



DEPARTMENT OF VETERANS AFFAIRS  
**OFFICE OF INSPECTOR GENERAL**

*Office of Healthcare Inspections*

VETERANS HEALTH ADMINISTRATION

Surrogate Decision-Maker,  
Clinical, and Patient Rights  
Deficiencies at the Robley  
Rex VA Medical Center in  
Louisville, Kentucky



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## Executive Summary

The VA Office of Inspector General (OIG) conducted an inspection to assess an allegation that providers at the Robley Rex VA Medical Center (facility) in Louisville, Kentucky, permitted an individual to make medical decisions on behalf of a patient although that individual had no legal authority to do so. While conducting a preliminary review of the patient's electronic health record (EHR), the OIG noted additional clinical and patient rights deficiencies. The OIG also reviewed the facility leaders' evaluation of deficiencies related to this patient's care.

The patient was in their 70s with a history of diabetes, high blood pressure, heart disease, chronic back pain, adjustment disorder, and mild cognitive impairment.<sup>1</sup> The patient, who had not previously received care at the facility, was brought to the facility's Emergency Department by ambulance in spring 2019 complaining of back pain.<sup>2</sup> An Emergency Department physician documented "suspect a baseline dementia with likely superimposed delirium" related to a urinary tract infection, determined that the patient was not safe for discharge, and recommended an involuntary admission pending formal psychiatric evaluation. Over the next three weeks, the patient's hospital course was marked by multiple intra-facility transfers, repeated episodes of confusion, agitation, and combative behavior, as well as the need for periodic use of physical restraints on the patient. The patient died five days after transfer to the hospice unit.

The OIG substantiated the allegation that a person (neighbor) with no legal authority made medical decisions for the patient due to the facility staff's failure to follow Veterans Health Administration (VHA) and facility policies and complete appropriate documentation. While the OIG considers it likely that the neighbor made the decisions in good faith, the decisions were nevertheless substantial and irreversible. This report also outlines clinical management and related deficiencies, patient rights deficiencies, and the facility's response to medical care deficits.

On the day of admission, a mental health provider noted the patient was "not decisional" and recommended a comprehensive mental health evaluation. Although the OIG found no documented evidence of comprehensive mental health assessments of the patient's decision-making capacity, staff noted the patient's ongoing confusion and impaired cognitive function throughout the hospitalization.

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<sup>1</sup> The OIG uses the singular form of they (their) in this circumstance for the purpose of patient privacy.

<sup>2</sup> The patient had been followed by neurology providers at another VA medical facility since 2017 for mild cognitive impairment. Since 2000, the patient was followed sporadically at sixteen different VA facilities by various providers including mental health providers for symptoms of anxiety that were thought to be due to ongoing pain and stress from a back injury suffered many years prior.

The OIG determined facility staff did not take appropriate steps to identify and confirm the eligibility of a surrogate when the patient lacked decision-making capacity. VHA policy requires staff to “make a reasonable inquiry” to locate other possible persons to give informed consent on behalf of the patient. To identify authorized surrogates, staff must examine all available information including the patient’s personal effects, the EHR, and VA benefits and pension records. Staff must document the process and outcome of efforts to identify a surrogate.<sup>3</sup> Staff who were interviewed reported varied understanding of the procedures and requirements for conducting a search for next of kin and documenting the results.

An Emergency Department nurse documented that the patient reported having family members, but the patient did not or could not provide names or phone numbers. Emergency Department staff subsequently found the neighbor’s name and contact number in the patient’s personal belongings and a social worker contacted the neighbor and made arrangements for the patient’s service dog that had been transported with the patient to the facility.

Although the patient was documented as “not decisional,” a social worker assisted the patient with signing a release of information form that permitted staff to speak with the neighbor. The improperly obtained authorization, which identified the neighbor as the approved recipient of the patient’s information, was repeatedly referenced in EHR notes and may have implied designation as a surrogate that later became central to the request for the neighbor making important medical care decisions. If the neighbor had been correctly verified as the surrogate, a release of information would not have been required, and the neighbor may have been legally authorized to consent for procedures and an autopsy on behalf of the patient.<sup>4</sup>

Despite the awareness of the patient’s possible family members and a social work consult specifically to locate the patient’s next of kin, social workers who provided services to the patient did not conduct a vigorous review to locate relatives, due to social workers’ varied understanding of the procedures and requirements. To identify the next of kin, clinical staff told the OIG that they searched the patient’s belongings and VHA records, but none of the social workers reviewed or requested a check of other VA records, such as VA benefits records. Staff uniformly acknowledged that a patient’s next of kin has priority over a neighbor as a “close friend” for selection as a surrogate decision maker.<sup>5</sup>

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<sup>3</sup> VHA Handbook 1004.01(2), *Informed Consent for Clinical Treatments and Procedures*, August 14, 2009, amended April 4, 2019. Persons are prioritized in order of healthcare agent, legal guardian or special guardian, next of kin, and close friend. Next of kin is considered a close relative of the patient who is eighteen years of age or older, and prioritized in order of spouse, child, parent, sibling, grandparent, and grandchild.

<sup>4</sup> VHA Directive 1605.01, *Privacy and Release of Information*, August 31, 2016.

<sup>5</sup> VHA Handbook 1004.01(2). A close friend is a person who shows care and concern for, and is familiar with, the patient’s health, activities, beliefs, and values.

The patient's neighbor, who was improperly established as the surrogate decision maker, was later asked to authorize admission to hospice for end-of-life care, as well as for autopsy. Three days after the patient's death, administrative staff located a patient's family member from VA benefits records. The EHR did not contain documentation of disclosure to the family member related to an unauthorized individual making decisions for the patient.<sup>6</sup>

The OIG found no documentation that the neighbor provided a statement describing the relationship with the patient or that the neighbor met the required "close friend" criteria until hospital day 20. If staff had followed processes and obtained the required documentation, they may have evaluated the relationship between the patient and neighbor more thoroughly and concluded that additional efforts were needed to locate the patient's next of kin.

The OIG also determined that the EHR did not contain sufficient documentation of physicians' clinical assessments to support diagnoses and treatment decisions. On hospital day 1, the consulting psychiatrist mentioned schizophrenia as a possible diagnosis without conducting an assessment using relevant criteria, despite the patient being an unlikely candidate for the diagnosis given age and lack of psychiatric history. The schizophrenia diagnosis was repeated across clinical providers and inpatient units for the remainder of the patient's hospitalization, even though the EHR contained no evidence of a focused assessment supporting the diagnosis. Providers may have used the schizophrenia diagnosis to make decisions about the patient's treatment and interventions, including a 72-hour psychiatric hold, admission to a locked mental health unit, and the use of high-risk medications.

While the patient's medical workup was wide-ranging and consisted of bloodwork, cerebral spinal fluid analysis, and multiple imaging tests, providers did not have a clear medical diagnosis. It appeared that providers alternatively considered a primary mental health disorder; however, the patient's psychiatric medications complicated the analysis of a psychiatric problem because these drugs also cause sedation or delirium in some vulnerable patients. The patient was on multiple medications without a documented plan to reassess how the patient responded when off medications prior to declaring the patient hospice ready.

The OIG determined that communication and collaboration across clinical disciplines and services were inconsistent and insufficient, which negatively affected the patient's continuity and quality of care and limited the way care was approached. Providers told the OIG that they did not provide further communication and collaboration because they were not asked to see the patient again, and the practice at the facility was not to intervene once a patient was not under their direct care. In this case, communication and collaboration were imperative because five clinical services' staff were considering multiple different diagnoses and interventions over the course of

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<sup>6</sup> VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018.

the hospitalization, the patient had a complicated clinical picture that was not improving, and the patient presented a behavior management challenge that required significant resources.

Providers prescribed moderate to high doses of antipsychotic and sedative medications concurrently to the patient but did not consistently document medication monitoring and oversight activities to ensure safe patient care. The unsupported, but often repeated, diagnosis of schizophrenia may have been central to providers' decisions to prescribe multiple high-risk medications.

The patient's behavior and care needs were challenging, and providers prescribed antipsychotic medications in an attempt to improve functioning and ensure the patient's and staff's safety. However, because the patient was older, was cognitively impaired, and had not been on antipsychotic medications in the past, a cautious approach and ongoing monitoring was indicated.<sup>7</sup> The OIG did not find evidence that providers attempted a trial of withdrawing and simplifying the patient's medication regimen, which may have improved cognitive function. Several providers told the OIG they were aware of medication warnings or had seen improvement in the patient's alertness or both when the medications were reduced or eliminated.

Inpatient psychiatrists did not clearly document medication reconciliation, and nurses did not consistently document the effectiveness of the patient's as-needed, high-risk medications as required by facility policy, for unclear reasons. Without review and oversight of the patient's medications across the hospitalization, providers may have been unaware of which medications the patient had already received and what effects medications had on the patient's condition. Further review of the patient's medication regimen to evaluate sensitivities, interactions, and toxicity may have revealed the opportunity to decrease psychoactive medications for a period of time and improve the patient's functioning.

After multiple transfers between wards and limited clinical successes, the patient was seen by a Geriatrics and Extended Care physician who referred the consult to the palliative care team. The palliative care team spoke with the patient's neighbor who authorized withholding life-sustaining treatments. The patient was then transferred to the hospice unit.

The OIG concluded that the patient's transfer to hospice was completed without fully pursuing other differential diagnoses and treatment options. The decision to request end-of-life care in the context of an undefined illness or potentially reversible disease should be considered prior to initiating a hospice referral. It was unclear to the OIG why the facility did not use the substituted consent process, as used for one of the patient's procedures, or the interdisciplinary committee process that was specifically designed for cases where determining the surrogate is difficult.

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<sup>7</sup> Ming Li, "Antipsychotic-induced sensitization and tolerance: Behavioral characteristics, developmental impacts, and neurobiological mechanisms," *Journal of Psychopharmacology* 30, no. 8 (2016): 749–770.

The OIG determined that staff did not consistently follow procedures designed to ensure the patient's rights were upheld with respect to involuntary admissions and behavioral restraints. Facility staff did not follow VA and The Joint Commission guidelines and Kentucky state law governing the patient's involuntary 72-hour admission status because staff were unaware of processes, responsibilities, and requirements. As a facility leader stated to the OIG, failure to appropriately authorize involuntary admissions places patients at risk for being kept on the locked mental health unit against their will.

The OIG identified deficits in the management and documentation of behavioral restraints for this patient. The patient was placed in clinical or behavioral restraints intermittently for 16 days during the hospitalization. The OIG also found deficits with staff training and competency on restraint usage. If staff are not adequately trained and competent in restraint usage, patient care and safety could be compromised.

The OIG found that facility leaders did not complete a thorough review of quality of care aspects to understand the reasons for the patient's atypical hospital course and outcome. The facility's process for identifying deaths requiring review did not include hospice deaths, and facility staff, therefore, incorrectly determined that additional review was not required. Providers largely denied to the OIG that care could have (or should have) been provided differently. The facility and provider responses did not appear, in the OIG's opinion, to acknowledge the deficiencies this case presented.

The OIG made 15 recommendations to the Facility Director focusing on the documentation of the mental health assessment of a patient's decisional capacity, the process for determining a reasonable inquiry to identify surrogates, medical assessments to support diagnosis and treatment decisions, medication management, and a review of the patient's hospice admission. Other areas of focus included patient rights such as developing a mechanism to ensure involuntary admissions are managed and documented, appropriate assessment and documentation of behavioral restraints, quality management processes, and disclosure.

## Comments

The Veterans Integrated Service Network Director concurred with all recommendations and agreed with the Facility Director's action plans (see appendixes C and D). The Facility Director concurred with and provided acceptable action plans for recommendations 1–10 and 12–15 (see appendix D). The Facility Director non-concurred with recommendation 11, because he did not believe that the findings supporting this recommendation were correct. The OIG disagrees with the Facility Director as the finding is supported by a review of the electronic health record. Nevertheless, the Facility Director provided an action plan to address this recommendation. The OIG considers all recommendations open and will follow up on the planned and recently

implemented actions to allow time for the facility to submit documentation of actions taken and to ensure that they have been effective and sustained.

The VHA National Center for Ethics in Health Care provided comments to clarify some statements in the draft report on surrogate identification, documentation, and decision making. In addition, the VHA's Office of Mental Health and Suicide Prevention also provided comments (see appendix E). The OIG considers these comments to be technical and stylistic in nature, and they do not change the OIG's understanding of the facts of this case or the recommendations.



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## Abbreviations

DNR	do not resuscitate
EHR	electronic health record
GEC	Geriatrics and Extended Care
ICU	intensive care unit
OIG	Office of Inspector General
TJC	The Joint Commission
UTI	urinary tract infection
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



## Introduction

The VA Office of Inspector General (OIG) conducted an inspection to assess an allegation that providers at the Robley Rex VA Medical Center (facility) in Louisville, Kentucky, permitted an individual to make medical decisions on behalf of a patient although that individual had no legal authority to do so.<sup>8</sup> While conducting a preliminary review of the patient’s electronic health record (EHR), the OIG noted additional clinical and patient rights deficiencies.

## Background

The facility, part of Veterans Integrated Service Network (VISN) 9, provides comprehensive health care in the areas of medicine; surgery; mental health; physical medicine and rehabilitation; Geriatrics and Extended Care; hospice and palliative care; and neurology. The Veterans Health Administration (VHA) classifies the facility as a Level 1b–high complexity facility.<sup>9</sup> From October 1, 2018, through September 30, 2019, the facility served 45,128 patients and had a total of 117 beds, 22 of which were located on the locked mental health unit.

## Decision-Making Capacity

Decision-making capacity is a clinical determination about a patient’s ability to make a particular type of health care decision at a particular time. In clinical practice, a patient’s decision-making capacity is generally presumed. However, when the patient’s medical condition or observed behavior raises questions about the patient’s decision-making capacity, the responsible provider

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<sup>8</sup> The OIG uses the term “providers” for healthcare providers including physicians, psychiatrists, physician assistants, nurse practitioners, and social workers.

<sup>9</sup> The VHA Facility Complexity Model categorizes medical facilities by complexity level based on patient population, clinical services offered, educational and research missions, and administrative complexity. Complexity levels include 1a, 1b, 1c, 2, or 3. Level 1a facilities are considered the most complex and Level 3 facilities are the least complex. VHA Office of Productivity, Efficiency and Staffing. (The website was accessed on November 14, 2019, and is an internal VA website not publicly accessible.)

must make an explicit determination based on an assessment of the patient's ability to do all of the following:

1. Understand the relevant information
2. Appreciate the situation and its consequences
3. Reason about treatment options
4. Communicate a choice<sup>10</sup>

## Surrogate Decision Maker

Decisions and consent for treatments and procedures may be made by a surrogate if a patient is determined to lack decision-making capacity. If the patient is unable to consent, medical care may be provided without consent only if emergent medical care is necessary to preserve the patient's life and waiting for a surrogate would increase risk to the patient's life or health. Healthcare agents, guardians, next of kin, and close friends often serve as surrogate decision makers.<sup>11</sup>

## Medications in Older Adults

The American Geriatric Society publishes a list of medications that are “typically best avoided in older adults” in general, and in patients with certain diseases or syndromes in particular. These medications are associated with risk of poor health outcomes, including confusion, falls, and mortality.<sup>12</sup> Further, the Food and Drug Administration issues “black box warnings” that appear on the drug labels for prescriptions that have potentially serious or fatal risks associated with taking them. The patient was prescribed several of these medications:

- An anticholinergic medication ([benztropine](#)) is used to prevent or treat the side effects affecting movement such as resting tremor, rigidity, and instability resulting from antipsychotic medications and should be avoided in older patients with dementia.
- Antipsychotic medications ([haloperidol](#), [olanzapine](#), [quetiapine](#), and [risperidone](#)), also called [neuroleptics](#), are used to manage psychotic symptoms such as hallucinations and delusions and can be used to decrease agitation in some patients. Elderly patients who are

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<sup>10</sup> VHA Handbook 1004.01(2), *Informed Consent for Clinical Treatments and Procedures*, August 14, 2009, amended April 4, 2019.

