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Preliminary risk analysis applied to the transmission of Creutzfeldt-Jakob disease

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Transmissible spongiform encephalopathy (TSE) is a degenerative disease of the central nervous system. As yet, there is no human screening test and no effective treatment. This disease is invariably fatal. General preventive measures are therefore essential. The objective of this study is to analyze and address on a prioritized basis the risks relating to the transmission of Creutzfeldt-Jakob disease during surgical operations by means of a preliminary risk analysis (PRA). The PRA produces 63 scenarios with maximum risk relating to operational and legal dangers. The study recommends a number of courses of action, such as training and internal controls, in order to reduce the risks identified. A procedure has been drawn up and assessed for each action. This PRA makes it possible to target and significantly reduce the potential dangers for transmission of Creutzfeldt-Jakob disease through the use of medical instruments.

1. Introduction

Transmissible spongiform encephalopathy (TSE) is a degenerative disease of the central nervous system, characterized by the accumulation of a pathological prion protein, PrPc (Alberganti 2008; Hyatt 2003). There is no human screening test and no specific treatment. Consequently, the disease is invariably fatal (Reason 2004). General preventive measures are therefore essential. Since 1994, a new form of Creutzfeldt-Jakob disease (CJD) has emerged, identified under the name of "new variant Creutzfeldt-Jakob disease" (nvCJD), which is probably caused by the transmission to humans of the bovine spongiform encephalopathy (BSE) agent. For several years, various preventive measures have been taken in health-care institutions in order to reduce the risks of TSE transmission. French Government circular DGS/DH No. 100 of December 11th 1995 sets out the precautions to be observed in surgical departments regarding the transmission risks of CJD (Nolan 2008). It is essential to take into account the risks related to the new variant form of Creutzfeldt-Jakob disease, the characteristics of which are extremely alarming. New recommendations for controlling the risk of transmission to humans of TSE were published by the World Health Organization (WHO) in September 2000 following an organized consultation in March 1999 (Gamage 2000). Those recommendations take account of the various experimental studies which highlight the exceptional resistance of the non-conventional transmissible agents (NCTAs) to the physical and chemical processes of inactivation and specify the parameters likely to explain this (in particular, desiccation). The official circular of March 14th 2001 reviews these concepts and specifies the principles to be observed in the management of medical instruments in order to reduce the transmission risk of NCTAs (Bartz 2007). It recommends that medical instruments be treated using the most effective process of NCTA inactivation, with due account being taken of the nature of the procedure and the level of risk to the patient.

Because of a suspected outbreak of CJD, as a result of which the operating suite was closed for one week, the Jean Verdier hospital set up a working group to look at measures to prevent a NCTA transmission risk. Its objective was to analyze and prevent the causes of such an incident. To that end, a functional analysis was carried out to identify the situations posing a danger and produce scenarios of the potential harmful effects. The ultimate aim was to reduce the risks of CJD transmission in the course of surgical operations.

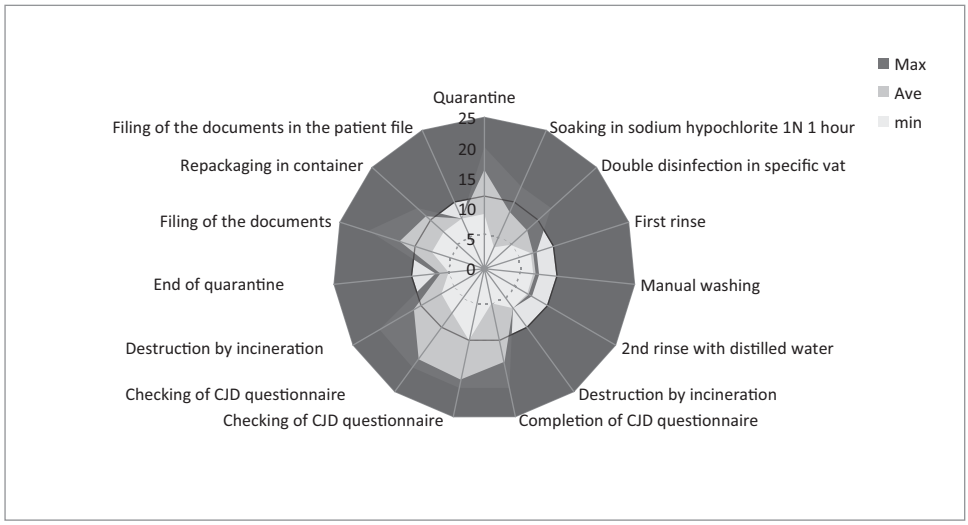
2. Investigations and results

2.1. PRA System

The management of medical instruments relating to the CJD transmission risk at the Jean Verdier hospital concerns surgery and anesthetics consultations, the central sterilization unit and the operating suite. Functions are defined for each activity (Table 1). The situations posing a danger are listed in Table 2. These situations are mapped on the basis of the stages and possible hazards (Table 3) with a criticality of 1 for the main risk

