimately he was discharged from the PT program because of reaching a "plateau state." Care then became "restorative," comprising such modalities as speech therapy and OT. At the Cheyenne VAMC, the patient was in a wheelchair but he could get up with assistance. He was monitored for his ability to swallow and was provided dietary recommendations to decrease the risk of aspiration.

On September 27, 2000, the patient released his wheelchair safety belt, stood up, and fell. This incident was followed by multiple tests, including a CT scan of his head, chest x-ray, and hip and femur x-rays. These studies were negative for acute fractures, and head CT scan revealed no acute changes. On September 29, 2000, the patient complained of right shoulder pain. Right shoulder x-rays were obtained, which were negative for fracture. On September 30, 2000, the patient complained of non-weight bearing leg pain. An x-ray ruled out fracture. The patient became febrile and a complete blood count (CBC) drawn on September 28, 2000 showed an elevated white blood at 13,600/mm³. The patient was diagnosed as having a left otitis media (middle ear infection) and treatment was initiated. However, treatment was not completed at the Cheyenne VAMC due to a request by the patient's family to transfer the patient to another facility. The patient was transferred to the United Medical Center (UMC) in Chevenne, WY. EE His antiparkinsonian medications at the time of discharge included

EE United Medical Center-West, 214 East 23rd Street, Cheyenne, WY 82001.

carbidopa/levodopa 200 mg three time daily, entacapone 200 mg three times daily, amantadine 100 mg every morning, and selegiline 5 mg daily.

The patient was hospitalized at UMC from September 30-October 12, 2000. At UMC, a non-VAMC neurologist saw the patient. He made some changes to the patient's antiparkinsonian medication regimen, including giving the patient a trial of Requip® (ropinirole). FF However, this new medication did not prove beneficial. discharge summary noted that the patient was disoriented and consistently demented since admission. Other UMC issues included evaluation of continuing right leg pain. severe swallowing dyskinesias, weaning off of phenytoin that had been instituted for seizure prophylaxis post-operatively due to the subdural hematomas evacuation, and physical therapy. On October 12, 2000, the patient was discharged to the Knoxville Antiparkinsonian medications at the time of discharge included VAMC. carbidopa/levodopa 10/100 mg in the morning, carbidopa/levodopa 25/1000 mg five times daily, selegiline 5 mg daily, entacapone 200 mg three times daily, and amantadine 100 mg daily.

It was hoped that the Knoxville VAMC could provide more aggressive and longer rehabilitative therapy than was available at the Cheyenne VAMC. The plan at the Knoxville VAMC was for comprehensive rehabilitation, and the patient was hospitalized there from October 12, 2000, to April 20, 2001. When admitted to the Knoxville VAMC, he was moderately confused and was not able to provide a reliable medical history. He was, however, able to follow one-step instructions with repetition.

On physical examination, a mild right entropion GG was noted and there was yellowish, dry discharge on the patient's evelid. The patient had poor dentition. He had a significant thoracic kyphosis and a gastrostomy-tube (G-tube) in his mid-epigastrium. His upper extremity active range of motion (ROM) and muscle strength were limited due to senile atrophy and general weakness. He had moderate deformities in all of the joints of both hands consistent with degenerative joint disease. The patient's active ROM in the right lower extremity was limited. He could not fully extend this extremity at the knee, and he was found to have moderately severe deformities in both knees and his left ankle. He had pain upon palpation and extension in the region of the hamstring and lateral thigh (side not stated). Functional assessment found that the patient was alert, oriented in one sphere, and able to follow one-step instructions upon repetition. The patient had dysphagia. He was able to feed himself with supervision and encouragement, although this was inconsistent. He used a wheelchair, but was unable to propel his wheelchair in a functional manner. He required significant assistance with transfers and ambulation and maximum assistance with his ADLs.

At the Knoxville VAMC the patient was on intermediate rehabilitation and then transferred to the NHCU after clinicians concluded that he reached his maximum level of function. The patient had a full range of rehabilitative modalities including PT, OT,

http://www.revoptom.com/handbook/SECT8a.HTM.