<sup>11</sup> VHA Handbook 1004.01(2).

<sup>12</sup> American Geriatrics Society 2019 Beers Criteria Update Expert Panel, “Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults” *Journal of American Geriatrics Society* 67, no.4 (January 29, 2019).

treated for behavioral problems associated with dementia may have an increased sensitivity and risk of side effects and [adverse outcomes](#) including death.

- A [benzodiazepine](#) medication ([lorazepam](#)) is a sedative. Older adults have an increased sensitivity to benzodiazepines, which can increase the risk of cognitive impairment, delirium, falls, and fractures.

Because providers must consider a variety of factors when making prescribing decisions, it could be a reasonable decision to prescribe these medications in certain circumstances. Providers should, however, consider risk versus harm, be aware of potential problems, and “start low and go slow” relative to initial and increasing dosages.<sup>13</sup>

## Neurocognitive Disorders

Neurocognitive disorders are the group of disorders that describe decreased mental function due to a medical disease other than a mental illness. These disorders are acquired, rather than developmental, and represent a decline from a previously attained level of functioning.<sup>14</sup>

### *Delirium*

Delirium, also referred to as [encephalopathy](#), has symptoms of disturbances in patients’ attention and cognition that can quickly come and go and may include psychomotor and emotional disturbances. The symptoms develop over a short period of time, are caused by a medical condition or substances, and are not better explained by another neurocognitive disorder.<sup>15</sup> Factors precipitating delirium include medications, immobilization due to physical condition or restraints, indwelling bladder catheters, malnutrition, and surgery.<sup>16</sup> If the underlying cause

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<sup>13</sup> Joseph Comaty, PhD, Geriatric Pharmacotherapy, *American Society for Advancement of Pharmacotherapy*, 2019. <https://www.apadivisions.org/division-55/publications/tablet/2015/12/geriatric-medicine>. (The website was accessed on October 30, 2019.)

<sup>14</sup> *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*, American Psychiatric Association, *Neurocognitive Disorders*. September 25, 2014 (online). <https://dsm.psychiatryonline.org/doi/full/10.1176/appi.books.9780890425596.dsm17>. (The website was accessed on September 11, 2019.)

<sup>15</sup> *Diagnostic and Statistical Manual of Mental Disorders, Neurocognitive Disorders*.

<sup>16</sup> Sharon K. Inouye, Matthew Growdon, Tamara Fong, “Chapter 47 - Delirium,” *Hazzard's Geriatric Medicine and Gerontology*, 7<sup>th</sup> ed. (New York: McGraw Hill, 2017). <https://accessmedicine.mhmedical.com/content.aspx?bookid=1923&sectionid=144521671#1136590380>. (The website was accessed on November 9, 2019.)

remains untreated, delirium may progress to stupor, coma, seizures, or death.<sup>17</sup> Elderly patients with delirium have an increased risk of death.<sup>18</sup>

### *Mild Cognitive Impairment*

Mild cognitive impairment is the stage of cognitive decline between normal aging and dementia with symptoms such as changes in memory, language, functioning, and attention, that are often not severe enough to require help. Very rapid cognitive decline is not typical for mild cognitive impairment and may suggest other causes.<sup>19</sup>

### *Dementia*

Dementia presents as cognitive decline from a previous level that may be due to Alzheimer's or similar diseases, traumatic brain injury, or substance or medication use. For a diagnosis of dementia, there must be both a concern about cognition, elicited with careful questioning, and an objective clinical assessment, such as neuropsychological testing. The distinction between delirium and dementia can be difficult because they may co-occur; however, a diagnosis of dementia may not be made when the symptoms occur exclusively with delirium or are explained by another mental disorder.<sup>20</sup>

## **Allegation and Related Concerns**

On June 12, 2019, the OIG received a complaint alleging that the facility allowed an individual, who had no legal authority, to make medical decisions on behalf of a patient.<sup>21</sup> During the preliminary review and subsequent site visit, the OIG noted clinical management deficiencies related to the patient's assessment, care communication and collaboration, medication monitoring and oversight, and hospice transfer. Review of the patient's hospital course raised concerns related to patient rights associated with a mental health 72-hour hold and restraints. The OIG also evaluated facility leaders' response to care deficiencies for this patient.

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<sup>17</sup> *Diagnostic and Statistical Manual of Mental Disorders, Neurocognitive Disorders.*

<sup>18</sup> Joost Witlox et al., "Delirium in Elderly Patients and the Risk of Post discharge Mortality, Institutionalization, and Dementia," *Journal of the American Medical Association* 304, no. 4 (July 28, 2010): 443–451.

<sup>19</sup> Kenneth M Langa and Deborah Levine, "The Diagnosis and Management of Mild Cognitive Impairment: A Clinical Review," *Journal of the American Medical Association* 312, no. 23 (December 17, 2014): 2551–2561.

<sup>20</sup> *Diagnostic and Statistical Manual of Mental Disorders, Neurocognitive Disorders.*

<sup>21</sup> The complainant originally reported that the patient was admitted with a large sum of money that was not provided to the family upon the patient's death. The complainant subsequently reported to the OIG that the money was received by the family but noted an additional concern related to the neighbor who was erroneously listed as the surrogate decision maker for the patient.

## Scope and Methodology

The OIG conducted a site visit July 30–August 1, 2019.

The OIG interviewed the Facility Director, Chief of Staff, Associate Director for Patient Care Services, and Chief of Member Services; physicians who cared for the patient; the Social Work Chief, supervisor, and social work staff; and other individuals who had relevant knowledge about the patient and processes under review.

The OIG reviewed January 1–July 31, 2019, documents, including relevant facility policies and procedures, committee meeting minutes, and staff training and competency records related to the issues identified. The OIG also reviewed the EHRs for patients transferred to the hospice and mental health units over a seven-month period in 2019 and for the identified patient’s hospitalization stay.

In this report, the OIG has generalized the narrative and case summaries and de-identified protected patient and quality assurance information.

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

The OIG substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the available evidence indicates that the alleged event or action more likely than not did not take place. The OIG is unable to determine whether an alleged event or action took place when there is insufficient evidence.

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, § 7, 92 Stat 1105, as amended (codified at 5 U.S.C. App. 3). The OIG reviews available evidence to determine whether reported concerns or allegations are valid within a specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leadership on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

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



## Limited Patient Case Summary

The patient was in their 70s with a history of [diabetes](#), high blood pressure, [heart disease](#), chronic back pain, [adjustment disorder](#), and mild cognitive impairment.<sup>22</sup> The patient, accompanied by a service dog, was brought to the facility's Emergency Department by ambulance in spring 2019 complaining of back pain. The patient, who had not received prior care at the facility, had been followed by neurology providers at another VA medical facility since 2017 for mild cognitive impairment. Since 2000, the patient was followed sporadically at sixteen different VA facilities by various providers including mental health providers for symptoms of anxiety that were thought to be due to ongoing pain and stress from a back injury suffered many years prior. The patient's last documented VA mental health clinic visit was in spring 2017. Despite symptoms of cognitive decline, the patient had been living independently, managing finances, and caring for the service dog.

The Emergency Department physician documented that the patient was a “rambling historian” who was difficult to redirect. Although the patient's physical examination was unremarkable, the physician documented, “suspect a baseline dementia with likely superimposed delirium” from the patient's [urinary tract infection \(UTI\)](#). The physician also documented that the patient had been intermittently volatile in the Emergency Department, noted that the patient was not safe for discharge, and recommended admission on an involuntary basis (72-hour psychiatric hold) pending formal psychiatric evaluation.<sup>23</sup>

A mental health nurse practitioner also evaluated the patient in the Emergency Department and concluded the patient's clinical presentation was consistent with delirium of medical origin. The mental health nurse practitioner documented the patient as “not decisional” and recommended a follow-up after the UTI cleared.<sup>24</sup>

Because the patient did not have decision-making capacity, a surrogate was needed to make medical care decisions. The patient told Emergency Department nursing staff of having family members and other relatives but could not, or would not, provide contact information. Social workers reportedly reviewed previous entries in the patient's EHR for next of kin contact

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<sup>22</sup> The OIG uses the singular form of they (their) in this circumstance for the purpose of patient privacy.

<sup>23</sup> Merriam-Webster, *Definition of volatile*. Volatile behavior is often rapidly changing and explosive. <https://www.merriam-webster.com/dictionary/volatile> (The website was accessed on December 5, 2019.) Kentucky Revised Statutes Chapters § 202A.026 and 202A.031. <https://apps.legislature.ky.gov/law/statutes/chapter.aspx?id=38119>. (The website was accessed on December 6, 2019.) Facility Memorandum 603-14-119-004, *Involuntary Hospitalization & Treatment*, December 3, 2018. A 72-hour hold order provides a means of involuntary admission or involuntary continued hospitalization for mentally ill patients.

<sup>24</sup> The OIG defines “not decisional” as a patient being unable to make decisions regarding medical care or lacking decision-making capacity.

information without success. The Emergency Department nurse caring for the patient found a neighbor's contact information in the patient's belongings, and the neighbor provided information about the patient's current living situation and previous medical and social history. In the absence of contact information for other family members, and because the neighbor appeared knowledgeable about the patient's circumstances, facility staff allowed the neighbor to engage in discussions regarding the patient's medical needs.

The patient was initially admitted from the Emergency Department to the general medical unit under a 72-hour psychiatric hold in late March. The patient's admission diagnoses included encephalopathy and a UTI. Over the next three weeks, the patient's hospital course was marked by repeated episodes of confusion, agitation, and combative behavior, as well as the need for periodic use of physical restraints.<sup>25</sup>

The patient was transferred five times to different units, including twice to the locked mental health unit, with diagnoses including dementia, delirium, and [schizophrenia](#). On each unit, antipsychotic and sedative medications were administered based on standing (every four hours) or as-needed (PRN) orders to manage agitation.<sup>26</sup> Although the patient continued to be confused and intermittently volatile, the patient experienced brief periods of clarity and improved functioning. An [electroencephalogram](#) performed six days after admission was interpreted as "severely abnormal" and indicative of severe and generalized brain dysfunction of unknown cause. Additional imaging studies revealed no acute findings and the results of a [lumbar puncture](#) were not clinically significant. Medical and radiological workups for the cause of the patient's confusion did not reveal metabolic or infectious causes.

On hospital day 19, the patient was "agitated and kicking at staff" and was placed in seclusion and physical restraints. The inpatient psychiatrist requested Geriatrics and Extended Care (GEC) and palliative care consults, referencing the patient's mental status changes and prolonged hospitalization without improvement, as well as delirium and dementia. Upon consultation, a GEC physician, who was also the hospice program physician, recommended the patient be admitted to inpatient hospice as the result of having "SEVERE ENCEPHALOPATHY (DELIRIUM), unclear cause (may be METABOLIC vs. TERMINAL, TOXIC; possibly TERMINAL in nature) [original text contains the capitalized words]." A provider's life-sustaining treatment note that same day described the patient as lacking capacity to make

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<sup>25</sup> Facility Policy 603-18-118-008, *Restraint and/or Seclusion Clinical and Behavioral*, June 4, 2018. Clinical restraints are used when patients interfere with medical devices required to support healing. Behavioral restraints, such as physical restraints or medication, are used to manage unanticipated severely destructive or aggressive behavior that poses imminent danger.

<sup>26</sup> Facility Policy 603-18-118-021, *Bar Code Medication Administration (BCMA)*, April 21, 2018. PRN means "as needed," an abbreviation derived from the Latin *pro re nata*.

treatment decisions and identified the neighbor as the surrogate decision maker.<sup>27</sup> The neighbor consented to a [Do Not Resuscitate \(DNR\)](#) order for the patient and authorized the patient's transfer to hospice. The patient's diagnosis at the time of transfer to the hospice unit was end-stage dementia with terminal restlessness.

In late afternoon of hospital day 19, the hospice and palliative care team documented that the patient had hours to days to live. Initially combative, the patient was prescribed standing doses of [morphine](#), haloperidol, and lorazepam every four hours, as well as hourly doses of the same medications PRN for pain, restlessness, and anxiety, respectively. The patient was largely unresponsive. On hospital day 24, the patient was noted to be without a pulse and was pronounced dead.

The neighbor, who was identified in the EHR as the patient's surrogate decision maker, declined autopsy. However, a patient's family member, who was located and contacted three days after the patient's death, requested an autopsy. Because of tissue erosion after three days, the scope of the autopsy and results were limited to the brain, which showed cerebral edema, encephalopathy resulting from lack of oxygen to the brain, and evidence of mild neurodegenerative changes. A detailed patient case summary is located in [appendix A](#).

## Inspection Results

The OIG substantiated the allegation that a person who had no legal authority made medical decisions for the patient. The OIG based this determination on the facility's failure to follow VHA and facility policies and complete appropriate documentation. This report also outlines clinical management and related deficiencies, patient rights deficiencies, and the facility's response to medical care deficits.

### 1. Patient's Decision-Making Capacity and Surrogate Decision-Maker Deficiencies

#### Failure to Evaluate the Patient's Decision-Making Capacity

The OIG found that comprehensive assessments of the patient's decision-making capacity were not documented. VHA requires that a provider clinically assess and document a patient's ability to make decisions.<sup>28</sup> On the day of admission, a mental health provider noted the patient was "not decisional" and recommended a comprehensive mental health evaluation when the patient's

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<sup>27</sup> VHA Handbook 1004.03, *Life-Sustaining Treatment Decisions: Eliciting, Documenting and Honoring Patient's Values, Goals and Preferences*, January 11, 2017. A life-sustaining medical treatment is "intended to prolong the life of a patient who would be expected to die soon without the treatment."

<sup>28</sup> VHA Handbook 1004.01(2).

UTI cleared. Although the OIG found no documented evidence of comprehensive mental health assessments of the patient’s decision-making capacity, staff documented the patient’s ongoing confusion and impaired cognitive function throughout the hospitalization.

## **Failure to Follow Facility Processes to Establish a Surrogate Decision Maker**

The OIG determined facility staff did not take appropriate steps to identify and confirm the eligibility of a surrogate when the patient lacked decision-making capacity. Staff obtained an invalid authorization for release of information, did not consistently follow VHA policy to “make a reasonable inquiry” to identify an appropriate surrogate, and did not obtain and complete the required documentation verifying the neighbor met criteria to make decisions on behalf of the patient.<sup>29</sup>

### *Invalid Authorization for Release of Information*

When a patient’s authorization is required to release individually-identifiable information, the authorization must be in writing and include specific information, including the patient’s signature. However, if a patient has been deemed to lack decision-making capacity, the patient is ineligible to authorize the release of information. If the neighbor had been correctly verified as the surrogate, a release of information would not have been required, and the neighbor may have been legally authorized to consent on behalf of the patient.<sup>30</sup>

On hospital day 1, an Emergency Department nurse documented that the patient reported having family members, but [the patient] “will not/cannot give us their names or phone numbers.” Emergency Department staff subsequently found the neighbor’s name and contact number in the patient’s personal belongings; the patient did not verbally provide staff with the neighbor’s name. The Emergency Department social worker contacted the neighbor to make arrangements for the patient’s dog.

