ORIGINAL ARTICLE

Management of Neurosurgical Instruments and Patients Exposed to Creutzfeldt-Jakob Disease

Ermias D. Belay, MD;[1] Jennifer Blase, MPH;[1] Lynne M. Sehulster, PhD;[2] Ryan A. Maddox, PhD;[1] Lawrence B. Schonberger, MD[1]

OBJECTIVE. To summarize the approaches used to manage exposure of patients to inadequately sterilized neurosurgical instruments contaminated as a result of Creutzfeldt-Jakob disease (CJD).

METHODS. Information on past CJD exposure incidents reported to the Centers for Disease Control and Prevention (CDC) was aggregated and summarized. In addition, inactivation studies were reviewed, and data from selected publications were provided for reference.

RESULTS. Nineteen incidents of patient exposure to potentially CJD-contaminated instruments were reported to the CDC, including 17 that involved intracranial procedures and 2 that involved ophthalmologic procedures. In more than 50% of incidents, the neurosurgical procedures were performed for diagnostic work up of the index patients. At least 12 of the hospitals had multiple neurosurgical sets, and the CJD-contaminated instruments could not be identified in 11 of 19 hospitals. In 12 of 15 hospitals with neurosurgical incidents, a decision was made to notify patients of their potential exposure.

CONCLUSIONS. Neurosurgical instruments used for treatment of patients with suspected or diagnosed CJD or patients whose diagnosis is unclear should be promptly identified and sterilized using recommended CJD decontamination protocols. Inability to trace instruments complicates appropriate management of exposure incidents. The feasibility of instituting instrument tracking procedures should be considered.

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Creutzfeldt-Jakob disease (CJD) is a rapidly progressive, invariably fatal, neurodegenerative disease. It is characterized by accumulation in the brain of abnormal conformers of a host-encoded protein known as the prion protein.[1] These abnormal proteins are believed to constitute the key component of "prions," the proteinaceous infectious agents responsible for CJD and other prion diseases.[2] In addition to CJD, human prion diseases include variant CJD, kuru, Gerstmann-Straussler-Scheinker syndrome, and sporadic and familial fatal insomnia.

CJD usually affects older adults between the ages of 55 and 75 years.[3] In approximately 85% of patients, the disease occurs sporadically without any known external source of infection. In 10%–15% of patients, CJD occurs as a familial cluster associated with inherited mutations of the prion protein gene. Iatrogenic transmission of CJD has been reported in less than 1% of patients, with exposure linked to the use of contaminated cadaveric pituitary hormones, dura mater and corneal grafts, and neurosurgical instruments.[4] Incubation periods typically range from years to decades.

The unusual resistance of prions to inactivation by standard chemical and physical decontamination methods led to recommendations for stringent reprocessing measures for surgical devices used to treat patients with suspected CJD.[5-7] Instrument reprocessing should be planned well in advance of patients with known or suspected CJD undergoing a surgical procedure. However, some patients may undergo a neurosurgical procedure before their CJD diagnosis is suspected or is known to the operating room staff. The CJD-contaminated instruments may then be reused to treat other patients after reprocessing with standard hospital sterilization procedures, potentially exposing patients to inadequately sterilized instruments. Such incidents have been reported to the Centers for Disease Control and Prevention (CDC). These incidents posed unique challenges to infection prevention professionals and hospital management staff, including difficulties in tracing instruments used weeks to months earlier on the index patient and in determining the most appropriate way to address the issue of patient exposure. Neurosurgical and selected ophthalmologic incidents reported to the CDC

Affiliations: 1. Division of High-Consequence Pathogens and Pathology, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia; 2. Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia.

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are summarized in this article, including an outline of approaches that can be used to manage similar incidents in other healthcare institutions.

METHODS

The CDC was contacted by US hospitals and state and local health departments when patient exposure to inadequately sterilized prion-contaminated surgical instruments was identified. Typically, instrument contamination occurred during a neurosurgical procedure involving a patient whose CJD diagnosis was confirmed after the procedure. The CDC consultation involved assessment of instrument contamination risk and potential CJD transmission to other patients who underwent operations soon after the index patient's procedure. As part of the consultation, information about the CJD exposure incidents was collected, including details about the index patient, surgical and diagnostic procedures, surgical equipment circulation, decontamination procedures, and patient exposure and notification. This information is aggregated and summarized to facilitate proper handling of similar incidents that may occur in other institutions. Examination of the various incidents allowed identification of issues pertinent to risk assessment, patient notification, and future prevention strategies. These issues and approaches in addressing them are summarized in this article.