FF A drug for the treatment of the signs and symptoms of idiopathic Parkinson's disease. http://www.rxlist.com/cgi/generic2/ropinirole_ids.htm. GG Inversion of the eyelid margin.

kinesiotherapy (KT), and speech therapy. The patient was seen by a neurologist, and his antiparkinsonian medications were adjusted. It was felt that his parkinsonism was under good control. Other problems evaluated and treated included dysphagia, severe cognitive and linguistic deficits, chronic blepharitis, glaucoma, seborrhea, chronic Vitamin B₁₂ deficiency, and gingivitis. Ultimately, arrangements were made by the patient's family with an adult day care center in lowa City to care for the patient during the day while this family member was working, and for the patient to live with his family at other times. He was discharged from the Knoxville VAMC on April 20, 2001, in a medically stable condition and with plans for continued care to be delivered by the lowa City VAMC. The patient's antiparkinsonian medications at the time of discharge were carbidopa/levodopa 25/100 mg five times daily, carbidopa/levodopa 10/100 mg daily, amantadine syrup 100 mg daily, selegiline 5 mg daily, entacapone 200 mg three time daily, and pergolide mesylate 0.05 mg twice daily. A follow-up appointment with lowa City VAMC was scheduled for May 18.

During July 5–20, 2002, the patient was hospitalized at the Ft. Meade, SD VAMC for a 2-week respite for his family. He was discharged on July 20, 2002, and then hospitalized at the Iowa City VAMC from March 5–April 29, 2003. He was admitted from the Iowa City VAMC Urgent Care Section due to dyspnea, weakness, and a general failure to thrive. The patient was also thought to have pneumonia, with both community-acquired pneumonia and aspiration pneumonia being diagnostic concerns. Broad-spectrum antibiotic coverage with Zosyn® (piperacillin/tazobactam) and Levaquin® (levofloxacin) was initiated. Vancomycin was also prescribed for a possible staphylococcal cellulitis of the abdominal wall. The patient was intubated overnight due to respiratory failure but was soon transferred to a general medical ward. However, the patient suffered further respiratory failure, and he required reintubation, mechanical ventilation, and readmission to the medical center's intensive care unit (ICU). During an extended ICU stay, there were attempts at removing the patient from a ventilator; however, they were unsuccessful.

At the Iowa City VAMC, the patient was initially placed on CVN (central venous nutrition—nutrition administered through a central intravenous line) to meet his nutritional needs. On April 7, the Interventional Radiology Service inserted a gastrojejunostomy tube and feeding was started through that tube. A tracheostomy was performed. The patient was diagnosed with multi-drug resistant Pseudomonas aeruginosa. He also was treated for urinary tract infections, malnutrition, and acute The Iowa City VAMC Neurology Service consulted on the patient concerning his parkinsonism. At the suggestion of the Neurology Service, the patient was continued on his antiparkinsonian medications. These medications were adjusted when the patient was shifted from CVN to jejunostomy tube feedings, in order to account for the protein binding of these medications. The patient was noted to have decubitus ulcers. These were treated with local care, resulting in significant improvement.

The patient's family was dissatisfied with several aspects of the patient's care at the lowa City VAMC. Other issues also arose. Iowa City VAMC staff believed that the

family member was engaging in activities that were painful to the patient and/or inappropriate. The medical record documents the following:

"[The patient's family member] remained at his bedside last night for 50 minutes practicing reflexology (by RN report.)"

"[Family member] was present and was pressing on the bottom of his feet with... thumbs and pulling on his toes. Pt. [patient] appeared to be in distress and very agitated. RN asked the [family member] to step out of the room."

"There is blurring of the line between being patient relative and member of the care team."

"It is my concern that we are continuing to treat this patient due to family member's request rather than what is medically necessary and appropriate."

"[The family member] changed his [the patient's] ET [endotracheal] tube dressing and applied chest massage towards the end of my visit."

"[The family member] performed rectal exam and found pt [patient] to be impacted...This is outside the guidelines."

An Ethics consultation was obtained, noting:

"Primary ethical concern at present time: Boundary violations by the patient's [family member].... Nursing, PT, and medicine services were encouraged to write-up guidelines for appropriate behavior for family members in the ICU. The patient's attending physician is to review guidelines with family. Any violation of the written boundaries by the family members is to be documented in reports of contacts. As in the hospital policy for any family member in situations such as this, the Hospital Director will review "boundary violations" for further course of action."

