



Complaint Summary for Public Viewing Reports for:  
CENTURA HEALTH-LITTLETON ADVENTIST HOSPITAL

Intake ID: CO00008066

Facility: CENTURA HEALTH-LITTLETON ADVENTIST HOSPITAL

Date of Complaint: 5/12/2006

Date of Investigation: 6/26/2006

Total Number of Allegations for Complaint: 1

Allegation: 1

Type: Infection Control

Findings: Unsubstantiated

**Allegation Detail:** The complainant reported that instruments used during surgery may have been contaminated with a protein that is not destroyed during the normal and standard sterilization procedure. The instruments may have been reused for other surgeries and possible contamination of other surgical patients may have occurred.

**Findings Detail:** On 6/26/06 through 6/26/06 an unannounced on-site investigation authorized by CMS (Centers for Medicare and Medicaid) was conducted by two surveyors. Policies/procedures, medical records, interviews with facility staff and tours were completed. The findings were:

On 2/12/06, a patient had sustained a fall at home and was brought to the ED (emergency department) at --- ----. A neurosurgical consultation was obtained and the patient was admitted to the ICU (intensive care unit) for close monitoring. --- ----. The patient received postoperative care at the hospital and was discharged and transferred to a long-term acute care facility --- ---- for further medical care. While at this second facility, an EEG (electroencephalogram) was performed and indicated abnormal brain waves. There was concern by the physician that this may be a suspected case of CJD (Creutzfeldt-Jakob Disease), a rapidly degenerating neurological disease which is always fatal. The surgeon and medical administration at the hospital --- ---- were notified of this concern by the second facility on 3/14/06. --- ----.

At 8:00 a.m. on 6/26/06 an interview was conducted with the Director of Nursing --- - ---. H/She had explained that the facility was notified on 3/14/06 and immediately reviewed their policy and procedure regarding CJD. By the evening of 3/14/06, the facility had quarantined all four sets of neurosurgical instruments to a locked storage center located off campus. The standard sterilization process routinely in place was heat sterilization at 272 degrees Fahrenheit for 4 minutes in a pre vacuum sterilizer. H/She explained the facility had consulted nearby hospitals within the area for additional information and replacement equipment for new emergent neurosurgical sets. --- ----. After literature review and research, it was determined to be acceptable to decontaminate the operating rooms with a diluted concentration (1:10) of sodium hypochlorite or bleach. All operating room suites, including the walls, surfaces and back tables were wiped with this solution and completed on the evening of 3/14/06. At the facility, a "higher level of sterilization" was instituted immediately, and required surgical instruments to be sterilized in a pre

vacuum sterilizer for 18 minutes at 272 degrees Fahrenheit. This was done and continues until new policies and procedures are in place, pending final approval and implementation.

The Director of Nursing explained there was an evaluation of all patient surgeries done during this time frame, from 2/13/06 through 3/14/06, when the facility first became aware of a diagnosis of CJD. --- ----.

On 3/15/06, the facility --- ---- contacted the CDPHE (Colorado Department of Public Health and Environment) for recommendations and consulted with an epidemiologist --- ---- on a regular basis. --- ----. By 5/9/06, the diagnosis of CJD was confirmed and throughout this period to the present, the facility has practiced sterilization at a heightened level.

A tool, "CJD Screening and Surgery Scheduling Form" was developed to assist with the pre screening process and potential identification of those patients considered to have suggestions of this disease. The scheduler would ask pertinent questions and if there were concerns for CJD, the scheduler would notify the operating room manager and infection control immediately, and establish the neurosurgical case for the end of the day. --- ----.

An interview on 6/26/06 with the facility's Patient Care Representative, --- ----, revealed the neurosurgeon and h/herself made home visits to the identified patients to disclose this important information. A dedicated phone number was established exclusively for these patients and included information for neurological evaluations with emotional support and counseling services offered. The patient representative explained this was managed by h/herself and has been "effective". --- ----. H/She mentioned there was a difference of opinion with regard to patient disclosure between the WHO (World Health Organization) and the CDC (Centers for Disease Control). --- ----, however the facility decided these patients had a right to know first, and provided full disclosure of this concern to these identified patients. Confidentiality of all of the patient identities have been maintained by the facility, and on 5/18/06 a conference was conducted by the facility and involved the media for public knowledge and medical information.

In summary, the allegation was unsubstantiated. When the facility became aware of a potential diagnosis of a possible CJD diagnosis on 3/14/06, the facility demonstrated appropriate actions through higher standards of sterilization processes. The facility reported this concern on 3/15/06 to the Colorado Department of Health and Environment for recommendations and follow through. Additionally, the facility provided full disclosure to those patients potentially exposed, but as of yet unaffected. The facility responded by offering ongoing neurological evaluations and counseling services. The autopsy confirmed the diagnosis of CJD. The facility provided a time line of events, and continues to maintain new sterilization practices for surgical instruments to be sterilized at 272 degrees Fahrenheit at 18 minutes. --- ----.