The core infection control issue in prion diseases is resistance of prions to inactivation by conventional chemical and heat sterilization methods.[8] Many studies have been done to evaluate prion resistance to various inactivation methods. These inactivation studies were reviewed, and data from selected publications were summarized for reference.

RESULTS

CJD Exposure Incidents

From January 1998 to December 2012, 19 incidents of suspected iatrogenic exposure to CJD-contaminated instruments were reported to the CDC (Table 1). All of the CJD index patients reported as part of these incidents died during this time period. The patient ages ranged from 43 to 80 years (mean age, 62 years), and 10 (56%) of the 18 patients with available information were female.

Two exposure incidents involved ophthalmologic procedures for cataract removal, whereas the remaining 17 incidents involved intracranial procedures for indications listed in Table 1. In over half of the patients, the intracranial procedures were probably performed as part of the patients' diagnostic evaluation. At the time of the procedures, operating room personnel were unaware of the possible CJD diagnosis in nearly all of the incidents. Hence, instruments were reprocessed using conventional methods, and recommended CJD decontamination protocols were not followed. For 18 incidents with available information, the median elapsed time from the date of the index surgical procedure to CJD suspicion or diagnosis was approximately 10 weeks (range, 1 day to 1 year).

At least 12 hospitals had multiple neurosurgical sets, making identification of contaminated instruments nearly impossible in some hospitals by the time of CJD diagnosis. For hospitals with available information, the number of neurosurgical sets per hospital ranged from 1 to 12. Overall, the CJD-contaminated sets could not be identified in 11 (58%) of the 19 hospitals. In these 11 hospitals, the exact number of patients exposed to the instruments used on the index patient could not be determined. Therefore, all patients who underwent surgical procedures from the time of the index patient's surgical procedure to the time at which the instruments were removed from circulation were regarded as potentially exposed to the contaminated instruments. Typically, before CJD was suspected, the neurosurgical instruments were reprocessed using conventional procedures, which included automated cleaning followed by standard steam autoclaving. After the CJD diagnosis, the instruments were taken out of circulation and subjected to the more stringent CJD decontamination protocols recommended by the CDC and the World Health Organization (WHO).[6,9]

Excluding 2 incidents that involved ophthalmologic procedures and 2 hospitals whose patient notification status is unknown, 12 (80%) of the remaining 15 hospitals decided to notify patients who were potentially exposed to inadequately sterilized neurosurgical instruments. Patient notification methods varied by hospital. Most hospitals sent out notification letters to affected patients. A limited number of hospitals used local newspaper advertisements as the sole notification method or in combination with mailed letters. In most cases, the postexposure message sent by hospital management was developed by multidisciplinary teams that included neurosurgeons, neurologists, infection prevention specialists, and hospital management staff.

Prion Inactivation Studies

Many studies have evaluated the susceptibility of prions to chemical and physical inactivation methods (Table 2).[10-22] Outcomes of these studies are influenced by the sterilization methods employed, the prion strains used, the nature of the starting material (eg, tissue macerates, brain homogenates, and contaminated stainless steel wires), and the laboratory method used to detect residual infectivity. To better simulate realistic hospital scenarios, more recent inactivation studies used stainless steel wires to evaluate the effectiveness of different decontamination and sterilization protocols.[13,18-20] The wires were contaminated by immersing them in infected brain homogenate, and infectivity was assayed by implantation of the wires into the brain of experimental rodents. Studies that have used these methods have reported survival of prion infectivity after autoclaving at 134°C for 18 minutes or more

TABLE 1. Incidents of Patient Exposure to Instruments Potentially Contaminated with Creutzfeldt-Jakob Disease Reported by US Hospitals