The family member's visitation privileges were restricted. On April 29, 2003, at the family member's request, the patient was transferred to St. Luke's Medical Center in Cedar Rapids, IA. The patient's antiparkinsonian medications at discharge included carbidopa/levodopa 25/100 mg two tablets four times daily, carbidopa/levodopa 50/200 mg 1 tablet five times daily, entacapone 200 mg one tablet as directed, and pergolide mesylate 0.05 mg one tablet three times daily.

From April 29 until approximately June 11, 2003, the patient was hospitalized at St. Luke's Medical Center in Cedar Rapids. At St. Luke's Medical Center, he was eventually weaned from his ventilator. The St. Luke's Medical Center discharge summary notes that after the patient was weaned off the ventilator and was deemed to be no longer in need of acute care, he was screened and accepted for nursing home care at the Knoxville VAMC, where he was admitted on June 18, 2003.

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HH St. Luke's Hospital, 1026 A Avenue NE, Cedar Rapids, IA 52406-3026.

Knoxville VAMC notes indicate that the patient's family member requested that the patient be "re-screened," and referred for rehabilitation therapy. However, staff at the Knoxville VAMC, upon review of his records, concluded that the patient was not a rehabilitation candidate. His antiparkinsonian medications included amantadine 50 mg per feeding tube every six hours; carbidopa/levodopa compound 45 milliliters (ml) at 2000, 2200, 2400, 0200, 0400 hours; and carbidopa/levodopa 70 ml compound at 0600, 0800, 1000, 1200, 1400, 1600 and 1800 hours. At the time of admission to the Knoxville VAMC, the patient was noted to be an elderly, frail man who was lying in bed on his side in semi-fetal position. He was in no acute distress. He opened his eyes when his name was spoken, and he grimaced with deep touch. Significant findings on physical examination included tachypnea with a respiratory rate of 28 breaths/minute, but otherwise normal vital signs; upper respiratory rhonchi and scattered crackles in the left lung base; a grade 2/6 systolic murmur radiating to the left axilla; an enterostomy and the left axilla; an enterostomy tube; slight right lower quadrant abdominal tenderness; external hemorrhoids; and bilateral lower extremity flexion contractures. The patient was not ambulatory, and he was a "total skilled care patient." He required "complete assistance for all aspects of his ADL's including bathing, hygiene needs, and medication management." The patient received feeding by enterostomy. He required a mechanical lift for transfer from bed to chair, and he was incontinent of bowel and bladder.

The patient received extensive care for his many medical problems at the Knoxville VAMC. Attempts at providing the patient with several rehabilitative modalities, including KT, OT, and PT were made, despite the clinical staff's general opinion that the patient had very limited or non-existent rehabilitation potential. The medical record reflects a dispute between the Knoxville VA staff and the patient's family member as to the nature of the patient's rehabilitation therapies. This was not dissimilar to what had been recorded at the lowa City VAMC.

Despite numerous meetings with the patient's family member, in which each party articulated its desires and expectations, a mutually acceptable plan of care could not be established. A Neurology Service consultation was placed as well as an Ethics Consult, because of "overwhelming and cumulative evidence regarding disparity between the patient's overall clinical profile and the next-of-kin's expectations." During his Knoxville VAMC hospitalization, the patient required frequent suctioning of his tracheostomy. Chest x-ray showed evidence of chronic pulmonary fibrosis. The patient's skin was noted to be very vulnerable in the sacral and coccygeal regions. This was attributed to his chronic severe contractures and incontinence. The medical record notes that a condom catheter was used to attempt to keep the perineal area dry, the patient was repositioned every 2 hours, and skin lotions were applied every shift. At the Knoxville VAMC, the patient had three episodes of displacement of his enterostomy tube.