Although a mental health nurse practitioner documented the patient was “not decisional” and no subsequent assessments were documented to suggest otherwise, a social worker facilitated the patient signing a release of information form that permitted staff to speak with the neighbor. The improperly obtained authorization was repeatedly referenced in EHR notes when staff spoke with the patient’s neighbor. The invalid authorization, which identified the neighbor as the approved recipient of the patient’s information, may have implied designation as a surrogate that later became central to the request for the neighbor making important care decisions.

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<sup>29</sup> VHA Handbook 1004.01(2).

<sup>30</sup> VHA Directive 1605.01, *Privacy and Release of Information*, August 31, 2016.

### *Inadequate Search for Next of Kin*

The OIG determined that staff did not follow VHA guidance in their search for an appropriate surrogate. When a patient lacks decision-making capacity, VHA policy requires staff to “make a reasonable inquiry” to locate other possible persons to give informed consent on behalf of the patient, prioritized in order of healthcare agent, legal guardian or special guardian, next of kin, and close friend. To identify authorized surrogates, staff must examine all available information including personal effects, the EHR, and other VA benefits and pension records. Staff must document the process and outcome of efforts to identify a surrogate.<sup>31</sup>

The OIG determined that initial efforts to identify the patient’s next of kin were limited. The patient told the Emergency Department nurse of having family, and additional EHR notes reflected staff’s awareness that the patient also had relatives in another country, at some point previously. Despite this awareness and a social work consult specifically to locate the patient’s next of kin, social workers providing services to the patient did not conduct a vigorous review to locate relatives. Social workers documented that the patient did not have a healthcare agent or a guardian, the first two priority categories for surrogate status. To identify the next priority (next of kin), clinical staff told the OIG that they searched the patient’s belongings, as well as facility and other VHA facilities’ records. None of the social workers reviewed, or requested a review of, other VA records such as VA benefits records.

The OIG confirmed that the patient’s EHR, dating back multiple years and across sixteen VHA facilities, did not identify an emergency contact or next of kin. The patient’s EHR documentation was inconsistent as to whether the patient had children or other relatives. Further, the patient had decision-making capacity in the past but repeatedly did not provide the name(s) of an emergency contact, including any children. The OIG acknowledges that the patient’s intent and wishes regarding VA communication with next of kin were unclear, further complicating the difficult task to find an appropriate surrogate. Nevertheless, absent an explicit instruction (and documentation in the EHR) that family members were not to be contacted, the patient’s family members were the next in line for consideration as a surrogate.<sup>32</sup>

While staff uniformly acknowledged that a patient’s next of kin has priority over a close friend for selection as a surrogate decision maker, they reported varied understanding of the procedures and requirements for conducting a search for next of kin and documenting the results.<sup>33</sup>

After the patient’s death, administrative staff found a reference to the patient’s ex-spouse in VA benefits records. While the contact number was no longer operational, this information prompted

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<sup>31</sup> VHA Handbook 1004.01(2). Next of kin is a close relative of the patient eighteen years of age or older. The order of priority is spouse, child, parent, sibling, grandparent, and grandchild.

<sup>32</sup> VHA Handbook 1004.01(2).

<sup>33</sup> VHA Handbook 1004.01(2).

administrative staff to query the Veteran Information System where they found two veterans with the same first and last name. Administrative staff then searched Veterans Benefits Administration records for contact information and ultimately located and contacted a member of the patient's family.

While the neighbor declined autopsy, the patient's family member requested one. As the family member's request was received three days after death, the scope of the autopsy and results were limited to the brain. The facility chaplain documented calling the family member and leaving a bereavement message on the family member's voice mail. It is unknown what information was provided to the patient's family member. Additionally, the EHR does not contain documentation of disclosure to the family related to an unauthorized individual making decisions for the patient.<sup>34</sup>

### *Failure to Timely Evaluate and Document that the Neighbor Met Requirements to be the Patient's Surrogate Decision Maker*

Clinical staff acknowledged the neighbor, as "a close friend," was eligible to serve as the surrogate decision maker, but staff did not complete the required documentation. VHA defines a close friend as a person who shows care and concern for, and is familiar with, the patient's health, activities, beliefs, and values. VHA requires social workers or other staff to document in the patient's EHR that the requirement of close friend has been met by (1) obtaining and documenting a signed, written statement from the close friend specifically describing "that person's relationship to, and familiarity with, the patient," and (2) completing a signed and dated progress note, verifying that this requirement has been met.<sup>35</sup>

EHR documentation consistently reflected staff discussions with the neighbor regarding the relationship with, and knowledge of, the patient's background and general activities.<sup>36</sup> However, the OIG found no documentation that the neighbor provided a statement describing the relationship with the patient. Further, the OIG did not find formal documentation that the

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<sup>34</sup> VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. Disclosure of adverse events is a discussion that takes place between a provider and patient or patient's personal representative about the occurrence of a harmful or potentially harmful adverse event. A patient's clinician may inform the patient or the patient's representative about clinically significant events that occurred (clinical disclosure). A more formal process may be pursued during which "facility leader(s), together with clinicians and others as appropriate, inform the patient or the patient's personal representative that an adverse event has occurred... and provide specific information about the patient's rights and recourse" (institutional disclosure).

<sup>35</sup> VHA Handbook 1004.01(2).

<sup>36</sup> Facility staff told the OIG that they spoke with the neighbor on the phone and in-person and determined the neighbor had known the patient for two years, seemed "close," and was able to give details of the patient's activities. The OIG did not have specific concerns about the neighbor's qualifications or motivation to be the surrogate beyond the procedural issues noted in this report.

neighbor met “close friend” criteria until the hospice social worker placed a signed statement in the patient’s EHR on hospital day 20.

### *Impact of Surrogacy-Related Process Failures*

Despite having brief periods of clarity, the patient lacked decision-making capacity for the entirety of the hospitalization.<sup>37</sup> The neighbor, who was improperly established as the surrogate decision maker, was later asked to authorize the patient’s admission to hospice for end-of-life care, as well as for autopsy. While the OIG considers it likely that the neighbor made the decisions in good faith, they were nevertheless substantial and irreversible.

If staff had followed processes and obtained the required documentation, they may have evaluated the relationship between the patient and neighbor more thoroughly and concluded that additional efforts were needed to locate the patient’s next of kin.

## **2. Clinical Management Deficiencies**

In the context of the patient’s admission for an undefined acute illness, the OIG found insufficient medical documentation of clinical assessments, inconsistent and insufficient care communication and collaboration, and inconsistent documentation of monitoring and oversight of high-risk medications to provide a satisfactory rationale to place the patient in hospice care within three weeks of initial presentation.

### **Clinical Assessment**

The OIG determined that the patient’s EHR did not contain sufficient documentation of physicians’ clinical assessments to support diagnoses and treatment decisions. The Joint Commission (TJC) requires providers assess and reassess patients to deliver the right care and treatment by collecting information about a patient’s health history, analyzing the information to understand the patient’s needs, and making decisions based on the analysis of the information.<sup>38</sup> On hospital day 1, the consulting psychiatrist documented schizophrenia as a possible diagnosis without conducting an assessment using relevant criteria, despite the patient being an unlikely candidate given age and lack of psychiatric history.<sup>39</sup> On hospital day 3, the same psychiatrist wrote, “I am leaning toward a [diagnosis of] schizophrenia,” again without documenting the

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<sup>37</sup> Although the patient had periods of being less confused throughout the hospitalization, the EHR did not reflect that decision-making capacity was re-evaluated at those times to determine if the patient could make decisions.

<sup>38</sup> The Joint Commission Standards Manual, *Hospital Accreditation Requirements Provision of Care, Treatment, and Services (PC)*, PC.01.02.01, January 1, 2019.

<sup>39</sup> Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, *American Psychiatric Association*, Schizophrenia Spectrum and Other Psychotic Disorders. September 25, 2014 (online). The psychotic features of schizophrenia typically emerge between the late teens and the mid-30s.

<https://doi.org/10.1176/appi.books.9780890425596.dsm02>. (The website was accessed on January 22, 2020.)

criteria and thought-process involved in the determination. The schizophrenia diagnosis was repeated across clinical providers and inpatient units for the remainder of the patient's hospitalization even though the EHR contained no documentation of a focused assessment supporting the diagnosis. Providers may have used the schizophrenia diagnosis to make decisions about the patient's treatment and interventions, including a 72-hour psychiatric hold, admission to a locked mental health unit, and the use of high-risk medications.

The OIG found additional clinical assessment failures reviewed below.

*Example A: During hospitalization, the patient had two documented falls, was periodically in physical restraints, and was noted to be restless and grimacing, which are nonverbal signs of pain. However, the patient's pain symptoms and potential causes were not evaluated until the hospice provider documented pain to be a "very likely significant contributor" to the patient's condition.*

*Example B: On hospital day 11, a neurologist saw the patient for the first time and diagnosed "encephalopathy in the setting of paranoid schizophrenia," despite being unable to speak with the patient or perform a complete examination due to the patient's heavy sedation. The neurologist reviewed the active medication list but did not document a review of the patient's history of medications during the hospitalization, medical history, or vital signs, and did not note the patient's fever that day. Although the assessment was incomplete, the neurologist made recommendations for treatment and testing. Further, the neurologist told the OIG that upon examination, the patient had increased muscle tone throughout the body, which the neurologist attributed to schizophrenia and the patient's presumed chronic use of antipsychotic medications.<sup>40</sup> The neurologist's apparent acceptance of the schizophrenia diagnosis and assumption the patient had been on long-term antipsychotic medications resulted in the neurologist not seeking alternative explanations for the patient's rigidity, such as pain or muscle spasms.*

The OIG acknowledges that the patient's symptoms and presentation were complex and confounding, and that the avenue for diagnosis and treatment was not straightforward. Nevertheless, providers' failures to document adequate assessments may have contributed to the patient's complicated hospital course and adverse clinical outcome.

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<sup>40</sup> George M. Brenner, PhD, and Craig W. Stevens, PhD, "Psychotherapeutic Drugs" in Brenner and Steven's Pharmacology, Fifth Edition. A potential side effect of long-term use of antipsychotic medications is Parkinsonism, which is characterized by rigidity and tremor. [https://www.academia.edu/37111529/Brenner\\_and\\_Stevens\\_Pharmacology\\_5\\_ed](https://www.academia.edu/37111529/Brenner_and_Stevens_Pharmacology_5_ed). (The website was accessed on January 16, 2019.)



While the patient’s medical workup was wide-ranging and consisted of bloodwork, cerebral spinal fluid analysis, and multiple imaging tests, providers did not have a clear medical diagnosis. It appeared that providers alternatively considered a primary mental health disorder; however, the patient’s psychiatric medications complicated the analysis of a psychiatric problem because these drugs also cause sedation or delirium in some vulnerable patients. The patient was on multiple medications without a documented plan to reassess how the patient responded when off medications prior to declaring the patient hospice-ready. Avoiding or reducing anticholinergic, benzodiazepine, and sedative-hypnotic medications in older patients may improve delirium.<sup>41</sup>

## Communication and Collaboration

The OIG determined that providers’ communication and collaboration across clinical disciplines and services were inconsistent and insufficient, which negatively affected the patient’s continuity and quality of care. TJC requires that processes be in place to communicate patient information during transitions in care and that hand-off communication allows for discussions between the giver and the receiver.<sup>42</sup> In this case, communication and collaboration were imperative because five clinical services were considering multiple different diagnoses and interventions over the course of the hospitalization; the patient had a complicated clinical picture that was not improving; and the patient presented a behavior management challenge that required significant resources.<sup>43</sup> Examples of communication and collaboration failures are described below:

*Examples C and D: A neurologist performed a limited assessment of the patient on hospital day 11, made recommendations for treatment, and documented that patient follow-up was “as needed.” The neurologist told the OIG of not being asked to, and did not, see the patient again. A psychiatrist told the OIG of not suggesting to a subsequent treatment team that steroids could be tried to treat possible encephalopathy. A psychiatrist told the OIG that the “practice here is that, once somebody is not under your care, that’s it.” The OIG noted that consultations with clinical colleagues assist to confirm diagnoses and shape treatment plans.<sup>44</sup>*

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<sup>41</sup> Jin H. Han, MD, MSc, Scott T. Wilber, MD, MPH, Altered Mental Status in Older Emergency Department Patients, *Clinical Geriatric Medicine*, February 2013. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3614410/> (The website was accessed on September 3, 2019.)

<sup>42</sup> The Joint Commission Standards Manual, PC.02.02.01, July 1, 2019.

<sup>43</sup> During the hospitalization, the patient was diagnosed with low back pain, UTI, delirium, encephalopathy, schizophrenia, acute psychosis, post-traumatic stress disorder, cerebral atrophy, altered mental status, dementia, alcohol dependence disorder in remission, and terminal restlessness.

<sup>44</sup> Kenneth M Langa and Deborah Levine, “The Diagnosis and Management of Mild Cognitive Impairment: A Clinical Review,” *Journal of the American Medical Association* 312, no. 23 (December 17, 2014): 2551–2561.

*In addition, several providers told the OIG that the patient's condition was possibly reversible and not fatal. However, the OIG found no documentation that these providers were consulted following their initial involvement with the patient, or that these providers discussed their opinions with treatment providers, who were responsible for the patient's care, prior to the patient's transfer to hospice care. While providers can and do disagree, their varied perspectives may offer an opportunity for a clinically robust discussion including options and recommendations.*

*Example E: On hospital day 15, a psychiatrist saw the patient on the general medical unit and wrote that the patient was in bed with a feeding tube, restraints, and a condom catheter, and that a physical therapy consult was ordered "which may clarify the issue in order to transfer to [the locked mental health unit]. If [the patient] is too weak to walk [the patient] would need to stay in a hospital bed on the medical unit." The plan also noted "assess ability to ambulate and if able to do so transfer to [the mental health unit]."<sup>45</sup>*

*The following day, a physical therapist was unable to complete a functional evaluation due to the patient's mental status issues and inability to engage in the process. Nevertheless, the patient was transferred that morning, a weekend day, without a functional assessment reflecting the patient, who was deconditioned and medically fragile, could adequately manage the mental health unit environment. Upon admission to the locked mental health unit, the patient was placed on 1:1 nursing observation for safety, aggression, and confusion. An EHR note shortly after admission reflected, "[Patient] is frequently needing 2-3 staff members to keep [patient] in [wheelchair] or in bed."*

*Staff told the OIG that the locked mental health unit was not designed or staffed to care for a patient with dementia and/or delirium. Further, the mental health unit staff were unable to use physical restraints on the patient for long periods of time.<sup>46</sup> In light of this, and in an apparent effort to manage agitation and behavior, the patient received lorazepam, as well as three doses of a new medication, olanzapine.*

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<sup>45</sup> The patient's feeding tube and restraints were discontinued prior to transfer to the mental health unit, but the patient still required assistance with activities of daily living and the patient was placed on 1:1 observation because of combativeness.

<sup>46</sup> National Patient Safety. *Mental Health Environment of Care Check List*. Furniture in the locked mental health unit should not have anchor points for hanging and, as a result, restraints can only be used in an open seclusion room monitored by staff. <https://www.patientsafety.va.gov/professionals/onthejob/mentalhealth.asp>. (The website was accessed on November 20, 2019.)

Overall, the OIG found that the patient’s providers did not consistently communicate and collaborate with other providers in ways that would promote robust discussion and a multidimensional view of the patient’s condition, thus limiting the way care was approached.

## **Medication Monitoring and Oversight**

The OIG noted that providers prescribed moderate to high doses of antipsychotic and sedative medications concurrently to the patient but did not consistently document medication monitoring and oversight activities to ensure safe patient care. Further, the unsupported but often repeated diagnosis of schizophrenia may have been central to providers’ decisions to prescribe multiple high-risk medications.