Hospital	Age, sex	Death year	Procedure type/ reason for procedure	Time from procedure to diagnosis	Identification of neurosurgery set	Notification decision
A	69, F	1998	Shunt for hydrocephalus	5 months	Not identified (1 of 4 sets)	Unknown
B	59, F	1998	Vasculitis or encephalitis[a]	2 days	Not identified (1 of 12 sets)	Unknown
C	70, F	1998	Cerebral vasculitis[a]	1 week	Not identified (1 of 5 sets)	Patients not notified
D	60s, M	2000	Uncontrollable seizures	3 months	Identified	Patients notified
E	66, F	2001	Brain biopsy to rule out vasculitis[a]	3 weeks	Identified	Patients notified
F	80, M	2001	Cataract surgery	2 months	Not identified	Patients not notified
G	43, M	2002	Chiari I decompression	1 year	Not identified	Patients notified
H	46, F	2004	Brain biopsy for undiagnosed encephalitis[a]	1 day	Identified	Patient to be notified within 2 years
I	67, F	2004	Cataract surgery	3 months	Not identified (1 of 8 sets)	Patients not notified
J	48, F	2004	Shunt for hydrocephalus	5 months	Not identified (1 of 2 sets)	First 16 patients notified
K	Unknown	2004	Brain biopsy to rule out vasculitis[a]	<2 weeks	Identified (1 of 6 sets)	Patients notified
L	58, F	2004	Brain biopsy for suspected encephalitis[a]	5 days	Not identified (1 of 9 or 10 sets)	Patients notified
M	68, M	2005	Evacuation of subdural hematoma, bilateral frontal-parietal burr holes	7 months	Not identified (1 of 4 sets)	Patients notified
N	61, M	2007	Frontal lobe meningioma	3 months	Not identified (1 of 12 sets)	Patients not notified
O	49, F	Unknown	Brain biopsy[a]	Unknown	Identified (only 1 set)	Patients notified
P	78, M	2011	Shunt for hydrocephalus	8 months	Not identified (1 of 2 sets)	Patients notified
Q	52, F	2012	Brain biopsy[a]	2 days	Identified	Patients notified
R	68, M	2012	Exploratory craniotomy[a]	12 days	Identified (1 of 5 sets)	Patients notified
S	74, M	2012	Evacuation of hematoma	4 months, 10 days	Identified (1 of 2 sets)	Patient notified

[a] Intracranial procedures most likely performed as part of the diagnostic assessment of the patients, indicating absence of a definitive diagnosis.

TABLE 2. Effectiveness of Various Prion Decontamination Methods Evaluated by Selected Inactivation Studies