On July 6, 2003, Knoxville VAMC nurses witnessed the patient's family member performing aggressive abdominal massage to the patient with a statement by the patient's family member that, "This helps increase his peristalsis." The medical record

An opening into the intestine through an incision in the abdominal wall. http://dictionary.reference.com/search?q=enterostomy.

notes that after this event the patient's abdomen was bruised. Restrictions were placed on the family member's visitation privileges. At the same time, the patient's family member sought placement for the patient elsewhere. Knoxville VAMC records indicate that on July 14, 2003, the patient was transferred to Mercy Medical Center in Des Moines, In "medically frail-but-stable condition." Overall, the patient's functional status on discharge was essentially the same as on admission. He was dependent in all aspects of care.

The patient's antiparkinsonian medications on discharge included amantadine 50 mg/5 ml via feeding tube every 6 hours; carbidopa/levodopa 25 mg/100 mg tab via feeding tube every 2 hours at 0900, 1100, 1300, 1500 and 1700 hours; and carbidopa/levodopa 12.5 mg/50 mg tab via feeding tube every 2 hours.

On August 2, 2003, the patient died at the Mercy Medical Center from adult respiratory distress syndrome with acute pneumonia, nineteen days after admission to that facility.

The Iowa Office of the State Medical Examiner performed an autopsy. KK Autopsy showed the following pathologic diagnoses:

- I. Adult respiratory distress syndrome.
 - A. Consolidation of both lungs, all five lobes.
 - B. Pulmonary edema and congestion.
- II. Acute pneumonia.
- III. Clinical diagnosis of Parkinson's disease.
 - A. Extensive cerebral atrophy.
 - B. Enlargement of the cerebral ventricles.
- IV. Healing contusions and abrasions of the right upper extremities and ecchymosis of the left dorsal upper extremity and contusions and abrasions of the left lower extremity.
- V. Severe arteriosclerotic cardiovascular disease.
 - A. Severe atherosclerosis of the aorta.
 - B. Calcific coronary artery atherosclerosis.
 - C. Atherosclerosis of the Circle of Willis.

^{JJ} Mercy Medical Center, Des Moines, 1111 6th Avenue, Des Moines, IA 50314-2611.

KK Iowa Office of the State Medical Examiner, Lucas State Office Building, 321 East 12th Street, Des Moines, IA 50319-0075.

- VI. Cardiomegaly.
- VII. Granular kidneys.
- VIII. Feeding tube and tracheostomy in place.
- IX. Bladder trabeculations.
- X. Absent appendix.
- XI. Healing laceration, left lateral head.

The cause of death was determined to be adult respiratory distress syndrome with acute pneumonia, and the manner of death was natural.

Postmortem examination of the brain showed marked atrophy of the cerebral hemispheres including that of the frontal and parietal and temporal cerebrum with several millimeters of space between the gyri. There was severe atherosclerosis with plaque formation in the Circle of Willis. The cerebral ventricles were enlarged. Microscopic examination of the brain was not performed.

4. Findings

<u>ALLEGATION: There Was a Pervasive Pattern of Institutional Mistreatment of the Patient</u>

This allegation is not substantiated.

Whether addressing specific allegations or reviewing the totality of care provided by VA clinicians and medical centers, the recurring theme and, in fact, the title of a compendium of hundreds of the complainant's allegations, is that there was institutional mistreatment of the patient.

We found that the patient received extensive care from the Department of Veterans Affairs. He received VA care for over 50 years beginning in the 1940s soon after WWII and continuing at numerous VA medical centers including those at Des Moines, IA; Knoxville, IA; Iowa City, IA; Ft. Lyon, CO; Denver, CO; Cheyenne, WY; Grand Island, NE; and Fort Meade, SD. The Veteran's Health Administration (VHA) appears to have provided the majority of this patient's medical care through his adult life. In reviewing thousands of pages of VA medical record documentation spanning more than 50 years, OHI found no pattern of institutional mistreatment of the patient—whether the institution considered is the Veterans Administration, the Department of Veterans Affairs, or any single VA medical center.

We did find that individual clinical decisions made over a 50-year period existed for which different clinicians might have made different decisions. For example, over the 22 years that the patient's parkinsonism was managed and antiparkinsonian

medications prescribed and adjusted, different neurologists might have designed different regimens. However, in general the patient responded well to treatment until he reached the later and advanced stages of his parkinsonism when his response to treatment was limited or absent. Likewise, the patient's many other medical conditions over his lifetime lent themselves to a variety of treatment approaches. Allegations of institutional mistreatment of the patient appeared to be particularly directed toward the lowa City and Knoxville VAMCs. Extensive review of medical records from these two institutions failed to reveal a pattern of negligence or mistreatment.