The patient’s behavior and care needs were challenging, and providers chose antipsychotic medications in an attempt to improve functioning and ensure the patient’s and staff’s safety. However, because the patient was older, was cognitively impaired, and had not been on antipsychotic medications in the past, a cautious approach and ongoing monitoring was indicated.<sup>47</sup>

The patient was administered multiple medications during the hospitalization including haloperidol, olanzapine, quetiapine, and risperidone, all of which are associated with risk of poor health outcomes in the elderly, including confusion, falls, and mortality.<sup>48</sup> According to general geriatric prescribing principles for antipsychotic medications, providers should “start low and go slow,” which necessarily requires clinicians to monitor medications to determine the lowest doses that achieve the desired results. Further, clinical medication review is indicated for older patients on multiple medications to eliminate medications that are not indicated or effective or that are duplicated.<sup>49</sup>

The OIG found that providers failed to monitor the patient’s medications in support of patient care and safety. At times, the patient’s cognition cleared when medications were reduced or withdrawn; however, the medications were frequently restarted, or additional medications were prescribed. Specifically, on hospital day 12, the patient’s PRN lorazepam was discontinued, and an ICU physician documented that the patient had “awakened from stupor with rigidity and has started to talk.” The next day, the patient was transferred to the medical unit and prescribed quetiapine for agitation, along with other medications. Several providers told the OIG they were

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<sup>47</sup> Ming Li, “Antipsychotic-induced sensitization and tolerance: Behavioral characteristics, developmental impacts, and neurobiological mechanisms,” *Journal of Psychopharmacology* 30, no. 8 (2016): 749–770.

<sup>48</sup> American Geriatrics Society 2019 Beers Criteria Update Expert Panel, “Updated AGS [American Geriatrics Society] Beers Criteria for Potentially Inappropriate Medication Use in Older Adults,” *Journal of American Geriatrics Society* 67, no.4 (January 29, 2019): 674–694.

<sup>49</sup> Robert L. Maher, Joseph T. Hanlon, and Emily Hajjar, “Clinical Consequences of Polypharmacy in Elderly,” *Expert Opinion on Drug Safety* 13, no. 1 (January 2014): 57–65.

aware of medication warnings and/or had seen improvement in the patient's alertness when they reduced or eliminated these medications. However, the OIG did not find evidence that providers attempted a trial of withdrawing and simplifying the patient's medication regimen, which may have improved cognitive function.

Inpatient psychiatrists' transfer notes did not clearly document medication reconciliation, in which the provider reviews the patient's active medications and reconciles this list with medications provided on other units, as required by facility policy.<sup>50</sup> The act of documenting each medication could have signaled to the psychiatrist the complexity of the patient's medication regimen.

Nurses did not consistently document the effectiveness of the patient's high-risk PRN medications in the Bar Code Medication Administration system as required. Facility policy required PRN effectiveness to be documented within 90 minutes of medication administration.<sup>51</sup> The OIG reviewed the patient's PRN medications administered during the hospitalization and determined that 25 of 74 (34 percent) PRN doses did not include subsequent documentation of medication effectiveness.<sup>52</sup> The act of documenting PRN effectiveness may have revealed that some medications were not consistently effective in managing the patient's agitation and behavior, and in some cases, may have been causing the symptoms or exacerbating the patient's condition.

Without review and oversight of the patient's medications across the hospitalization, providers may have been unaware of which medications the patient had already received and what effects medications had on the patient's condition. Further review of the patient's medication regimen to evaluate sensitivities, interactions, and toxicity may have revealed the opportunity to decrease psychoactive medications for a period of time and improve the patient's functioning.

## **Transfer to Hospice**

The OIG reviewed the patient's EHR and determined there were concerns related to the patient's transfer to hospice. The OIG found the patient, whose condition was declining for unknown reasons, was clinically challenging. After multiple transfers between wards and limited clinical successes, the patient was seen by a GEC physician who referred the patient to the palliative care

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<sup>50</sup> Facility Policy 603-17-119-003, *Medication Reconciliation*, August 19, 2017.

<sup>51</sup> Facility Policy 603-18-118-021. Bar Code Medication Administration is software used to validate the administration of medications.

<sup>52</sup> The OIG reviewed all PRN medications, not just psychoactive medications.

team.<sup>53</sup> On hospital day 19, the GEC physician diagnosed the patient as having “SEVERE ENCEPHALOPATHY (DELIRIUM), unclear cause (may be METABOLIC vs. TERMINAL, TOXIC; possibly TERMINAL in nature) [original text contains the capitalized words].” The palliative care team spoke with the patient’s neighbor who relayed the patient’s wishes to not have life-sustaining measures and consented to the plan for hospice and comfort care. The GEC physician changed the patient’s status to DNR and transferred the patient to the hospice unit.

### *Determination of Terminal Status*

The OIG found that providers failed to attempt additional interventions and rule out diagnoses that may have clarified the patient’s condition, terminal or not, prior to hospice transfer. Although the patient had a similar presentation two weeks prior that prompted transfer to the intensive care unit (ICU), for this transfer, providers changed the patient’s status to DNR and transferred the patient to hospice, and did not consider readmission to the ICU. The time from initial GEC consultation to the patient’s transfer to hospice was less than two hours. Providers did not reduce or discontinue medications for a period of time that may have allowed the patient’s confusion to clear. Further, providers did not wait for completion of laboratory test results to rule out other conditions that have a similar neurological presentation. The test results, although negative, were received and documented after the patient’s death.

As noted previously, the decision to request end-of-life care in the context of an undefined illness or potentially reversible disease should be considered prior to initiating a hospice referral. The OIG concluded that the transfer to hospice was completed without fully pursuing other differential diagnoses and treatment options.

### *Hospice Transfer and Life-Sustaining Treatment Decisions*

The OIG noted that throughout the patient’s hospitalization, facility staff discussed the patient’s care with the neighbor. Although the neighbor was told about, and verbally agreed to, the patient’s lumbar puncture on hospital day 11, the facility did not use this agreement as authorization for the lumbar puncture. Rather, the facility appropriately instituted a substituted consent process in which a clinical leader consented for the patient’s lumbar puncture.

If a patient does not have a surrogate decision maker, the patient’s physician can provide substituted consent for certain treatments and procedures. If the patient’s physician recommends

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<sup>53</sup> VHA Directive 1140.09, *Geriatrics Consultation*, June 28, 2017. GEC consultants usually function as both primary care providers and specialists on the management of older and medically complex patients. VHA Directive 1139, *Palliative Care Consult Teams (PCCT) and VISN Leads*, June 14, 2017. Hospice and palliative care interdisciplinary teams provide a continuum of services for comfort and support for persons with serious illness in a variety of settings. Hospice is intended for individuals diagnosed with a known terminal condition with a prognosis of six months or less.

withholding or withdrawal of treatment, a committee, such as the Integrated Ethics Council, acts as an advocate for the patient. The multidisciplinary committee reviews the recommendation, seeks input from the patient’s cultural, ethnic, or religious group if possible, and submits a written report to the Chief of Staff. The Chief of Staff must review and approve or disapprove the committee’s recommendation and the facility director may concur, not concur, or request review by the Office of General Counsel.<sup>54</sup>

When the recommendation for hospice care and life-sustaining treatment decisions was made, the facility contacted the neighbor for consent. These decisions were significant, and it was unclear to the OIG why the facility did not use the substituted consent process, as done for the lumbar puncture, or the interdisciplinary committee process that was specifically designed for cases like this.<sup>55</sup>

### *Documentation Regarding Cause of Death*

The physician who pronounced the patient’s death documented the cause as “complications related to dementia, including but not limited to poor oral intake and likely multiorgan failure.” The autopsy, which was limited to the brain, showed cerebral edema, accumulation of fluid and swelling in the brain, encephalopathy resulting from lack of oxygen to the brain, and evidence of mild neurodegenerative changes. The autopsy report reflected that brain changes “[fell] short of a definitive diagnosis of Alzheimer’s disease.” The hospice physician; however, offered a differing summary and wrote that the autopsy results showed brain changes “not suggestive of typical Alzheimer’s disease but rather atypical rapidly progressive dementia underlying an acute encephalopath[y] process” and that the clinical diagnosis of schizophrenia was ruled out. The OIG concluded that the pathology results did not support a rapidly progressing dementia nor did the results evaluate schizophrenia.

## **3. Patient Rights Deficiencies**

During this review, the OIG determined staff did not consistently follow procedures designed to ensure patient rights were upheld with respect to 72-hour involuntary admission holds and behavioral restraints.

### **72-hour Involuntary Admission Hold**

Facility staff did not follow VA policy, TJC guidelines, and Kentucky law governing the patient’s involuntary 72-hour admission status.<sup>56</sup> The patient was transferred to the locked

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<sup>54</sup> VHA Handbook 1004.01(2).

<sup>55</sup> VHA Handbook 1004.01(2).

<sup>56</sup> VHA Handbook 1160.06, *Inpatient Mental Health*, September 16, 2013. The Joint Commission Standards Manual. Kentucky Revised Statutes Chapter § 202A.

mental health unit during hospitalization; however, staff did not follow required processes or complete appropriate documentation because staff stated they were unaware of responsibilities and requirements.

VHA facilities must adhere to their respective state's laws regarding involuntary admissions, and consultation with Office of General Counsel is recommended due to the variation in state laws.<sup>57</sup> The Kentucky Revised Statutes 202A require patients who are involuntarily hospitalized to be

- Mentally ill,
- A danger to self or others as a result of mental illness, and
- Able to benefit from treatment.

Further, hospitalization must be the least restrictive alternative mode of treatment.

The statutes require that within 24 hours of the admission, an authorized staff physician certifies and documents that the patient should be involuntarily hospitalized. For patients who remain hospitalized, and who do not or cannot consent to voluntary admission, there must be a petition to the court that includes two mental health professionals' certifications. In addition, facility policy requires providers to document in the EHR the specific reasons for seeking termination or continuation of a patient's involuntary admission status.<sup>58</sup>

### *The Patient*

The patient's involuntary 72-hour hold order was entered by the Emergency Department physician on hospital day 1 in the early morning. The Emergency Department physician wrote, "if a subsequent involuntary petition is not filed, the patient must be released by [the next day at 7:00 a.m.]" The Emergency Department physician documented the requirement to release the patient the following day, which was likely an error because the order was for a 72-hour hold, and the actual requirement for release would have been at least three days later in accordance with Kentucky statutes. However, the OIG found no evidence that providers followed procedures to continue the patient's involuntary admission status after the initial 72-hour hold expired. Further, the OIG determined that the patient was transferred to the locked mental health unit without appropriate 72-hour hold authorization. The OIG found no documentation that the patient regained decision-making capacity and agreed to voluntary admission, that an additional 72-hour hold was ordered, or that a court petition was filed. Due to the lack of documentation, it was unclear whether providers discussed the transfers with the neighbor. The OIG interviewed three staff who were not able to define either the process or who the responsible persons were for ensuring adherence to policy and legal requirements for the 72-hour involuntary hold.

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<sup>57</sup> VHA Handbook 1160.06.

<sup>58</sup> VHA Handbook 1907.01, *Health Information Management and Health Records*, March 19, 2015.

## *Other Patients*

To evaluate whether other patients were involuntarily admitted to the locked mental health unit without appropriate authorization, the OIG reviewed EHRs for 12 patients on 72-hour holds who were transferred from the medical unit to the locked mental health unit between January 1, 2019, and July 29, 2019. The OIG found four 72-hour hold orders for three patients that included incorrect dates and times for patient release, resulting in patients being held involuntarily without an accurate physician order. Additionally, for one of the patients, a physician documented the patient agreed to a voluntary admission after a hold expired even though the patient's decision-making capacity and cognitive functioning had not been evaluated. Another patient did not have either a voluntary or involuntary admission status documented after the hold expired and continued to be hospitalized for eight more days. As a facility leader stated to the OIG, failure to appropriately authorize involuntary admissions places patients at risk for being kept on the locked mental health unit against their will.

## **Restraints**

The OIG identified deficits in the management and documentation of behavioral restraints for the patient at issue.<sup>59</sup> Clinical restraints, such as hand mittens and soft wrist restraints, can be applied to support medical healing when a patient is attempting to interfere with a physical treatment or device (for example, an intravenous line, a ventilator tube, or a dressing) and less restrictive approaches have not prevented this interference. Behavioral restraints, such as mechanical restraints like keyed hand and leg cuffs, are used to manage an emergency or unanticipated situation in which severely aggressive and destructive behaviors place the patient and staff in imminent danger.<sup>60</sup> Facility policy requires nurses to assess and document the patient's mental status and circulation every two hours for patients in clinical restraints and every 15 minutes while the patient is in behavioral restraints to ensure patient safety.<sup>61</sup>

The patient was placed in clinical or behavioral restraints, including two-point and four-point restraints, intermittently for 15 days including 11 times in clinical restraints and six times in behavioral restraints. The OIG reviewed the EHR for these episodes of care and determined clinical restraint documentation was compliant, but the behavioral restraint documentation was not consistently compliant with TJC requirements and facility policy. Specifically, on hospital days 5, 8, and 15, nurses did not document the 15-minute behavioral restraint assessments as required.

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<sup>59</sup> VHA Handbook 1160.06. The Joint Commission Standards Manual, RC.02.01.05. 38 CFR § 17.33 (d). Facility Policy 603-18-118-008.

<sup>60</sup> Facility Policy 603-18-118-008.

<sup>61</sup> Facility Policy 603-18-118-008.



Consistent assessment and monitoring of patients in restraints by qualified staff is essential, because patients who are immobilized for extended periods of time are at an increased risk of developing blood clots.<sup>62</sup>

### *Restraint-Related Training and Competency*

The OIG determined that the facility did not meet certain TJC requirements related to restraint training. TJC requires the facility to train staff on the use of restraints and seclusion and assess their competence at orientation, before caring for patients in restraints or seclusion, and on a periodic basis thereafter as specified in the facility policy.<sup>63</sup> Facility policy requires nursing staff to receive training in restraint usage to satisfactorily demonstrate the knowledge, skill, and ability to use alternatives to restraints; however, the policy does not specify initial training and competency requirements or the frequency of periodic follow-up training and competency assessment.<sup>64</sup> The facility's restraint coordinator told the OIG that staff are to receive initial and annual restraints training.

The OIG found deficits with staff training and competency on restraint usage and documentation. The OIG reviewed training and competency files for the 26 staff members who provided care for the patient while in restraints.<sup>65</sup> Although all 26 staff members received training for restraints and seclusion upon hire (which included quick-release soft wrist restraints), annual training was lacking. Nine of 26 (35 percent) staff members completed restraint and seclusion annual training and 2 of 26 (8 percent) completed the annual behavioral restraint training. When staff are not adequately trained and competent in restraint usage, patient care and safety could be compromised.

## **4. Facility Leaders' Response**

The OIG found that facility leaders did not complete a thorough review of certain quality of care aspects of this case to understand the reasons for the patient's atypical hospital course and outcome.

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<sup>62</sup> Emeka Kesieme, Chinenye Kesieme, Nze Jebbin, Eshiobo Irekpita, Andrew Dongo, Deep vein thrombosis: a clinical review, *Journal of Blood Medicine*, 2011 <https://www.ncbi.nlm.nih.gov/pubmed/22287864> (The website was accessed on November 14, 2019.)

<sup>63</sup> The Joint Commission Standards Manual PC.03.05.17; Facility Policy 603-18-118-008.

<sup>64</sup> Facility Policy 603-18-118-008.