Publication	Year	Prion strain	Source material	Assay used	Decontamination methods	Transmission, % (infected/total)	Log reduction
Taylor et al[10]	1997	22A scrapie strain	Brain macerates	VM mice, IC	Immersed in H_2O, 1 h then autoclaving in H_2O, 121°C; 30 min	100 (11/11)	...
					Autoclaving in NaOH (2M), 121°C; 30 min	0 (0/18)	...
Taylor et al[11]	1998	263K scrapie strain	Brain macerates	Hamsters, homogenate, IC	Autoclaving, 134°C; 18 min (1 cycle)	100 (10/10)[a]	3.3
					Autoclaving, 134°C; 18 min (2 cycles)	60 (3/5)[a]	4.6
Fichet et al[14]	2004	263K scrapie strain	Stainless steel wires in 10% homogenate	Hamsters, implanted	NaOCl (20,000 ppm), 20°C; 1 h	0 (0/8)	>5.6
					NaOH (1N), 20°C; 1 h	0 (0/12)	>5.6
					Autoclaving (dry),[b] 134°C; 18 min	60 (6/10)	4 to 4.5
					Autoclaving in H_2O, 134°C; 18 min	0 (0/11)	> 5.6
Yan et al[15]	2004	263K scrapie strain	Stainless steel wires in 10% homogenate	Hamsters, implanted	Autoclaving, 134°C; 18 min	10 (1/10)	...
					NaOH (1 M) bath, 24 h then autoclaving 134°C; 18 min	20 (2/10)	...
					Enzymatic detergent (2%) wash then autoclaving, 134°C; 18 min	100 (10/10)	...
					Alkaline detergent (pH, 11) wash 70°C; 10 min then autoclaving, 134°C; 18 min	22 (2/9)	...
Jackson et al[16]	2005	RML strain	Stainless steel wires in 10% or 20% homogenate	Tg20 mice, implanted	Autoclaving, 121°C; 20 min (20% homogenate)	33 (2/6)[c]	...
					Autoclaving, 134°C; 20 min (20% homogenate)	25 (1/4)[c]	...
					Autoclaving, 134°C; 20 min (10% homogenate)	100 (13/13)	...
Peretz et al[22]	2006	Sporadic CJD strain	Stainless steel wires in 10% homogenate	Tg23372 mice, implanted	Autoclaving, 121°C; 30 min	0	...
					Autoclaving, 121°C; 2 h	73	...
					Autoclaving, 134°C; 2 h	46	...
Fernie et al[17]	2007	301V BSE, 263K scrapie, or 22A scrapie strains	Brain macerates	VM mice or LVG hamsters, homogenate, IC	Autoclaving, 134°C; 18 min (301V, VM mice)	64 (9/14)	...
					Autoclaving, 134°C; 18 min (263K, LVG hamsters)	13 (2/16)	...
					Autoclaving, 134°C; 18 min (22A, VM mice)	0 (0/15)	...
Giles et al[21]	2008	301V BSE, cattle BSE	Stainless steel wires in 10% homogenate	Tg2091 or Tg4092 mice, implanted	Autoclaving, 134°C; 2 h (301V strain, Tg 2091 mice)	14	...
					Autoclaving, 134°C; 2 h (cattle BSE strain, Tg 4092 mice)	89	...
Lehmann et al[18]	2009	263K scrapie strain	Stainless steel wires in 20% homogenate	Hamsters, implanted	Autoclaving, 134°C; 18 min	57	4.11
Rogez-Kreuz et al[19]	2009	263K scrapie strain	Stainless steel wires in 10% homogenate	Hamsters, implanted	Autoclaving, 134°C; 18 min	50	≥5 to 6
					NaOH (1 N), room temperature, 1 h then autoclaving, 134°C; 18 min	28	≥5 to 6
					Enzymatic detergent (2%), 37°C; 10 min then autoclaving, 134°C; 18 min	100	4.0
					Alkaline detergent A (1%), 70°C; 10 min then autoclaving, 134°C; 18 min	0	≥5 to 6

NOTE. BSE, bovine spongiform enchephalopathy; h, hours; IC, intracerebrally inoculated; LVG, Lakeview Golden; min, minutes.

[a] Transmission rates are from hamsters injected with 10^{-1} dilution group.

[b] Wires were placed on support during autoclaving at 134°C.

[c] All infected mice did not display clinical signs and survived to the end of the experiment but were classified as infected after neuropathological examination.

(Table 2).[13-16,19,20,22] Two studies in particular reported survival of infectivity despite subjecting the wires to detergent washing before autoclaving at 134°C for 18 minutes.[15,19] In these same studies, a decontamination protocol with sodium hydroxide (NaOH) treatment followed by autoclaving at 134°C for 18 minutes was not completely effective, which indicates that prion sterilization protocols that combine chemical treatment with autoclaving should be carefully selected. Most effective decontamination protocols combining chemical treatment and autoclaving are summarized in Table 3.

DISCUSSION

Six cases of CJD, dating from the late 1950s to 1976, have been linked to exposure to prion-contaminated neurosurgical instruments and devices.[1,23] Four of these cases were associated with contaminated neurosurgical instruments, whereas 2 involved reuse of implantable electroencephalogram depth electrodes originally used in treating a patient with known CJD.[24] Although the absence of CJD cases linked with exposure to neurosurgical equipment since the 1980s is reassuring, recent investigations have highlighted the difficulties associated with documenting such transmissions.[1,25] In these investigations, an accurate assessment of a causal link with procedures that occurred many years in the past was not possible because of the unavailability of medical records and closure of hospitals. However, several studies have documented that a history of neurosurgical procedures among patients with CJD is uncommon, being reported in less than 4% of such patients.[26-28]

Infection prevention professionals' awareness about the need for additional precautions when operating on patients with CJD has increased over the years, mainly because of increased publicity about the transmissibility of prion diseases and the resistance of prions to conventional sterilization methods. Despite this heightened awareness, incidents of patient exposure to inadequately sterilized neurosurgical instruments are reported to the CDC. Hospital staff often find themselves in a quandary when these incidents occur. Usually, weeks to months have elapsed by the time the incidents are discovered after confirmation of CJD in the index patient. Availability of multiple neurosurgical sets can hinder identification of the set used to treat the index patient, further complicating proper handling of these exposure incidents.