Of all the patient's many conditions, his parkinsonism was his primary medical issue. Review of the patient's parkinsonism, its diagnosis, and treatment showed that it was well within community standards for that condition. The complainant stated to us that patients do not die of Parkinson's disease and that was an indication of institutional neglect and poor care. While Parkinson's disease is not considered a cause of death, and, in fact, this patient's cause of death was adult respiratory distress syndrome with acute pneumonia, it is a progressive neurodegenerative disorder with neuronal degeneration in the midbrain that ultimately affects multiple organ systems. Progressive impairment of motor and autonomic function can naturally lead to physiologic impairment such as impaired respiration, dysphagia, gastroparesis, and severe debility. Typically patients with long-standing and advanced Parkinson's disease die of complications of generalized debility such as pneumonia, as was the case here. Thus, while the complainant's assertion that patients do not die of Parkinson's disease is correct, it does not follow that this patient therefore experienced poor care.

The primary quality of care concern that OHI reviewers found in this case was the several falls at the Ft. Lyon, CO VAMC. One of these falls resulted in a hip fracture. In 2000 the patient was diagnosed with a combination acute and chronic subdural hematoma. A fall is one possible etiology of that diagnosis. The patient had several risk factors for falls—his age, advanced parkinsonism, dementia, and partial blindness. He sustained at least nine falls between October 1995 and February 2000. The records do not reveal that the patient was ever restrained or that safety devices, including bed alarms, were employed. However, deeper exploration of this issue is exceedingly difficult due to the closure of the Ft. Lyon VAMC and its conveyance to the State of Colorado in May 2001.

In addition to our review of primary VA materials and our interviews with VA clinical staff, further buttressing the finding of a lack of institutional mistreatment, is that on the occasions that the patient was treated at non-VA medical facilities, care plans and treatments generally mirrored those of VA facilities.

We found no evidence of physical neglect, mistreatment, or abuse of the patient by VA clinicians. This finding is supported not only by the medical record, but by the patient's autopsy report and our discussions with the Iowa State Medical Examiner who performed an autopsy of the patient.

<u>CONCLUSIONS AND DISCUSSION REGARDING: There Was a Pervasive Pattern</u> of Institutional Mistreatment of the Patient

For the reasons indicated above as well as those indicated in the case history, we conclude that no pattern of institutional mistreatment existed.

ALLEGATION: VA Misdiagnosed the Patient's Parkinson's Disease

The complainant alleged:

"I'm not sure when he was started on Sinemet, but he was on Symettrel for a long time. He never really had the tremors that somebody with Parkinson's disease that he had like slowness of movement and bradykinesia."

"He [the patient] was treated for a condition that he didn't have, is what I really believe."

"The cause of death was acute respiratory distress syndrome. The brain showed no depigmentation of the substantia nigra. It showed no Lewy bodies. So, there was no Parkinson's disease. The pathologist ... wrote that [the patient] had clinical—that the medical records documented that [he] had clinical Parkinson's disease. She [the pathologist] didn't come out and say that there was no pathological evidence, but she had no pathological findings."

Review of the patient's medical records indicate that he had a parkinsonian movement disorder clearly diagnosed by November 17, 1982. This neurologic picture was characterized by resting tremor, speech monotone, facial masking, drooling, prominent eyes, and cogwheel rigidity. Initially there was no bradykinesia or dysphagia, but both symptoms soon expressed themselves. Furthermore, the patient's symptoms, as documented in the medical record, were responsive to carbidopa/levodopa and amantadine.

Parkinson's disease is a progressive neurodegenerative disorder. There exists presently no simple biologic marker that can confirm a diagnosis of Parkinson's disease before death. For example, there is no blood test, x-ray, or other test that permits the clinician to unequivocally make a diagnosis of Parkinson's disease. As such, the diagnosis of Parkinson's disease is made on a clinical basis. Its major signs include tremor, rigidity, and akinesia, all of which this patient had. Lang and Lozano point out that, "The combination of asymmetry of symptoms and signs, the presence of a resting tremor, and a good response to levodopa best differentiates Parkinson's disease from parkinsonism due to other causes." We therefore found it reasonable that VA clinicians diagnosed the patient with Parkinson's disease—Lang and Lozano's statement characterizes the patient in this case.