<sup>65</sup> Facility Policy 603-18-118-008. "All direct care staff in the clinical settings where restraints may be used are trained and competent to prevent the use of restraint and/or seclusion through non-physical interventions, and/or provide for the patient's care and safety when restraints and/or seclusion are used."

Peer reviews, evaluations of episodes of care by peers (providers of similar background, training, and experience) are conducted to improve patient care.<sup>66</sup> Facility staff initiated a review of one provider's care while the patient was hospitalized. The peer reviewer suggested additional reviews that were not followed-up.

VHA also requires facility staff to review all patient deaths during inpatient hospitalization, including hospice deaths, to determine if a peer review is required.<sup>67</sup> However, the facility's process for identifying deaths requiring review did not include hospice deaths, and facility staff therefore incorrectly determined that an additional review was not required.<sup>68</sup> Peer reviews focusing on the continuum of care through the patient's death may have provided a more comprehensive overview of the patient's care needs and challenges such that future care could be improved for other patients.

This report outlines multiple junctures where providers failed to render sufficient continuity and quality of care, including assessment documentation, communication and collaboration, and medication monitoring and oversight. Prior to interview, the OIG requested that clinicians directly involved in the patient's care review the EHR to re-familiarize themselves with the case and their respective roles. Despite this retrospective review, clinicians largely denied to the OIG that care could have (or should have) been provided differently. The facility and provider responses did not appear, in the OIG's opinion, to acknowledge the learning opportunities this case presented.

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<sup>66</sup> VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. An episode of care includes all services provided to a patient during a specific period of time.

<sup>67</sup> VHA Directive 1190.

<sup>68</sup> VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. An additional review may have included a root cause analysis, a process to identify causal factors.

## Conclusion

The OIG substantiated that a person with no legal authority made medical decisions for the patient due to the facility's failure to follow policies and complete appropriate documentation. Initially in the Emergency Department, the patient was assessed to be "not decisional." The OIG found that mental health assessments of the patient's decision-making capacity were not documented during the hospitalization despite evidence of the patient's cognition improving at times.

The OIG determined facility staff did not take appropriate steps to identify and confirm the eligibility of a surrogate when the patient lacked decision-making capacity. Staff obtained an invalid authorization for release of information, did not consistently follow VHA policy to make a "reasonable inquiry" to identify an appropriate surrogate, and did not obtain and complete the required documentation verifying the neighbor met criteria to make decisions on behalf of the patient. The patient's neighbor, who was improperly established as the surrogate decision maker, was later asked to authorize admission to hospice for end-of-life care, as well as for autopsy. Three days after the patient's death, administrative staff located and contacted a family member who was the next of kin.

The OIG found insufficient documentation of clinical assessments, inconsistent and insufficient care communication and collaboration, and inconsistent documentation of monitoring and oversight of high-risk medications. The OIG acknowledges that the patient's symptoms and presentation were complex and confounding, and that the avenue for diagnosis and treatment was not straightforward. Despite wide-ranging medical workups, providers had not identified a clear diagnosis, and it appeared that providers alternatively considered a primary mental health disorder to explain the patient's clinical situation. However, the EHR did not contain sufficient documentation to demonstrate that some physicians conducted adequate clinical assessments to support diagnoses and treatment decisions, and an unsupported schizophrenia diagnosis may have been used to make decisions about the patient's treatment and interventions.

Communication and collaboration across clinical disciplines and services were inconsistent and insufficient. In this case, communication and collaboration were imperative because providers with five clinical services were considering multiple different diagnoses and interventions over 24 days; the patient had a complicated clinical picture that was not improving; and the patient presented a behavior management challenge that required significant resources. Providers' communication and collaboration patterns did not promote robust discussion and a multidimensional view of the patient's condition, thus limiting the way care was approached.

Providers prescribed moderate to high doses of antipsychotic and sedative medications, which are associated with risk of poor health outcomes in the elderly, but did not consistently document medication monitoring and oversight activities to ensure safe patient care. At times, the patient's cognition cleared when medications were reduced or withdrawn; however, the medications were

frequently restarted, or additional medications were prescribed. While several providers told the OIG that they were aware of medication warnings or had seen improvement in the patient's alertness when they reduced or eliminated these medications, the OIG did not find evidence that providers attempted a trial of withdrawing and simplifying the patient's medication regimen, which may have improved cognitive function. In addition, inpatient psychiatrists' transfer notes did not clearly document the patient's active medications and reconcile this list with medications provided on other units, as required; and nurses did not consistently document the effectiveness of the patient's high-risk PRN medications.

The OIG concluded that the patient's transfer to hospice was completed without fully pursuing other differential diagnoses and treatment options. The decision to request end-of-life care in the context of an undefined illness or potentially reversible disease should be considered prior to initiating a hospice referral.

Staff did not consistently follow procedures designed to ensure the patient's rights were upheld with respect to 72-hour involuntary admission holds and behavioral restraints. The patient was admitted to the medical unit and transferred to the locked mental health unit although the EHR did not contain evidence that staff followed appropriate processes to secure authorization. Staff the OIG interviewed stated they were not able to define the process and responsible persons for ensuring adherence to policy and legal requirements for the 72-hour involuntary hold. The OIG found four 72-hour hold orders for three other patients that included incorrect dates and times for patients' release, resulting in patients being held involuntarily without an accurate physician order.

The OIG found that behavioral restraints documentation was not consistently compliant with TJC requirements and facility policy. For the patient, nurses did not document the 15-minute assessments as required on hospital days 5, 8, and 15. The OIG also found deficits with staff training and competency on restraint usage and documentation. While all 26 staff members who cared for the patient during the hospitalization received training for restraints and seclusion upon hire, annual training for a majority of staff was lacking. Nine of 26 (35 percent) completed restraint and seclusion annual training and 2 of 26 (8 percent) completed the annual behavioral restraint training.

After leaders were informed of the circumstances of the patient's death, the OIG found that the facility did not complete a thorough review of quality of care aspects to understand the reasons for the patient's atypical hospital course and outcome. Providers largely denied to the OIG that care could have, or should have, been provided differently. The facility and provider responses did not appear, in the OIG's opinion, to acknowledge the learning opportunities this case presented.

## Recommendations 1–15

1. The Robley Rex VA Medical Center Director ensures staff document clinical assessments of patients' decision-making capacity throughout hospitalization as required by Veterans Health Administration policy.
2. The Robley Rex VA Medical Center Director evaluates social worker practices related to facilitating the release of information when a patient lacks decision-making capacity, and takes action as indicated.
3. The Robley Rex VA Medical Center Director establishes "reasonable inquiry" parameters for determination of a surrogate as required by Veterans Health Administration policy and provides staff education as needed.
4. The Robley Rex VA Medical Center Director ensures that when patients lack decision-making capacity, staff verify and document the status of surrogates, and the efforts to identify surrogates, according to Veterans Health Administration policy.
5. The Robley Rex VA Medical Center Director evaluates the quality and comprehensiveness of clinical documentation in support of diagnoses and treatment decisions across the patient's hospitalization, and takes action as indicated.
6. The Robley Rex VA Medical Center Director ensures interdisciplinary and cross-service communication and collaboration for complex patients and monitors compliance.
7. The Robley Rex VA Medical Center Director ensures providers complete medication reconciliation for patients transferred to the mental health unit(s) as required by Veterans Health Administration and Robley Rex VA Medical Center policies.
8. The Robley Rex VA Medical Center Director ensures compliance regarding completion of documentation of PRN (as needed) medication effectiveness as required by Veterans Health Administration and Robley Rex VA Medical Center policies.
9. The Robley Rex VA Medical Center Director reviews clinical decision-making and administrative processes relative to the patient's admission to hospice, and takes appropriate actions as indicated.
10. The Robley Rex VA Medical Center Director develops a mechanism to ensure involuntary admissions (72-hour holds) for current and future patients are managed and documented according to Veterans Health Administration and Robley Rex VA Medical Center policies, and Kentucky state laws.
11. The Robley Rex VA Medical Center Director develops a mechanism to ensure that patients in behavioral restraints are assessed every 15 minutes as required, and that documentation complies with Veterans Health Administration policy.

12. The Robley Rex VA Medical Center Director ensures that its policy on restraints and seclusion is updated to reflect the frequency of training requirements, and that staff are appropriately trained and competent in the use of restraints as required by Veterans Health Administration and Robley Rex VA Medical Center policies.

13. The Robley Rex VA Medical Center Director takes action to ensure processes for reviewing inpatient deaths is consistent with Veterans Health Administration policy.

14. The Robley Rex VA Medical Center Director reviews the patient's continuum of care and evaluates if additional peer reviews and/or other quality reviews are warranted, and takes action as indicated.

15. The Robley Rex VA Medical Center Director reviews the circumstances related to an unauthorized individual making decisions for the patient and conducts appropriate disclosure to the patient's representative as warranted.

## Appendix A: Detailed Patient Case Summary

The patient, in their mid-70s, had a history of diabetes, high blood pressure, heart disease, chronic back pain, adjustment disorder, and mild cognitive impairment.<sup>69</sup> The patient, accompanied by a service dog, was brought to the facility Emergency Department by ambulance in spring 2019. Prior to this, the patient had been living independently, including managing finances.

The patient had not received prior care at the facility but had been followed for mild cognitive impairment by neurology providers at another VA medical facility since 2017. The patient was also followed sporadically at several VAs since 2000, including by mental health providers for symptoms of anxiety that were thought to be due to ongoing pain and stress from a back injury suffered many years prior. The patient's last mental health clinic visit was in spring 2017.

### Emergency Department

In the Emergency Department, the patient complained of back pain. The Emergency Department physician documented the patient was alert and oriented, "healthy appearing," and in "no acute distress." Vital signs were normal, and a physical examination was unremarkable except to note that the patient was confused, "redirectable with difficulty," and "intermittently volatile."<sup>70</sup>

The Emergency Department physician diagnosed a UTI from an abnormal urinalysis and suspected that the patient had a baseline dementia with a delirium from the infection. The Emergency Department physician wrote orders for the patient to receive intravenous antibiotic medication and a 5 milligram (mg) dose of intramuscular haloperidol.

A mental health nurse practitioner saw the patient in the Emergency Department and concluded that the patient's clinical presentation was consistent with a delirium of medical origin. The mental health nurse practitioner documented the patient as "not decisional" and recommended a follow-up psychiatric assessment once the UTI cleared.

The patient was admitted to the facility's general medical unit under a psychiatric 72-hour hold. The patient's admission diagnoses included encephalopathy and a UTI.

### General Medical Unit

On the general medical unit, providers continued antibiotics for the UTI and antipsychotic medications PRN for agitation. The consulting psychiatrist concurred with the diagnosis of

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<sup>69</sup> The OIG uses the singular form of they (their) in this instance for patient privacy concerns.

<sup>70</sup> The patient wanted to burn approximately \$15,000 with a lighter believing it was counterfeit and could not explain the travel to the facility from Ohio. The patient reported having family members but was unable to provide family contact information.

encephalopathy and recommended risperidone, if needed, for symptoms of agitation. The consulting psychiatrist documented that the patient might have untreated paranoid schizophrenia. The patient remained agitated throughout hospital day 1, and received another dose of haloperidol and two doses of risperidone.

On hospital day 2, EHR documentation reflected the patient was “upset” and oriented to self and location but not to the date. Later in the morning, the covering psychiatrist was unable to complete a full evaluation because of concern that the patient might be physically aggressive. The covering psychiatrist documented the patient may have untreated schizophrenia as well as an encephalopathy and recommended transfer to the locked inpatient mental health unit.

Initially, the patient had an elevated total bilirubin test that was documented as present prior to admission, the patient’s additional test during the hospitalization showed improvement. Blood tests for hepatitis, a viral infection of the liver, were negative. The laboratory studies of the patient’s electrolytes, thyroid function, vitamin levels, ammonia level, lactic acid, and coagulation studies were all within normal range. Although the patient had a history of diabetes, the patient’s glucose levels were well controlled.

The patient had a period of confusion and agitation, and broke a window. The patient had cut hands from the broken glass but warned staff not to approach. A hand x-ray did not show additional acute injury. The patient was transferred to the locked mental health unit; the documented diagnosis was encephalopathy.

**Table A.1. Psychoactive Medications on the General Medical Unit**

Medication	Dosage	Number of Times Administered
Haloperidol	5 mg	1
Risperidone	2 mg	2

*Source: OIG analysis of patient’s EHR*

## Mental Health Unit

The receiving mental health unit nurse documented the patient was “combative” and refused medications, assessment, and treatment. The patient was further described as “agitated and unable to be redirected” and “cursing and attempting to strike other staff members.” The patient received intramuscular injections of haloperidol and lorazepam. The covering psychiatrist documented that the patient responded “I don’t know” to most of the interview questions posed, did not document a mental status examination, and deferred on a diagnostic impression due to the limited information obtained. The plan was to continue hospitalization and obtain collateral information and previous hospital records. Later that day, the patient was given a dose of risperidone and a third dose of antibiotic.



On the morning of hospital day 3, the patient refused all medications and was clear and coherent throughout the day. At midday, the patient was able to participate in an intake interview with the social worker.

On the morning of hospital day 4, the patient's nurse documented that the patient stayed in bed throughout the night. The medication administration log indicated that the patient received a PRN dose of risperidone in the early morning.

The consulting psychiatrist saw the patient again and documented "leaning toward" a diagnosis of schizophrenia. The EHR did not contain clinical evidence or documentation in support of this potential diagnosis. The consulting psychiatrist discontinued the antibiotics prescribed for the UTI because the patient was not taking them. A repeat urinalysis was considered but not ordered.

The patient was administered a PRN dose of risperidone in late morning of hospital day 4. By midafternoon, the patient was noted to be walking through the unit "looking for [the] dog," and the patient received a third PRN dose of risperidone.

That afternoon, the social worker had the patient sign a release of information to allow contact with the patient's out-of-state neighbor to discuss the current hospital stay.

The patient received a fourth PRN dose of risperidone in the early evening.<sup>71</sup> Around 30 minutes later, another mental health nurse practitioner was called by nursing staff because the patient remained agitated despite the risperidone doses. The nurse practitioner did not see the patient but documented a concern, in light of the four doses of risperidone that the patient had already received, for the possibility of the patient experiencing a movement disorder related to the antipsychotic medication. The nurse practitioner "encouraged" the mental health unit nurse to use benztropine to "see if this is helpful." The patient was administered the medication 10 minutes later. The EHR did not contain documentation of a face-to-face examination of the patient or follow-up, and no further documentation of the effects of the medication were evaluated by the ordering nurse practitioner or other providers.

Shortly after administration of the benztropine, the patient communicated discomfort but would not allow nursing staff to check vital signs. Approximately an hour later, a nurse documented the patient was still walking through the unit and when attempts were made to redirect, the patient "swung" at nursing staff. The patient was placed in seclusion with the door open and administered intramuscular doses of haloperidol and lorazepam but remained "combative and kicking and hitting." The nurse documented contacting the on-call mental health nurse practitioner to assess the patient, but the EHR did not contain documentation of a response.

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<sup>71</sup> A nursing note the following day referenced an event that included police presence to "encourage cooperation" from the patient. This was the only indication of possible agitation prompting a dose of risperidone.

Approximately 30 minutes later, a nurse called the medical “express team” to assess the patient for delirium. The express team found the patient to be sweaty and agitated, “requiring four nurses to hold [the patient] down” and recommended a higher level of care. The patient was transferred to the ICU. The diagnosis at transfer to the ICU was altered mental status.