To prevent future occurrence of similar incidents, hospital infection prevention policies should be reviewed by integrating lessons learned from the unique characteristics of the CJD incident under investigation. In 2011, the Joint Commission published a sentinel event alert summarizing lessons learned from a CJD exposure incident that can be applied to other hospitals.[29] If not already in place, CJD infection prevention guidelines tailored to the institution should be developed and periodically updated as necessary. In over half of the exposure incidents described in Table 1, the intracranial procedures were likely performed as a diagnostic work-up for the patients. In such scenarios, exposures could potentially be prevented if CJD is included in the patient's presurgical assessment. Neurosurgical instruments used to treat patients whose diagnosis is unclear, particularly for brain biopsy, should be regarded as potentially contaminated with the CJD agent. Such instruments should be quarantined until a nonprion disease diagnosis is identified or should be regarded as contaminated and sterilized using the recommended CJD decontamination protocols. Efficient communication among treating physicians, operating room staff, infection prevention professionals, and central sterilization department supervisors is crucial to ensure that appropriate measures are instituted to identify instruments that need special handling.

CJD exposure risk after neurosurgical procedures varies

TABLE 3. Prion Decontamination Protocols For Reusable Surgical Instruments and Surfaces

World Health Organization and Centers for Disease Control and Prevention recommended options
1. Immerse in 1 N or 2 N NaOH and heat in a gravity displacement autoclave at ≥121°C for 30 minutes in an appropriate container (see text, warnings, and references). Clean and sterilize by conventional means.
2. Immerse in 1 N NaOH or NaOCl 20,000 ppm for 1 hour. Transfer into water and autoclave (gravity displacement) at ≥121°C for 1 hour. Clean and sterilize by conventional means.
3. Immerse in 1N NaOH or NaOCl (20,000 ppm) for 1 hour. Rinse instruments with water, transfer to open pan, and autoclave at ≥121°C (gravity displacement) or at 134°C (porous load) for 1 hour. Clean and sterilize by conventional means.
Decontamination of surfaces
Surfaces can be treated with 2N NaOH or sodium hypochlorite (20,000 ppm) for 1 hour.
Ensure surfaces remain wet for entire time period and then rinse well with water.
Before chemical treatment, it is strongly recommended that gross contamination of surfaces be reduced because the presence of excess organic material will reduce the strength of either NaOH or sodium hypochlorite solutions.
Warnings
NaOH should not be autoclaved in aluminum containers or in contact with aluminum.
Some poor-quality stainless steel instruments may be corroded by exposures to NaOH solutions; many metal instruments are corroded by exposures to NaOCl solutions.
Autoclave containers should have rims and lids designed to allow NaOH condensates to collect and drip back into the pan.
NaOH solutions are very caustic when hot and should be allowed to cool close to ambient temperature before handling using appropriate precautions

depending upon the type of procedure, number of neurosurgical sets in circulation, time elapsed and number of operations performed after the procedure, and adequacy of routine instrument reprocessing methods (eg, multiple reprocessing and reuse). When assessing potential CJD exposure incidents, the following issues should be considered and critically evaluated.

Confirmation of CJD Diagnosis

Before taking drastic measures, such as notifying potentially exposed patients or exposing expensive instruments to harsh decontamination treatments, the CJD diagnosis should be confirmed in the index patient. Testing of brain tissue samples obtained at autopsy or biopsy is required to confirm a CJD diagnosis. Several types of tests can be performed on the brain tissue, including histopathology, immunohistochemistry, and Western blot analysis.[30] Brain autopsy specimens have a higher diagnostic yield than brain biopsy specimens. Because CJD lesions are multifocal, careful sampling of the affected region is required to maximize the yield of brain biopsy testing.[30] A negative brain biopsy result does not necessarily rule out a prion disease diagnosis. Cerebrospinal fluid (CSF) analysis for 14-3-3 and tau proteins can help in the clinical diagnosis of CJD; however, because they are nonspecific markers of rapid neuronal death, positive results do not confirm a CJD diagnosis.[31] Recently, real-time quaking-induced conversion analysis of CSF has shown promising results as a premortem diagnostic tool by detecting the presence of minute amounts of prions.[32] Whenever possible, diagnostic support should be obtained from sources experienced in diagnosing CJD, such as the National Prion Disease Pathology Surveillance Center. This pathology center was established by the CDC to provide prion disease diagnostic support to US physicians.[30] If there is doubt about the diagnosis or while awaiting diagnostic clarification, the surgical instruments can be quarantined or reprocessed using the CJD decontamination protocols.