Lang AE, Lozano AM. Parkinson's disease – first of two parts. *N Engl J Med* 1998;339:1044-1053.

Additionally, we note that 12 or more attending-level neurologists evaluated the patient over a 22-year period, all coming to the conclusion that the patient suffered from Parkinson's disease. These neurologists were employed at several institutions, some following the patient for extended time periods. They evaluated the patient at different stages of his illness and documented their findings and clinical reasoning.

The complainant raised the issue of exposure to heavy metals such as lead in the years that he worked as a mechanic—apparently as an etiology for his neurodegenerative disorder. Indeed, several toxins such as carbon disulfide, carbon monoxide, cyanide, manganese, methanol, and MPTP^{MM} may cause symptoms of parkinsonism. We noted that the patient worked in the automotive industry. However, even had the patient's parkinsonism not been true Parkinson's disease as alleged, the treatment strategy would be largely the same.

CONCLUSIONS AND DISCUSSION REGARDING: VA Misdiagnosed the Patient's Parkinson's Disease

We concluded on the basis of extensive medical record documentation of the patient's symptoms and signs over a greater than 20-year time period that the patient had parkinsonism and that this parkinsonism was reasonably diagnosed as Parkinson's disease. The autopsy studies that would definitively rule in or rule out a diagnosis of Parkinson's disease were not performed. Overall, the patient's medical record does not contradict the diagnosis of Parkinson's disease made or affirmed by over 12 attendinglevel neurologists over a greater than 20-year period.

ALLEGATION: VA Did Not Employ All Possible Modalities of Treatment for the Patient's Parkinson's Disease

This allegation is partially substantiated.

The medical record reflects aggressive attempts at pharmacological treatment of the patient's parkinsonism. Numerous medications in the neurologist's armamentarium available for that condition were attempted at some point in the patient's course.

There are many hopeful approaches to the treatment of Parkinson's disease such as pallidotomy, thalamotomy, neurotrophic proteins, neuroprotective agents, neural tissue transplants, and genetic engineering to modify the genetic code of individual cells to create dopamine-producing cells from other cells. Most of these treatments are The patient in this case would not have been a considered highly experimental. candidate for many or all such therapies because of their, as yet, experimental nature and/or due to his general debility.

Reference:http://www.mydr.com.au/default.asp?Article=3299.

¹⁻methyl-4-phenyl-1,2,3,6-tetrahydropyridine—a street drug used as a synthetic heroin that has been associated with drug-induced Parkinson's disease.

Furthermore, the patient did, in fact, receive attempts at many of the newer medical approaches to parkinsonism. Beyond the mainstays of amantadine and carbidopa/levodopa, the patient was tried on dopamine mimics such as pramipexole (Mirapex®) and ropinirole (Requip®), both of which only relatively recently received FDA approval (1997), as well as tolcapone (Tasmar®), a catechol-O-methyltransferase (COMT) inhibitor that attempts to block the breakdown of levodopa prior to it reaching the brain. Additionally, several less traditional therapies were employed such as Vitamin E and Coenzyme-Q10 (CoQ10).

<u>CONCLUSIONS AND DISCUSSION REGARDING: VA Did Not Employ All Possible</u> Modalities of Treatment for the Patient's Parkinson's Disease

Overall, the medical record reflects that the patient's parkinsonism was treated aggressively. It is, however, correct that not all possible modalities were attempted. This appears to be primarily because several of them are in an experimental stage and/or the patient was not an appropriate candidate for them.

ALLEGATION: Housestaff Were Inadequately Supervised

This allegation was not substantiated.

The complainant made statements to OHI such as:

"...the residents are not supervised. They are not supervised. I mean, that is criminal. The patients are sort of experimented on by the residents with no supervision."

The two primary affiliated teaching hospitals in which the patient received care were the Denver VAMC, which is affiliated with University of Colorado Health Sciences Center, and the Iowa City VAMC, which is affiliated with the University of Iowa College of Medicine. The complainant's allegation centers primarily around the latter.