**Table A.2. Psychoactive Medications on the Mental Health Unit**

Medications	Dosage	Number of Times Administered
Haloperidol	4–5 mg	2
Risperidone	2 mg	5
Lorazepam	2 mg	2
Benztropine	1 mg	1

*Source: OIG analysis of patient’s EHR*

## ICU and Medical Step-Down Unit

A receiving ICU nurse described the patient as disoriented and confused. An ICU physician ordered restraints, laboratory tests, and imaging studies. The ICU physician also ordered medications for the patient’s chronic medical conditions, and risperidone, haloperidol, and lorazepam PRN for agitation. The patient received intravenous fluids. In an unsuccessful attempt to acquire a [magnetic resonance imaging](#) study, the patient received two doses of intravenous lorazepam.<sup>72</sup>

On the morning of hospital day 5, the ICU physician documented the patient was “deeply asleep” with stable vital signs and a diagnosis of “psychotic episode.” Later in the afternoon, the consulting psychiatrist documented the patient was “mumbling incoherently,” intermittently followed one-step commands, and was moderately confused. The consulting psychiatrist diagnosed encephalopathy with a secondary diagnosis of paranoid schizophrenia, and recommended reducing and/or discontinuing medications for behavior management to provide “as much diagnostic clarity as possible.” However, the ICU providers did not follow the recommendations.<sup>73</sup>

On hospital day 7, the patient underwent an electroencephalogram that the consulting psychiatrist interpreted as “severely abnormal” and indicative of severe and generalized brain dysfunction of unknown cause. The ICU physician documented the patient was “somnolent, yet

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<sup>72</sup> A patient receiving an MRI needs to remain still during the imaging study; lorazepam is a medication that reduces brain activity and promotes relaxation.

<sup>73</sup> A repeat urinalysis was also done on this day (day 5) that showed improvement after the initial urinalysis done in the Emergency Department and after the patient received antibiotic therapy. All of the patient’s other cultures during the hospitalization were not clinically significant.

arousable, says few words, still on restraints” and the diagnosis was changed to “schizophrenia, acute psychosis.”

On hospital day 8, a tube feeding was started, and on hospital day 9, the patient underwent imaging studies, which revealed no acute findings. The patient had an elevated C-reactive protein, a protein manufactured in the liver that is used to measure inflammation or infection.<sup>74</sup>

On hospital day 10, an ICU medical resident met with the patient’s neighbor and discussed the details of the patient’s condition.

On hospital day 11, the ICU physician documented the patient was “in stupor, arousable, mumbles words,” and had a fever and “generalized rigidity” of muscles. The ICU physician continued the diagnosis of schizophrenia.

Later that day, a neurologist saw the patient, but due to the patient’s heavy sedation, was unable to speak with the patient or perform a complete neurologic examination. Based on the information available, the neurologist diagnosed the patient with “encephalopathy in the setting of paranoid schizophrenia” and recommended lumbar puncture, which was performed with substituted consent provided by the ICU medical director. The ICU physician documented tests were “negative for meningitis/encephalitis.” In the afternoon of hospital day 12, the ICU physician discontinued all PRN lorazepam and documented that the patient had awakened from “stupor with rigidity” and had started to talk. On hospital day 13, the tube feeding was discontinued and by evening, the patient was transferred from the ICU to the medical unit with a diagnosis of schizophrenia. At transfer, the patient remained in restraints and was prescribed medications for the chronic medical illnesses as well as low-dose quetiapine twice daily.

**Table A.3. Psychoactive Medications on the ICU and Medical Step-Down Unit**

Medication	Dosage	Number of Times Administered
Haloperidol	2 mg to 5 mg	9
Risperidone	2 mg	1
Lorazepam	1 mg	9
Quetiapine	50 mg to 100 mg	10

Source: VA OIG analysis of patient’s EHR

## Medical Unit

The medical team continued the diagnosis of schizophrenia, but the consulting psychiatrist noted that the etiology of the patient’s condition remained unclear and considered the possibility of an

<sup>74</sup> The OIG was unable to determine the clinical importance of the elevated C-reactive protein, because there can be multiple causes and the test was done after the patient was treated with antibiotics.

encephalopathy. Due to divergent diagnostic impressions, care was transferred to the Mental Health Service although the patient remained on the medical unit due to physical frailty and an inability to walk. The physical therapist was consulted but could not complete an evaluation two days later due to the patient’s mental status issues.

On hospital day 15, the inpatient psychiatrist documented the patient was “pleasant and not agitated when seen.” It was also noted that a physical therapy consult to evaluate the patient’s ability to ambulate was pending, prior to transferring the patient to the mental health unit. The documented diagnosis was “major neurocognitive disorder, Alzheimer's type.”

The psychiatry resident wrote orders in the morning of hospital day 15 to discontinue the feeding tube, urinary catheter, and medical restraints.<sup>75</sup> After the urinary catheter was discontinued, the patient was incontinent of urine throughout the course of the evening. In the afternoon, despite no documentation of agitation, the patient received the first dose of PRN medication since hospital day 11 by an intramuscular injection of lorazepam. Later that afternoon, the patient was described as “very [weak] when standing and could not walk,” and the psychiatry resident documented the patient was delirious with “unclear” cause and wrote orders to change medications.

Early in the morning of hospital day 16, the patient received a dose of intravenous lorazepam. There is no documentation from the ordering provider regarding the clinical indication for which the medication was prescribed. A few hours later, the patient fell with no injury, and the covering medical resident evaluated the patient. Approximately two hours later, the patient received a second dose of PRN lorazepam.

The patient was transferred to the locked mental health unit on hospital day 16, a weekend day, with a diagnosis of altered mental status secondary to schizophrenia and paranoia.

**Table A.4. Psychoactive Medications on the Medical Unit**

Medications	Dosages	Number of Times Administered
Lorazepam	1 mg	3
Quetiapine	100 mg	4
Olanzapine	5 mg	1

*Source: OIG analysis of patient’s EHR*

## Mental Health Unit

On arrival to the locked mental health unit, the weekend psychiatrist noted the patient was “awake and alert” and documented a diagnosis of “dementia with psychotic features.” Over the

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<sup>75</sup> The restraints were not removed until approximately four hours later.

course of the day, the patient received three doses of olanzapine and two doses of PRN lorazepam.

On the morning of hospital day 17, a nurse documented the patient was “unable to communicate” and administered a PRN dose of lorazepam. The weekend psychiatrist, who had not assessed the patient prior to transfer, described the patient as “approaching baseline.” A social worker documented that during an afternoon visit with the neighbor, the patient was staring at the floor and “grasping with ... thumb and index finger as if for an item that wasn’t there.”

During hospital day 18, the patient was described as intermittently “oriented to self,” and walking the hallway looking for the service dog. In late afternoon, the patient was given a PRN dose of olanzapine. In the evening, the patient was described as “not agitated, just very confused and active,” but approximately 30 minutes later was found to be agitated. That evening, the patient received another dose of olanzapine and a PRN dose of lorazepam. That night, the patient received the standing dose of olanzapine. An hour and a half later, the patient fell. The nurse documented the patient had “upper back redness and abrasions” and provided first aid. A nurse documented notifying the covering medical team early the next morning, who saw the patient, but a physician did not document a physical assessment. The nurse also documented that the patient remained combative with staff, and received a PRN dose of lorazepam.

Later in the morning of hospital day 19, a nurse assessed the patient for pain and documented the patient was “sighing” and “moaning,” moving cautiously, rubbing the site of injury, and was also noted to be tense and rigid with attempts at passive movements by staff. The patient was provided acetaminophen for pain relief, and a dose of PRN olanzapine approximately 30 minutes later. The inpatient psychiatrist placed a consult to the GEC service referencing the patient’s “mental status changes and prolonged hospitalization without improvement. Delirium and dementia.” The inpatient psychiatrist documented the patient was “delirious, disoriented, hallucinating, combative” and medications were changed from olanzapine back to haloperidol. The nurse gave the patient another dose of acetaminophen for continuing pain-related behavior from the fall the night prior and documented reddened areas on the upper portion of the patient’s back. The patient received a dose of PRN haloperidol.

In the afternoon, the patient was “aggitated [*sic*]and kicking at staff” and was placed in open-door seclusion in four-point behavioral restraints. The patient received PRN haloperidol and lorazepam. A little over 30 minutes later, while the patient was in four-point restraints, the GEC physician responded to the consult placed that morning and evaluated the patient. The GEC physician diagnosed the patient as having “SEVERE ENCEPHALOPATHY (DELIRIUM), unclear cause (may be METABOLIC vs. TERMINAL, TOXIC; possibly TERMINAL in nature) [original text contains the capitalized words].”

Approximately two hours later in the afternoon of hospital day 19, the GEC physician, who was also the hospice physician, wrote orders to transfer the patient to the hospice unit. Fifteen

minutes later, the physician’s assistant spoke to the neighbor. As a consequence of the discussion, the neighbor authorized that no life-sustaining treatments were to be administered and no cardiopulmonary resuscitation was to take place in the setting of a cardiac arrest. Within another twenty minutes, the hospice and palliative care team documented that the patient had hours to days to live. The patient’s diagnosis at transfer was end-stage dementia and terminal restlessness.

**Table A.5. Psychoactive Medications on the Mental Health Unit**

Medications	Dosage	Number of Times Administered
Haloperidol	5 mg	2
Lorazepam	1 mg	6
Olanzapine	5 mg	8

*Source: OIG analysis of patient’s EHR*

## Hospice Unit

Initially combative, the patient was prescribed standing doses of morphine, haloperidol, and lorazepam every four hours, as well as hourly doses of the same medications PRN for pain, restlessness, and anxiety respectively. The next morning, documentation reflected that the patient was resting comfortably, but did not respond to name or touch.

From hospital day 20 to hospital day 24, the patient remained unresponsive and received both standing and PRN hourly doses of the prescribed medications. In the evening of hospital day 24, the patient was noted to be “nonresponsive, no breathing, no pulse, no cardiac sounds” with “no family at bedside.” A medical resident pronounced the patient dead and documented the cause as “complications related to dementia, including but not limited to poor oral intake and likely multiorgan failure.”

The neighbor, who was reflected in the EHR as the surrogate decision-maker, declined autopsy. A family member, who was located three days later, requested an autopsy. The autopsy was complicated by the three-day delay, and it was decided that a “brain only” autopsy could be completed. The brain autopsy showed cerebral edema, encephalopathy resulting from lack of oxygen to the brain, and evidence of mild neurodegenerative changes. The findings were insufficient for a diagnosis of Alzheimer’s disease.

**Table A.6. Psychoactive Medications on the Hospice Unit**

Medication	Dosage	Total Number of Times Administered	Scheduled	PRN
Haloperidol	5 mg	38	29	9
Lorazepam	1–1.5 mg	39	29	10
Morphine	1–3 mg	40	30	10

*Source: OIG analysis of patient's EHR*

## Appendix B: Executive in Charge Memorandum

### Department of Veterans Affairs Memorandum

Date: March 24, 2020

From: Executive in Charge, Office of the Under Secretary for Health (10)<sup>76</sup>

Subj: OIG Draft Report, Surrogate Decision-Maker, Clinical, and Patient Rights Deficiencies at the Robley Rex VA Medical Center (VIEWS 02533627)

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review the draft report on patient care at Robley Rex VA Medical Center. The Veterans Health Administration's (VHA) National Center for Ethics in Health Care provides comments to clarify some statements in the draft report on surrogate identification, documentation, and decision making. VHA's Office of Mental Health and Suicide Prevention provides comments regarding statements and conclusions in the draft report regarding clinical assessments and decision-making for this patient.
2. The Medical Center Director comments respond to the recommendations.
3. If you have any questions, please email Karen Rasmussen, M.D., Director, GAO/OIG Accountability Liaison at [VHA1OEGGOALAction@va.gov](mailto:VHA1OEGGOALAction@va.gov).

(Original signed by:  
Richard A. Stone, M.D.  
Executive in Charge

### OIG Addendum to the Executive in Charge Memorandum

The OIG reviewed comments received from VHA (see appendix E), which were restricted to ethics- and mental health-related issues. Many of the comments proffered wording changes that were not substantive in nature. Remaining comments expressed disagreement with certain statements made in the report based on VHA's interpretations of policy requirements. The OIG considered, but did not agree with, these interpretations (see appendix E).

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<sup>76</sup> The Executive in Charge has the authority to perform the functions and duties of the Under Secretary for Health.



## Appendix C: VISN Director Memorandum

### Department of Veterans Affairs Memorandum

Date: March 12, 2020

From: Director, VA MidSouth Healthcare Network (10N9)

Subj: Healthcare Inspection—Surrogate Decision-Maker, Clinical, and Patient Rights Deficiencies at the Robley Rex VA Medical Center in Louisville, Kentucky

To: Director, Office of Healthcare Inspections, Rapid Response Team (54RR00)  
Director, GAO/OIG Accountability Liaison Office (VHA 10EG GOAL Action)

1. I have reviewed and concur with the findings and recommendations in the OIG Report entitled, Healthcare Inspection—Surrogate Decision-Maker, Clinical, and Patient Rights Deficiencies at the Robley Rex VA Medical Center in Louisville, Kentucky. I concur with the action plans submitted by the Medical Center Director.
2. We thank the OIG for the opportunity to review and respond to the Report of this Healthcare Inspection.
3. Should you have any questions or require additional information, please contact the Quality Management Officer, VA MidSouth Healthcare Network, VISN 9.

*(Original signed by:)*

Cynthia Breyfogle, FACHE  
Network Director

## Appendix D: Facility Director Memorandum

### Department of Veterans Affairs Memorandum

Date: March 12, 2020

From: Director, Robley Rex VA Medical Center (603/00)

Subj: Healthcare Inspection—Surrogate Decision-Maker, Clinical, and Patient Rights Deficiencies at the Robley Rex VA Medical Center in Louisville, Kentucky

To: Director, VA MidSouth Healthcare Network (10N9)

1. As we endeavor to keep the Veteran as the center and focus of all we do, I thank all those who entrust us with the care of their loved ones, our Nation's heroes. It is the highest calling in healthcare. It is a calling of commitment, courage and compassion. The opportunity to serve our Veterans through the course of life, and in this case, to the end of life, is a great honor and privilege.
2. In our journey to become a High Reliability Organization (HRO), we humbly go about our work with the constant reminder that every patient experience and encounter provides opportunity for learning and growth. To that end, we are thankful to the OIG for this opportunity to exemplify our Commitment to Resilience, an essential HRO principle.
3. I have reviewed the findings and recommendations in the OIG report entitled, Surrogate Decision-Maker, Clinical, and Patient Rights Deficiencies at the Robley Rex VA Medical Center in Louisville, Kentucky. I concur with all but one of the fifteen recommendations. I do not concur with Recommendation 11 for reasons stated in the action plan.
4. I am requesting closure on Recommendations 5, 9, 11, 12, 14, and 15. For all other Recommendations, action plans have been provided with target dates of completion set for October 1, 2020 to provide adequate time for evidence of sustainment.
5. If you have questions or require additional information, please contact either the VISN Quality Management Officer or the local Chief of Quality Management.

*(Original signed by:)*

Stephen Black, FACHE  
Medical Center Director

## Facility Director Response

### Recommendation 1

The Robley Rex VA Medical Center Director ensures staff document clinical assessments of patients' decision-making capacity throughout hospitalization as required by Veterans Health Administration policy.

Concur.

Target date for completion: October 1, 2020

#### Director Comments

A required assessment of clinical decision-making capacity has been added to all admission H&P [history and physical] templates. To augment this change, education will be provided to all clinical staff and providers regarding the requirement for this assessment and the need to reassess decision-making capacity as clinically indicated during the episode of care. This education will also include a review of the implications of lack of decision-making capacity on informed consent, end of life care decisions, release of information and other actions that require decision-making capacity. Monitoring will consist of random audits beginning in April 2020 of 30 H&P notes per month by the Chief of Social Work to the local Integrated Ethics Board, for review monthly, to achieve 95% compliance for six months post-implementation.