Table 1: Functions and stages of PRA system

Functions	Stages
Consultations	To supplement the CJD questionnaire
Operating suite	Checking of CJD questionnaire
	Double disinfection in specific vat
	Filing of the documents in the patient file
Central sterilization unit	Checking of CJD questionnaire
	First rinse
	Manual washing



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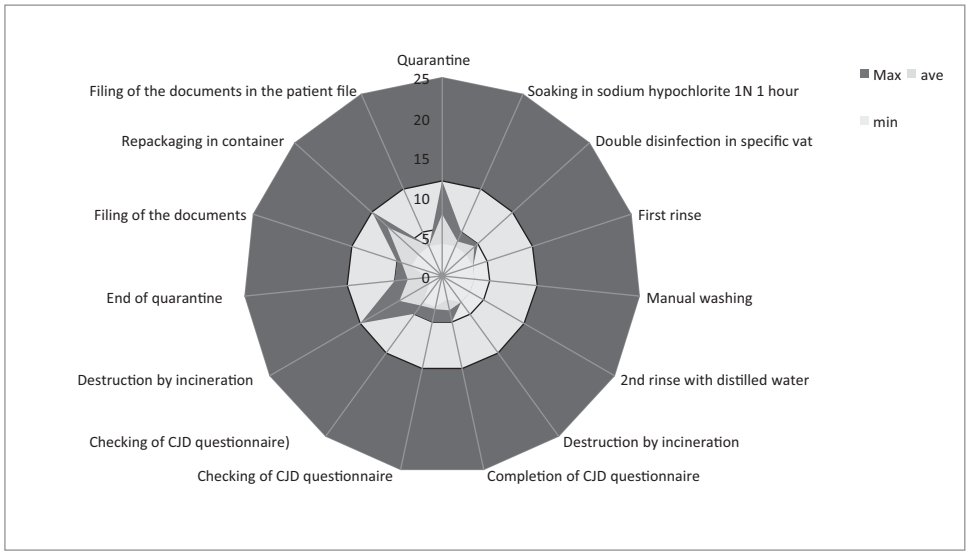

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Fig. 1: Kiviat Diagrams of the initial risks (A) and after implementation of the risk reduction plan (B)

and a criticality of 2 for a minor risk. This process identified 62 "criticality 1" points and 69 "criticality 2" points. It was decided to deal only with the "criticality 1" situations in order to ensure coordinated management of the CJD transmission risk.

2.2. PRA Scenario

In order to evaluate each situation posing a danger, descriptions were given of the severity, probability, effort, and level of acceptance of risks (Table 1). Severity comprises 5 levels ranging from S1 to S5 (S1 representing a minor incident and S5 a catastrophic incident). The probability of dangerous situations was defined by the working group. Acceptance comprises 3 levels ranging from C1 to C3, C1 representing an acceptable risk and C3 an unacceptable risk. The concept of effort comprises 4 levels ranging from E0 to E3, E0 representing no effort to reduce the initial risks and E3 a significant effort. For each scenario, the cause of the potential dangerous situation was evaluated in the light of the possible consequences and by employing the above criteria. PRA Scenario shows 62 scenarios represented on the Kiviat and Farmer diagrams (Fis. 1 and 2). The Kiviat diagram showing the initial risks proves that the maximum dispersion of risk has an impact on the sterilization and consultations sectors, whereas the average risk dispersion diagram impacts on completion of the questionnaire and repackaging of the containers. Following implementation of the risk reduction plan (Figs. 1 and 2), the potential dangerous situations are reduced in C2 and are thus acceptable and under control.

2.3. Risk reduction plan

The dangerous situations resulting from PRA scenario in C3 were indexed and a risk reduction plan drawn up. This plan comprised 58 actions divided into 5 categories: purchase of material (2 actions), traceability of instruments (6 actions), quality assurance (16 actions), management (2 actions), and training program (32 actions). A plan was established for each action, outlining a specific period for each, according to the effort required. The majority of actions require immediate implementation. For each action, a process is agreed upon which specifies the target scenario, the person responsible, the description of the action, the objectives, and the rate of the residual risks.