We found that typically housestaff (interns, residents, fellows) entered very detailed notes and that these notes were typically cosigned and/or accompanied by lengthy attending physician notes. Interviews with the ICU attending physicians, several of the ICU nurses, and respiratory therapists who routinely saw the patient further validated that housestaff were highly supervised. Attending physician notations such as, "I discussed the interval history, exam, and laboratory evaluation with [physician-intraining] and other members of the ICU housestaff service," were common.

We found that during after-hours, a resident was available. Also, if needed, an attending in house ("Medical Officer of the Day") could be called. A pulmonary critical care fellow was available if needed, and an attending pulmonary/critical care physician was always on call. We found, in the course of our interviews and by reviewing medical

NN Parkinson's Disease: New Treatments Slow Onslaught of Symptoms. http://www.fda.gov/fdac/features/1998/498_pd.html.

record notes, that it was clear that if anyone, including the nurses, was concerned with the care provided on off tours, they felt comfortable calling the pulmonary/critical care attending physician.

<u>CONCLUSIONS AND DISCUSSION REGARDING: Housestaff Were Inadequately</u> Supervised

Chart notes reflect adequate supervision of housestaff.

<u>ALLEGATION: Bruising Occurred as a Result of Improper and Inadequate</u> Medical Treatment

This allegation is not substantiated.

The complainant made statements to OHI such as:

"...all of which she [the pathologist who performed the autopsy] indicated showed skin lesions and other signs of other evidence that she [the pathologist] felt was consistent was poor care at both a VA facility and/or a private facility."

On autopsy, the patient was found to have abrasions, ecchymosis, and contusions.

The etiology of these skin lesions is indeterminate. The lowa State Medical Examiner who performed the autopsy on the patient told OHI that the patient's lesions did not have the pattern or nature characteristic of skin lesions caused by abuse. The medical examiner further informed OHI that if she had concluded there was abuse, she would have reported such a conclusion in the autopsy report. No such conclusion is in the autopsy report.

In part, the patient's skin lesions may be attributable to the patient's inherent agerelated skin fragility, skin breakdown in a catabolic state, and incontinence. At the lowa City VAMC our interviews with the ICU nursing staff as well as our medical record reviews demonstrated a consistent assessment of the patient's skin condition. Nurses provided frequent turning, oral care, and skin care.

CONCLUSIONS AND DISCUSSION REGARDING: Bruising Occurred as a Result of Improper and Inadequate Medical Treatment

Abrasions, ecchymosis, and contusions were identified at autopsy. They are also seen in pictures of the decedent that the complainant sent to OHI. Nevertheless, neither the graphicness of the pictures, nor the findings of skin lesions establish poor care or abuse. Any interpretation of the patient's skin when he died must take into consideration that the patient was a cachectic on and bedridden patient. He had at least five coexisting conditions which made the development and progression of skin lesions

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^{oo} Cachexia is general physical wasting and malnutrition usually associated with chronic disease.

inevitable, even in the face of good skin care. These conditions included incontinence, contractures, a catabolic state, fever (which impairs healing), and an unresponsive state which would prevent recognition of painful areas and movement to take pressure off of vulnerable areas.

ALLEGATION: Hospital Management Has Warned Some VA Employees About Probable Adverse Consequences and Repercussions That Could Befall Them if They Agreed to Provide Written Support for the Complainant

This allegation is not substantiated.

In the course of our interviews with lowa City VAMC staff we learned that the complainant had asked several of them to write testimonial letters on the complainant's behalf. The requested letters, as described to OHI, were of a nature that would attest to the excellence of the complainant's care of the patient. Several VAMC employees told us that they declined to write such letters. They told us that the decision not to write such a letter was strictly their own. We found no evidence that any VAMC employee was warned about adverse consequences and/or repercussions if they agreed to provide a written statement of support for the complainant.

CONCLUSIONS AND DISCUSSION REGARDING: Hospital Management Has Warned Some VA Employees About Probable Adverse Consequences and Repercussions That Could Befall Them if They Agreed to Provide Written Support for the Complainant

There was no evidence of any managerial action to deter employees from providing letters of support for the complainant.