Type of Surgical Procedure

Risk of instrument contamination and potential for subsequent patient exposure depend on the type of procedure performed. Because the brain has the highest prion infectivity titer, intracranial procedures pose a higher risk of instrument contamination than ophthalmologic procedures.[6] Delicate, reusable instruments (eg, cranial probes) that are directly applied to the brain of patients with CJD but cannot be autoclaved pose a greater risk of prion exposure than instruments that can be autoclaved. It may be prudent to consider such instruments as single-use devices. The risk of instrument contamination during spinal surgical procedures, such as discectomy, laminectomy, and decompression procedures, should be considered equivalent to that associated with general surgical procedures performed in any other anatomical location. Spinal surgery that does not involve dural tear or direct contact with the spinal cord or CSF carries a lower risk of prion exposure than procedures involving manipulation of central nervous system tissues. No known CJD transmission via instruments used during ophthalmologic procedures has been reported. The only vehicles of CJD transmission involving ophthalmologic procedures were corneal grafts obtained from CJD decedents.[33]

Number of Neurosurgical Sets and Multiple Reuses

The CJD diagnosis for the index patient may not be suspected or confirmed until months after the initial neurosurgical procedure. During the interim, the instruments may have been used to treat many other patients and reprocessed multiple times using standard autoclaving methods. Multiple instrument reprocessing may be adequate to completely remove any residual prion infectivity. Modeling data developed by the UK CJD Incidents Panel indicated that most instruments reused and reprocessed for 10 or more cycles are unlikely to pose a significant risk of prion exposure to subsequent patients.[34] The modeling scenarios used various assumptions that were derived from limited available data on prion contamination.

As shown in Table 1, almost half of the hospitals had multiple neurosurgical sets, which made identification of instruments used to treat the index patient with CJD nearly impossible. This created an additional level of complexity for hospitals that elected to notify patients who underwent a neurosurgical procedure before instrument sterilization using CJD decontamination protocols. All patients, including those who presumably underwent neurosurgical procedures using uncontaminated instruments, were included in the notification. The notification message should account for the likelihood that most patients probably were not exposed to the neurosurgical instruments used to treat the index patient. To avoid this confusion and allow identification of instruments used to treat specific patients, the feasibility of implementing instrument tracking procedures should be considered. In addition, as a general prudent practice, mixing instruments from neurosurgical sets with those of other general surgical sets should be avoided.

Management of Patients and Instruments after Exposure

Instruments used to treat patients whose CJD diagnosis was suspected or confirmed after a neurosurgical procedure should be reprocessed using CJD decontamination protocols as soon as possible after diagnosis. Alternatively, the instruments can be quarantined if the CJD diagnosis is unclear. The instruments should be kept moist by immersing them in saline during the quarantine period. If tracing of instruments used on the index patient is not possible, all neurosurgical sets should be treated with the CJD decontamination protocol, particularly if the instruments have not been reused and reprocessed for 10 or more cycles.

Because patient exposure scenarios can be variable and the

healthcare team and hospital management staff are more knowledgeable about the potential negative consequences of disclosure of such incidents, decisions about patient notification are best handled by an ad hoc hospital review board. In addition to the issues already discussed, the review board may wish to consider the following factors before making decisions: (1) the ability to identify potentially contaminated neurosurgical instruments and link them to exposed patients; (2) the low risk of transmission; (3) the potential negative consequences of informing patients about possible exposure to a fatal, untreatable brain disease with a long incubation period; (4) the absence of a practical CJD test to screen live patients; and (5) the absence of any meaningful intervention, such as prophylactic treatment, to ameliorate the risk of developing CJD.