### Recommendation 2

The Robley Rex VA Medical Center Director evaluates social worker practices related to facilitating the release of information when a patient lacks decision-making capacity, and takes action as indicated.

Concur.

Target date for completion: October 1, 2020

#### Director Comments

All inpatient Social Workers have been re-educated regarding the release of information (ROI) process. Along with this education, the social workers have been instructed to consult the facility Chief of Health Information Management or the facility Privacy Officer for any questions or concerns regarding the ROI process. Social Work staff will report inpatient ROI requests at their daily huddles with Social Work leadership and track through the Social Work Service's daily management system. Each case discussed will be re-reviewed by the Chief of Social Work Service, to achieve 95% compliance for six months post-implementation, and documentation of the reviews will be reported to the Quality, Safety and Value Board beginning April 2020.

### **Recommendation 3**

The Robley Rex VA Medical Center Director establishes “reasonable inquiry” parameters for determination of a surrogate as required by Veterans Health Administration policy and provides staff education as needed.

Concur.

Target date for completion: October 1, 2020

#### **Director Comments**

An Appendix to Hospital Memorandum 603-17-11-063, October 11, 2017 Life-Sustaining Treatment Decisions and Hospital Memorandum, 603-16-11-028, December 28, 2018 Informed Consent for Clinical Treatments and Procedures has been developed and implemented. This appendix puts into practice a procedure to be followed to assure a reasonable inquiry for determination of a surrogate is completed. All inpatient social workers have been educated on the process. The process for reasonable inquiry will include: 1) Consult to Social Work Services to complete reasonable inquiry 2) Review of the Electronic Medical Record (EMR) 3) Review of remote clinical data (if present) 4) Contacting Business Office to search Veterans Benefits/Pension Records and 5) Searching of patients belongings/effects. The Chief of Social Work will be responsible for conducting audits of process compliance through social work documentation on 100% of cases in which surrogacy is sought for six months, providing re-education as necessary. A list of cases reviewed, and the results of compliance audits, to achieve a target of 95% or greater, sustained, will be reported to the Integrated Ethics Board starting in April 2020.

### **Recommendation 4**

The Robley Rex VA Medical Center Director ensures that when patients lack decision-making capacity, staff verify and document the status of surrogates, and the efforts to identify surrogates, according to Veterans Health Administration policy.

Concur.

Target date for completion: October 1, 2020

#### **Director Comments**

The action plan for this recommendation is consistent with the action plan provided for Recommendation 3. Please refer to the comments for Recommendation 3.

## **Recommendation 5**

The Robley Rex VA Medical Center Director evaluates the quality and comprehensiveness of clinical documentation in support of diagnoses and treatment decisions across the patient's hospitalization, and takes action as indicated.

Concur.

Target date for completion: Complete, Requesting Closure.

### **Director Comments**

The Robley Rex VA Medical Center is committed to the highest standards in quality of care and clinical documentation. The Medical Center completed evaluation of the quality and comprehensiveness of clinical documentation, clinical decisions, and administrative processes in support of diagnoses, treatment decisions, continuity of care, and transfer to hospice across the patient's hospitalization, and has taken appropriate actions. The Medical Center has many processes in place including real-time coding/documentation reviews, ongoing professional practice evaluations, and focused professional practice evaluations conducted by management and peers. In addition, the Medical Center has a robust peer review for quality management program. The documentation and diagnostic accuracy related to the potential organic mechanism responsible for the patient's symptoms were initially examined and referred to peer review on day 8 of Veteran's hospitalization. The Peer Review Process was initiated on day 13 of Veteran's hospitalization. Three separate peer reviewers evaluated this case.

### **OIG Comment**

The OIG considers this recommendation open and will follow up on the recently implemented actions provided by the Robley Rex VA Medical Center Director to allow time for the facility to submit documentation of actions taken and to ensure that corrective actions have been effective and sustained.

## **Recommendation 6**

The Robley Rex VA Medical Center Director ensures interdisciplinary and cross-service communication and collaboration for complex patients and monitors compliance.

Concur.

Target date for completion: October 1, 2020

### **Director Comments**

Prior to the OIG's investigation, complex patients were being identified and discussed at a daily 0800 [8:00 a.m.], interdisciplinary patient flow/clinical leadership huddle, attended by, but not

limited to, executive leadership, utilization management, mental health, medicine, social work, nursing, and discharge planning. Since the OIG's visit, the Medical Center has expanded the number of disciplines and Services involved at the 0800 huddle and added a second-level huddle to be able to discuss, track, and improve communication and processes around cases that need additional attention. Prior to the OIG's visit, only attendance was being documented for the 0800 huddle. Huddle minutes are now being recorded and will be submitted to the OIG as evidence of sustained compliance for six months.

## **Recommendation 7**

The Robley Rex VA Medical Center Director ensures providers complete medication reconciliation for patients transferred to the mental health unit(s) as required by Veterans Health Administration and Robley Rex VA Medical Center policies.

Concur.

Target date for completion: October 1, 2020

### **Director Comments**

Education will be given to all mental health admitting staff regarding medication reconciliation during transfers, in accordance with VHA Handbook 1160.06, September 16, 2013 Inpatient Mental Health Services and Hospital Memorandum 603-17-119-003, August 19, 2017 Medication Reconciliation. Random audits will be conducted by the Mental Health Service Chief on 25% of transferred patients on a monthly basis, for six months, to ensure medication reconciliation has been completed per policy. Audits will be discontinued after 95% is achieved and sustained for six months. Quality Measures of this process will be reported to the Health Care Delivery Board starting April 2020.

## **Recommendation 8**

The Robley Rex VA Medical Center Director ensures compliance regarding completion of documentation of PRN (as needed) medication effectiveness as required by Veterans Health Administration and Robley Rex VA Medical Center policies.

Concur.

Target date for completion: October 1, 2020

### **Director Comments**

All inpatient nursing staff will be re-educated on documentation of prn effectiveness. Nurse Manager will audit 80% of PRN effectiveness sheets for every shift to ensure the assessments and documentation is being completed. Audits will be discontinued after 95% sustainment for

six months. Quality Measures for this process will be reported to the Quality Safety and Value Board starting April 2020.

## **Recommendation 9**

The Robley Rex VA Medical Center Director reviews clinical decision-making and administrative processes relative to the patient's admission to hospice, and takes appropriate actions as indicated.

Concur.

Target date for completion: Complete – refer to response to recommendation 5; Requesting Closure.

### **Director Comments**

The Medical Center completed evaluation of the quality and comprehensiveness of clinical documentation, clinical decisions, and administrative processes in support of diagnoses, treatment decisions, continuity of care, and transfer to hospice across the patient's hospitalization, and has taken appropriate actions. Documentation that this patient met VHA policy criteria (Directive 2008-041), evidence-based practice guidelines, and Medicare guidelines for hospice admission is well documented in the notes of the Geriatrics and Extended Care (GEC) physician on day 19 of Veteran's hospitalization. The response to Recommendation 5 outlines three separate peer reviewers evaluated this case. Additionally, according to VHA Directive 1139, Medical Centers are to have a Palliative Care team who are available to be consulted when there are questions about goals of care or the appropriateness of admission to hospice. It was this process that correctly resulted in examination by the GEC provider and subsequent decision to accept the patient to hospice. The GEC provider utilized the surrogate identified by the previous care teams to further support the decision to admit the patient to hospice. The Medical Center attests that the clinical decision-making surrounding the admission to hospice was consistent with policy and evidence-based practice guidelines. No further action needed.

### **OIG Comment**

The OIG considers this recommendation open and will follow up on the recently implemented actions provided by the Robley Rex VA Medical Center Director to allow time for the facility to submit documentation of actions taken and to ensure that corrective actions have been effective and sustained.

## **Recommendation 10**

The Robley Rex VA Medical Center Director develops a mechanism to ensure involuntary admissions (72-hour holds) for current and future patients are managed and documented

according to Veterans Health Administration and Robley Rex VA Medical Center policies, and Kentucky state laws.

Concur.

Target date for completion: October 1, 2020

### **Director Comments**

All Attending Medicine physicians, Attending Emergency Room Physicians and Attending Mental Health Providers will be re-educated on the entering of 72-hour hold orders and will receive an electronic tutorial on how to place the 72-hour hold order. Six months of random audits of 75% of 72-hour holds between April and September 2020, will be conducted by the Chiefs of Emergency Medicine, Inpatient Mental Health Service and Medicine Services on patients placed on a 72-hour hold from their respective areas to ensure 72-hour hold orders are entered and documented correctly. Audits will be discontinued after 95% compliance is achieved and sustained. Audit results will be reported to the Health Care Delivery Board starting April 2020.

### **Recommendation 11**

The Robley Rex VA Medical Center Director develops a mechanism to ensure that patients in behavioral restraints are assessed every 15 minutes as required, and that documentation complies with Veterans Health Administration policy.

Non-Concur.

Target date for completion: Complete; Requesting Closure.

### **Director Comments**

The Robley Rex VA Medical Center non-concurs with this recommendation because the findings in the report underlying this recommendation are incorrect. The OIG report lists three deficiencies in 15-minute charting of behavioral restraints on hospital days 5, 8 and 15. On all three dates listed, the Veteran was either in the Intensive Care Unit or on a Medical-Surgical ward in clinical restraints. This is consistently documented in the chart as well as in the Clinicomp software. In all three of these instances the physician inadvertently selected the incorrect order for behavioral restraints and the order was subsequently discontinued and rewritten for clinical restraints. All clinical restraint documentation was completed per hospital policy and Joint Commission standards. As there is always room for improvement, we are currently looking at our electronic restraint order sets to find a way to make the differences between the two order types more apparent.



## OIG Comment

The OIG disagrees with the facility's stance that the findings for this recommendation were incorrect. The OIG electronic health record review supports the findings. The OIG supports facility efforts to clearly define the differences between behavioral and clinical restraints order sets and considers this recommendation open. The OIG will follow up on (1) the Robley Rex VA Medical Center Director's plan to review the electronic restraint order sets and (2) modifications that make the differences in the order types more apparent.

## Recommendation 12

The Robley Rex VA Medical Center Director ensures that its policy on restraints and seclusion is updated to reflect the frequency of training requirements, and that staff are appropriately trained and competent in the use of restraints as required by Veterans Health Administration and Robley Rex VA Medical Center policies.

Concur.

Target date for completion: N/A; Requesting Closure.

## Director Comments

The Robley Rex VA Medical Center has ensured that local policy sets a higher standard than national policy and Joint Commission requirements regarding training frequency by requiring initial training and then biannually, thereafter. At the time of this review, all applicable staff were trained on use of restraints and seclusion.

We note that the draft report incorrectly stated that staff were not trained which was likely due to variable training documentation: 1) Not all staff take the same training, as the Medical Center offers three different trainings which cover the required content plus some additional content based on the nurse's area, 2) Some staff had not been employed long enough to require an annual review, 3) Some staff were no longer employed, but were listed on the audit sheet. This has been clarified and re-submitted for OIG consideration.

## OIG Comment

The OIG considers this recommendation open to allow time for the facility to submit documentation to support the asserted requirements or conditions, including training of applicable staff, and to ensure that corrective actions have been effective and sustained.

## Recommendation 13

The Robley Rex VA Medical Center Director takes action to ensure processes for reviewing inpatient deaths is consistent with Veterans Health Administration policy.

Concur.

Target date for completion: October 1, 2020

### **Director Comments**

A Standard Operating Procedure (SOP) has been developed and implemented that establishes a procedure for occurrence screen review in compliance with VHA Directive 1190, *Peer Review for Quality Management*, dated November 21, 2018. The Quality Management/Utilization Management Supervisor will audit occurrence screens for six months to ensure all death screens are being completed consistent with the new SOP and Veterans Health Administration policy. Audit results will be reported to the Quality, Safety, and Value Committee with a target of 100% compliance with reviewing all Code 109 deaths.

### **Recommendation 14**

The Robley Rex VA Medical Center Director reviews the patient's continuum of care and evaluates if additional peer reviews and/or other quality reviews are warranted, and takes action as indicated.

Concur.

Target date for completion: Complete; Requesting Closure.

### **Director Comments**

The Medical Center completed evaluation of the quality and comprehensiveness of clinical documentation, clinical decisions, and administrative processes in support of diagnoses, treatment decisions, continuity of care, and transfer to hospice across the patient's hospitalization, and has taken appropriate actions. Please see the Medical Center Director's response to Recommendation 5. The action requested in this recommendation was taking place concurrent to the OIG's review. No further action needed.

### **OIG Comment**

The OIG considers this recommendation open and will follow up on the recently implemented actions provided by the Robley Rex VA Medical Center Director to allow time for the facility to submit documentation of actions taken and to ensure that corrective actions have been effective and sustained.

### **Recommendation 15**

The Robley Rex VA Medical Center Director reviews the circumstances related to an unauthorized individual making decisions for the patient and conducts appropriate disclosure to the patient's representative as warranted.

Concur.

Target date for completion: Complete; Requesting Closure.

### **Director Comments**

A review of the events that led up to the to the patient's friend and neighbor being identified as the surrogate for the patient was completed. Appropriate disclosure to the next of kin was completed on March 5, 2020. This discussion has been documented in the patient's electronic healthcare record utilizing the Institutional Disclosure Note.

### **OIG Comment**

The OIG considers this recommendation open to allow time for the facility to submit documentation of all required actions taken.

## Appendix E: VHA Comments to Report

### National Center for Ethics in Health Care Comments

#### OIG Comment

The OIG appreciates the feedback from National Center for Ethics in Health Care. The OIG considers the comments to be technical and stylistic in nature, and they do not change the OIG's understanding of the facts of this case or the recommendations.

#### Comment 1

**Draft location:** n/a

**Current language:** n/a

**Comment and justification:** The National Center for Ethics in Health Care has reviewed the draft report from an ethics perspective and thus our comments are restricted to ethics-related issues, not clinical ones. We advise that the document clearly communicate how the facility errors identified in the report should be used as a basis to improve the quality of future health care practices.

#### Comment 2

**Draft location:** p. ii

**Current language:** "If the neighbor had been correctly verified as the surrogate, a release of information would not have been required, and the neighbor would have been legally authorized to consent for procedures and an autopsy on behalf of the patient."

**Comment and justification:** The authority of an individual to make health care decisions and autopsy decisions may be different. A surrogate decision maker that can make health care decisions may not have the authorization to make autopsy determinations as defined in VHA Handbook 1004.01 and VHA Handbook 1601B.04 respectively. In general, a next-of-kin may be the authorized decision maker for both scenarios but that may not be the case for a "close friend." Our office advises verifying with Decedent Affairs and OGC if the neighbor as close friend would have qualified as the patient's personal representative and thus been able to authorize an autopsy.

#### Comment 3

**Draft location:** p. iii and p.11

**Current language:** "The EHR did not contain documentation of disclosure to the son related to an unauthorized individual making decisions for the patient." ... "Additionally, the EHR does

not contain documentation of disclosure to the son related to an unauthorized individual making decisions for the patient.”

**Comment and justification:** VA’s commitment to transparency obligates the facility to disclose to the son the error in identifying the decision-maker for the patient, the process and knowledge gaps that may have led to the problem, as well as the improvements instituted to prevent a recurrence. However, from a policy perspective, VHA handbook 1004.08, *Disclosure of Adverse Events to Patients*, does not require such a disclosure because the failure to properly identify the appropriate decision-maker is not considered an adverse event in the terms of the policy. The event at the facility would be considered a *wrong*, not a *harm*, as defined in the policy. We advise removing the reference to the policy when referring to this deficiency and emphasizing the ethical considerations as we describe above.