ALLEGATION: Physical Therapy was Insufficient and Inadequate

This allegation is not substantiated.

Review of this patient's medical records and our interviews indicate that the patient received substantial amounts of inpatient and outpatient PT. For example, one physical therapist told us, "I would say [the patient received] nearly 60 visits of outpatient therapy and we were working primarily to improve his range of motion and mobility." During the patient's inpatient lowa City VAMC hospitalization, there were 44 documented visits by the PT department. An osteopathic consultant to OHI reported that the average outpatient receives ten to twelve sessions of physical therapy.

<u>CONCLUSIONS AND DISCUSSION REGARDING: Physical Therapy was Insufficient and Inadequate</u>

Overall, the interviews with the physical therapists and records reviewed demonstrated that PT notes and evaluations were detailed, conscientious, and thorough. Our osteopathic consultant concluded that there was a thoughtful approach to this aspect of

the patient's care. In view of his mental status and physical limitations, the level of physical therapy for the patient was appropriate.

ALLEGATION: Staff Simply Wanted to Let the Patient Die

This allegation is not substantiated.

The complainant made statements to OHI such as:

"[The patient's] wishes weren't respected. The power of attorney wasn't respected. Nobody was respected. It was just the—there was just a concerted effort to end his life."

We found that staff attempted to follow the wishes of the patient and his family in regard to aggressiveness of treatment in the face of his advanced parkinsonism, insofar as they could without harming the patient. And, indeed, treatment was aggressive.

However, we also found that when a care modality was deemed futile or potentially harmful, it was withheld. For example, rehabilitative care was truncated at the Knoxville VAMC when it became apparent that such efforts were futile. Medical records at the lowa City and Knoxville VAMCs reflect concern on the part of physical therapists that PT not harm the patient, particularly given his contractures and overall fragility.

The issue of aggressiveness of care raised complex ethical and legal issues. VA clinicians appeared to give the patient the benefit of any doubt when it came to providing unconventional therapies. For example, at the family member's request, at the lowa City VAMC, CoQ10 was given as therapy for the patient's parkinsonism even though the attending neurologist believed it would be of little benefit. The patient was given BoTox® (botulinum toxin type A) injections in his hamstring muscles, in an attempt to relieve his contractures. Additionally, in the last months of his life, we found that the patient saw numerous specialists at the lowa City and Knoxville VAMCs.

CONCLUSIONS AND DISCUSSION REGARDING: Staff Simply Wanted to Let the Patient Die

We found that the medical record reflected a commitment to the patient's care and not simply to let him die as alleged. Treatment interventions such as CVN, intubation, continuing PT and OT, as well as subsequent enteral feeding reflect a commitment to aggressive care.

<u>ALLEGATION: Medical Records Have Been Improperly Revised With</u> Addendums, After-The-Fact

This allegation is not substantiated.

In the course of the patient's extensive VA care, VA clinicians at multiple facilities wrote addenda to their notes. These addenda contained information relevant to the patient's

clinical status and care. For example addenda contained information such as laboratory values, observations of potentially harmful actions toward the patient, contacts to VAMC staff about the patient, and information regarding records retrieval from other institutions.

We found no evidence to support a finding that chart entries were falsified, fabricated, altered, or entered at any time other than that which was stated in the note.

<u>CONCLUSIONS AND DISCUSSION REGARDING: Medical Records Have Been</u> <u>Improperly Revised With Addendums, After-The-Fact</u>

Addenda and "late-entry" nursing notes are routinely part of a medical record. We concluded that the content of the addenda found in this patient's record such as laboratory values, observations of potentially harmful actions toward the patient, telephone contacts, and information regarding records retrieval from other institutions was appropriate.

5. Recommendations

There are no recommendations.

6. Comments

The Director of the VA Iowa City Health Care System concurred with the facts contained in the report and stated that since no recommendations were made in the report, there was no need to submit an action plan.

(original signed by:)
JOHN D. DAIGH JR., M.D.
Assistant Inspector General for
Healthcare Inspections

APPENDIX A

OIG Contact and Staff Acknowledgments

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APPENDIX B

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