Notification of potentially exposed patients creates ethical and legal concerns. However, no overriding public health justification exists to mandate notification of potentially exposed patients. Some exposed patients may have life-threatening conditions that led them to undergo the neurosurgical procedure in the first place. These patients may not survive long enough to develop CJD even if exposure was certain. Other patients may become severely depressed and suicidal upon hearing that they were exposed to an agent causing untreatable and invariably fatal disease. Therefore, the deleterious effects of patient notification should be carefully considered and balanced with the certainty of exposure, level of risk, and right of patients to be informed about their own exposure. In those incidents on which the CDC has consulted, a decision to notify potentially exposed patients was made by three-fourths of the hospitals. In the remaining hospitals, hospital staff reviewed the situation and decided that patient notification was unwarranted under those specific circumstances. Hospital review boards can differ in their recommendation regarding patient notification depending on the prevailing hospital policy, composition of the review board, number of patients involved, type of procedure, certainty of CJD diagnosis in the index patient, and time elapsed between potential instrument contamination and alleged patient exposure.

CJD Decontamination Protocols

Because of uncertainties inherent in inactivation studies and the variability of results depending on experimental design, some researchers may disagree on appropriate sterilization protocols to decontaminate neurosurgical instruments used to treat patients with CJD.[5,7,35] In 1999, the WHO convened a consultation group of international prion disease experts to develop consensus infection control guidelines for prion diseases.[6] Although over a decade has passed since the guidelines were developed, the key recommendations are still applicable and are endorsed by prion disease researchers at the CDC, US Food and Drug Administration, and National Institutes of Health, among other prominent prion disease experts.[5] All surgical instruments that have direct contact with high- and low-infectivity tissues of patients with suspected or diagnosed prion disease should be sterilized using one of the options summarized in Table 3. The instruments should be kept moist by immersing them in saline to avoid air drying during and after the surgical procedure. The list of high- and low-infectivity tissues is periodically updated and summarized by the WHO.[36] Instruments used to treat patients with unclear diagnosis undergoing a craniotomy procedure should be regarded as potentially contaminated and reprocessed using one of the options listed in Table 3 unless an alternative nonprion disease diagnosis is identified.

CJD-contaminated instruments may have been cleaned in an automated instrument washer together with other surgical instruments. However, cross-contamination of those instruments during the cleaning cycle is unlikely because enzymatic cleaners interfere with protein binding and alkaline pH aids in protein denaturation. Additionally, continuous water motion in the washer helps to keep such damaged proteins in suspension, thereby minimizing the potential that the CJD agent will stick to the instruments in the load. As a precaution, the washer could be run for an empty cycle after removing all instruments.[6]

Under option 1 in Table 3, contaminated instruments are autoclaved while immersed in 1N NaOH solution. Options 2 and 3 allow for sequential treatment of instruments first by immersing them in 1N NaOH or sodium hypochlorite followed by autoclaving. Unlike option 3, option 2 allows maintenance of instrument moistness as the instruments are transferred from the chemical directly into water and decontaminated by gravity displacement autoclaving while immersed in water. At the conclusion of the decontamination step, all 3 options require additional routine sterilization of the instruments by conventional washing and autoclaving used in the hospital (Table 3).

NaOH and sodium hypochlorite are corrosive chemicals, and their handling requires suitable personal protective equipment and proper secondary containment. The use of appropriate containment pans and lids has been shown to prevent escape of NaOH vapors and spills that may damage the autoclave.[37] Because NaOH is much less corrosive, its use is preferred to that of sodium hypochlorite. An experimental study indicated that much of the instrument damage from autoclaving in NaOH was cosmetic and would not affect instrument performance.[38]

CONCLUSIONS

CJD exposure incidents create infection control management dilemmas that are further complicated by the availability of multiple neurosurgical sets and difficulty in tracing contaminated instruments. Potential exposures can be prevented by including CJD in the patient's presurgical assessment, particularly if a brain biopsy is planned. Mixing neurosurgical instruments with general surgical sets should be avoided, and

the feasibility of implementing instrument tracking procedures should be considered. The experiences and approaches summarized above can help infection prevention professionals manage potential exposure incidents should they occur in the future.

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Address correspondence to Ermias Belay, MD, 1600 Clifton Road, Mailstop A-30, Atlanta, GA 30333 (ebelay@cdc.gov).

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