## Comment 4

**Draft location:** p. iii-iv

**Current language:** “It was unclear to the OIG why the facility did not use the substituted consent process, as used for one of the patient’s procedures, or the interdisciplinary committee process that was specifically designed for cases where determining the surrogate is difficult.”

**Comment and justification:** “Substituted consent” is not a term established in VHA Handbook 1004.01 and as such should be avoided. We advise defining this process in the context of the existing VA policy (i.e., VHA Handbook 1004.01), that is, “the alternative process for decision-making when the patients lacks decision-making capacity and does not have a surrogate”. Additionally, the “interdisciplinary committee process” described in the report (and referenced to VHA Handbook 1004.03) is inaccurate. The appropriate term is the “multidisciplinary committee review process.” Finally, this multidisciplinary committee review process is not for when “determining the surrogate is difficult,” as described in the report, but rather when the patients lacks decision-making capacity and does not have a surrogate.

## Comment 5

**Draft location:** p.8

**Current language:** “VHA requires that a provider clinically assess and document a patient’s ability to make decisions.”

**Comment and justification:** This reads like an overstatement. Practitioners are required to obtain and document informed consent for all treatments and procedures, but they are not required to assess or document patients’ decision-making capacity for every clinical decision. Patients are presumed to have decision-making capacity unless an appropriate clinical evaluation determines that the patient lacks decision-making capacity, the patient is a minor, or the patient has been ruled incompetent by a court of law.

## Comment 6

**Draft location:** p.10

**Current language:** “Nevertheless, absent an explicit instruction (and documentation in the EHR) that family members were not to be contacted, the patient’s children were the next in line for consideration as a surrogate.”

**Comment and justification:** Our office is uncertain of VA’s legal authority to contact a legally authorized decision-maker like a next-of-kin if there are either verbal or written evidence of the patient’s desire to not contact family members. We believe that such patient preferences are worthy of respect and should be followed when legally permissible, but we do not know if VA can avoid contacting an authorized surrogate in the hierarchy of decision-makers according to VHA Handbook 1004.01 simply based on patient preference. We are also aware of the process described in VHA Handbook 1605.01 that veterans have the right to request VHA to restrict disclosures of the individual’s individually-identifiable health information to next-of-kin, family, or significant others involved in the individual’s care. This may or may not be relevant to this case.

## Comment 7

**Draft location:** p.18

**Current language:** “The GEC physician changed the patient’s status to DNR and transferred the patient to the hospice unit.”

**Comment and justification:** We advise more clinically accurate language as follows: “The GEC physician updated the LST plan to include a DNR order and transferred the patient to the hospice unit.”

## Comment 8

**Draft location:** p.19

**Current language:** “Rather, the facility appropriately instituted a substituted consent process in which a clinical leader consented for the patient’s lumbar puncture.”

**Comment and justification:** See comment #3 for language on the alternative process for decision-making when the patient lacks decision-making capacity and does not have a surrogate.

## Comment 9

**Draft location:** p.19

**Current language:** “If the patient’s physician recommends withholding or withdrawal of treatment, a committee, such as the Integrated Ethics Council, acts as an advocate for the patient.”

**Comment and justification:** IntegratedEthics® is one word and should include the ® symbol after it is mentioned.

## Office of Mental Health and Suicide Prevention Comments

### OIG Comment

The OIG appreciates the feedback from Office of Mental Health and Suicide Prevention. The OIG considers the comments to be technical and stylistic in nature, and they do not change the OIG’s understanding of the facts of this case or the recommendations.

#### Comment 1

**Draft location:** Page 4

**Current language:** “Although the patient was documented as “not decisional,” a social worker assisted the patient with signing a release of information form that permitted staff to speak with the neighbor. The improperly obtained authorization, ....”

**Comment and justification:** This is not necessarily improper – “not decisional” may refer to a specific clinical task (e.g. consent for voluntary admission) rather than a global assessment. For example, someone might be able to consent for information release but not for voluntary admission (or brain surgery). This is a clinical decision and it’s unclear from the report whether documentation supporting this action exists.

#### Comment 2

**Draft location:** Page 5

**Current language:** “If staff had followed processes and obtained the required documentation, they may have evaluated the relationship between the patient and neighbor more thoroughly and concluded that additional efforts were needed to locate the patient’s next of kin.”

**Comment and justification:** This language implies that evaluating the neighbor’s connection with the patient more thoroughly would have led to a different action than was taken – however, there is no explanation of what the evaluation might have uncovered that would have caused this.

#### Comment 3

**Draft location:** Page 5

**Current language:** "... the consulting psychiatrist mentioned schizophrenia as a possible diagnosis without conducting an assessment using relevant criteria, despite the patient being an unlikely candidate given age and lack of psychiatric history."

**Comment and justification:** This language suggests the clinician should and could have conducted an exam that assessed the validity of schizophrenia. However, this is not possible to do when a patient is encephalopathic/delirious (diagnosed in the ED and confirmed after admission). However, consideration of schizophrenia as a "possible" underlying diagnosis (which could be assessed after resolution of the delirium) was justified because of the overlapping symptoms of delirium and schizophrenia. It is also possible that schizophrenia was a diagnosis that was previously made or considered during the patient's previous contacts with multiple VAs but the report does not include sufficient information to evaluate this possibility.

#### **Comment 4**

**Draft location:** Page 5

**Current language:** "... however, the patient's psychiatric medications complicated the analysis of a psychiatric problem because these drugs also cause sedation or delirium in some vulnerable patients."

**Comment and justification:** This is possible but stated as though it were factual – there are many possible explanations of a worsening clinical picture in a patient this complicated.

#### **Comment 5**

**Draft location:** Page 5

**Current language:** "Providers told the OIG that they did not provide further communication and collaboration because they were not asked to see the patient again and the practice at the facility was not to intervene once the patient was not under their direct care."

**Comment and justification:** This is not unreasonable – in fact it is good clinical practice because it keeps the lines of authority and accountability clear. Consultants should not "intervene" – they should provide opinions and support when asked by the attending physician or primary treatment team.

#### **Comment 6**

**Draft location:** Page 6

**Current language:** "The unsupported, but often repeated, diagnosis of schizophrenia may have been central to providers' decisions to prescribe multiple high-risk medications."

**Comment and justification:** This diagnosis of schizophrenia was previously mentioned in this report as "possible" – it is therefore not fair to label it as "unsupported" now. Furthermore [*sic*],



there is no evidence in the report that any treatment decisions were made in the belief that schizophrenia was the primary diagnosis.

## Comment 7

**Draft location:** Page 6

**Current language:** “The OIG did not find evidence that providers attempted a trial of withdrawing and simplifying the patient’s medication regimen, which may have improved cognitive function.”

**Comment and justification:** The report does not make clear the basis for this assertion. In fact, on page 43 of this report, there is language stating that on hospital day 15 “the patient received the first dose of PRN medication since hospital day 11” which indicates an effort to reduce prn medications. There is no documentation in the report than a reduction of standing psychotropic meds was not attempted (for example, tables A.3 and A.4 only show total doses given over the timeframes in question).

## Comment 8

**Draft location:** Page 32

**Current language:** “The peer reviewer suggested additional reviews (related to antipsychotic medication dosing, appraisal of medical providers’ evaluation of the possible causes of the patient’s delirium, and the communication processes between the relevant clinical services) that were not followed-up.”

**Comment and justification:** The report does not indicate whether the suggestions were at least considered.

## Comment 9

**Draft location:** Beginning on page 39

**Current language:** Tables A.1 through A.6

**Comment and justification:** These summary tables are of limited utility – since the report contends that care did not meet certain quality standards, it would be necessary to know what standing psychotropic meds, prn psychotropic meds, and what non-psychotropic meds (which can interact with psychotropic meds) the patient was given over the designated time period (represented as a timeline) before drawing any conclusions.

## Comment 10

**Draft location:** Page 42

**Current language:** “On hospital day 7 (March 28, 2019), the patient underwent an electroencephalogram that the consulting psychiatrist interpreted as “severely abnormal.”

**Comment and justification:** Without having access to the record, I would question the accuracy of this statement. Most psychiatrists aren’t competent to interpret EEGs unless they have undergone special fellowship training. This would normally be done by a neurologist.

## **Comment 11**

**Draft location:** Page 46

**Current language:** Table A.6

**Comment and justification:** Columns denoting prn medications administered, in addition to columns denoting scheduled medications administered, are helpful. (As mentioned previously - see Comment 9 - adding a timeline would be even better.)

## Glossary

**adjustment disorder.** A stress-related condition where an individual experiences more stress than would normally be expected in response to a stressful or unexpected event and the stress causes significant problems in relationships, work, or school.<sup>77</sup>

**adverse outcomes.** Untoward events, incidents, unintended injuries, or other adverse occurrences directly associated with medical care.<sup>78</sup>

**benzodiazepine.** Depressant that produces sedation, induces sleep, relieves anxiety, and prevents seizures.<sup>79</sup>

**benztropine.** An anticholinergic drug used to treat the symptoms of Parkinson's disease or similar symptoms caused as side effects of other drugs.<sup>80</sup>

**diabetes.** A group of diseases that affect how the body uses blood sugar (glucose).<sup>81</sup>

**do not resuscitate (DNR)/do not attempt resuscitation (DNAR).** A DNR/DNAR order describes resuscitation interventions to be performed in the event of a life-threatening emergency.<sup>82</sup>

**electroencephalogram.** A test that detects electrical activity in the brain using small electrodes attached to the scalp.<sup>83</sup>

**encephalopathy.** A disease of the brain with multiple causes that alters brain function or structure and is characterized by an altered mental status.<sup>84</sup>

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<sup>77</sup> Mayo Clinic. *Adjustment Disorder. Symptoms and Causes.* <https://www.mayoclinic.org/diseases-conditions/adjustment-disorders/symptoms-causes/syc-20355224>. (The website was accessed on October 22, 2019.)

<sup>78</sup> VHA Handbook 1050.01.

<sup>79</sup> United States Drug Enforcement Administration. *Benzodiazepines.* <https://www.dea.gov/factsheets/benzodiazepines>. (The website was accessed on November 20, 2019.)

<sup>80</sup> Merriam-Webster. *Medical Definition of Benztropine.* <https://www.merriam-webster.com/medical/benztropine>. (The website was accessed on November 20, 2019.)

<sup>81</sup> Mayo Clinic. *Diabetes, Symptoms and Causes.* <https://www.mayoclinic.org/diseases-conditions/diabetes/symptoms-causes/syc-20371444>. (The website was accessed on October 21, 2019.)

<sup>82</sup> Breault, Joseph L. DNR, DNAR, or AND? Is Language Important? US National Library of Medicine, Ochsner, J. 2011 Winter, 11(4): 302-306. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3241061/>. (The website was accessed on November 5, 2019.)

<sup>83</sup> Mayo Clinic. *Electroencephalogram.* <https://www.mayoclinic.org/tests-procedures/eeg/about/pac-20393875>. (The website was accessed on October 23, 2019.)

<sup>84</sup> National Institute of Neurological Disorders and Stroke, *Encephalopathy Information* (online). <https://www.ninds.nih.gov/Disorders/All-Disorders/Encephalopathy-Information-Page>. (The website was accessed on November 12, 2019.)

**haloperidol.** A medication used to treat nervous, emotional, and mental conditions.<sup>85</sup>

**heart disease.** A range of conditions that affect the heart, including coronary artery disease, heart rhythm problems, and heart defects.<sup>86</sup>

**lorazepam.** A benzodiazepine tranquilizer used to relieve anxiety and insomnia and to control epileptic seizures.<sup>87</sup>

**lumbar puncture.** The insertion of a needle between two vertebrae in the lower back to remove a sample of cerebrospinal fluid.<sup>88</sup>

**magnetic resonance imaging.** (MRI) A noninvasive diagnostic technique that produces computerized images of internal body tissues.<sup>89</sup>

**morphine.** A narcotic analgesic used to relieve moderate or severe pain.<sup>90</sup>

**neuroleptic.** An antipsychotic medication.<sup>91</sup>

**olanzapine.** An antipsychotic drug administered especially in the short-term treatment of schizophrenia and acute manic episodes of bipolar disorder.<sup>92</sup>

**quetiapine.** An antipsychotic drug used to treat schizophrenia and bipolar disorder.<sup>93</sup>

**risperidone.** An antipsychotic drug used to treat schizophrenia.<sup>94</sup>

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<sup>85</sup> Mayo Clinic. *Halperidol (intramuscular route)*. <https://www.mayoclinic.org/drugs-supplements/haloperidol-intramuscular-route/description/drg-20072783>. (The website was accessed on October 22, 2019.)

<sup>86</sup> Mayo Clinic. *Heart Disease. Symptoms and Causes*. <https://www.mayoclinic.org/diseases-conditions/heart-disease/symptoms-causes/syc-20353118>. (The website was accessed on October 22, 2019.)

<sup>87</sup> Merriam-Webster. *Definition of Lorazepam*. <https://www.merriam-webster.com/dictionary/lorazepam>. (The website was accessed on November 4, 2019.)

<sup>88</sup> Mayo Clinic, *Lumbar Puncture, Tests and Procedures*. <https://www.mayoclinic.org/tests-procedures/lumbar-puncture/about/pac-20394631>. (The website was accessed October 20, 2019.)

<sup>89</sup> Merriam-Webster. *Definition of Magnetic Resonance Imaging*. <https://www.merriam-webster.com/dictionary/magnetic%20resonance%20imaging>. (The website was accessed on November 5, 2019.)

<sup>90</sup> Mayo Clinic. *Morphine (Injection Route) (Oral Route)*. <https://www.mayoclinic.org/drugs-supplements/morphine-injection-route/description/drg-20074202> and <https://www.mayoclinic.org/drugs-supplements/morphine-oral-route/description/drg-20074216>. (The website was accessed on November 4, 2019.)

<sup>91</sup> Merriam-Webster. *Definition of Neuroleptic*. <https://www.merriam-webster.com/dictionary/neuroleptic>. (The website was accessed on November 20, 2019.)

<sup>92</sup> Merriam-Webster. *Medical Definition of Olanzapine*. <https://www.merriam-webster.com/medical/olanzapine>. (The website was accessed on November 20, 2019.)

<sup>93</sup> Merriam-Webster. *Medical Definition of Quetiapine*. <https://www.merriam-webster.com/medical/quetiapine>. (The website was accessed on November 4, 2019.)

<sup>94</sup> Merriam-Webster. *Definition of Risperidone*. <https://www.merriam-webster.com/dictionary/risperidone>. (The website was accessed on November 4, 2019.)

**schizophrenia.** A serious mental disorder in which people interpret reality abnormally. Schizophrenia may result in some combination of hallucinations, delusions, and extremely disordered thinking and behavior that impairs daily functioning.<sup>95</sup>

**urinary tract infection.** An infection in any part of the urinary system (kidneys, ureters, bladder and urethra.)<sup>96</sup>

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<sup>95</sup> Mayo Clinic. *Schizophrenia, Symptoms and Causes*. <https://www.mayoclinic.org/diseases-conditions/schizophrenia/symptoms-causes/syc-20354443>. (The website was accessed on October 21, 2019.)

<sup>96</sup> Mayo Clinic. *Urinary Tract Infection, Symptoms and Causes*. <https://www.mayoclinic.org/diseases-conditions/urinary-tract-infection/symptoms-causes/syc-20353447>. (The website was accessed on October 17, 2019.)

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