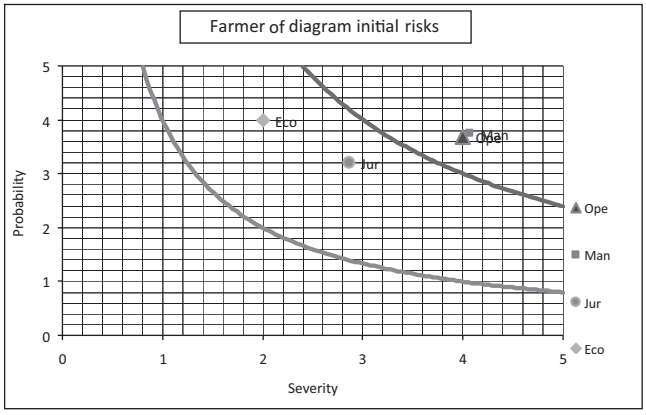
Table 2: Potentially dangerous situations

General Situations	Specific situations	Dangerous situations
Operational	Environment and equipment	No storage cupboard for equipment placed in quarantine
		Chemical products out of stock
		No management of waste
	Data processing procedures	Breakdown of data-processing network
	Data processing	Failure to comply with CJD procedures
		No CJD procedure
		Complexity of the documents
		Non-identified containers
Management	Organization	Mix with non-contaminated instruments
		Absence of coordination group
		Overwork
		No trained theater staff
		No trained sterilization staff
	Communication	No questionable patient
		Oral transmission
Legal	Lawful	Failure to comply with NCTA circular
Economic	Financial	Cost of repurchase of medical instruments

3. Discussion

Hospitals are confronted daily with various difficulties of traceability of storage, transport, and distribution of the medical instruments sterilized by the central sterilization unit. The risk of CJD transmission to a patient undergoing an operation is potentially disastrous for its human, collective, legal and financial consequences. Various preventive measures have been taken in health care institutions in particular in order to reduce the level of risk. However, evaluation of these measures has not been properly quantified. The preliminary analysis of the CJD transmission risks was applied to the Jean Verdier hospital, in tandem with a functional analysis, and the mapping of (i) situations posing a danger and (ii) the risks involved. An analysis of the general dangers in the system shows that 49.2% of operational dangers have a vulnerability of level 1 and that 25.4% of the material dangers are also of vulnerability level 1. The analysis of the Kiviat diagrams on the general risks shows the graphic correlation between the managerial risk and the operational risk. The legal and economic dangers are in the area of acceptability under control. Following implementation of the risks reduction plan, the managerial and operational risks move into acceptability area under control. The analysis of the Kiviat diagrams on the different stages of the system shows that the stages of quarantine, destruction, completion and checking of the CJD questionnaire, filing of the documents and repackaging are in the unacceptable zone. Following implementation of the risk reduction plan, the stages of destruction, preparation and quarantine just fall into the area of acceptability under control. The efforts to be carried out must be focused on staff training and on the absolute need for complying with the CJD circular (some aspects of which are standard practice). Partial compliance with the CJD circular shows a probability of CJD transmission higher than 40% and a probability of legal proceedings of approximately 20%.

The preliminary analysis of the risks of CJD transmission to a patient undergoing surgery reveals the situations posing a danger which must be addressed without fail. The PRA has enabled us to lay down the objectives to be met in order to ensure a completely safe system for the recirculation of reusable medical instruments in a hospital environment and to thus control the risks inherent in any suspected case of CJD.



(A)

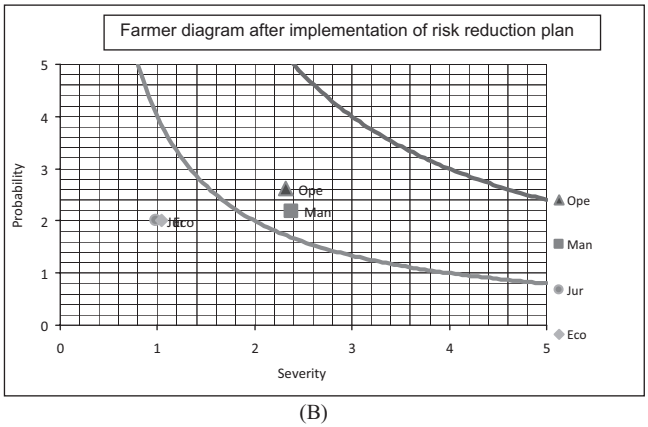


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Fig. 2: Farmer diagrams of the initial risks (A) and after implementation of the risk reduction plan (B)

4. Experimental

To identify the possible CJD transmission risks, a working group was set up comprising representatives of the following departments: sterilization, risk management, operating suite, surgery consultations, and finance departments.

4.1. Selection of the working group members

The members of the committee were selected by the risk manager (chair of the committee) and the sterilization pharmacist (vice-chair of the committee) who initiated the project. All the selected members were required to read and sign the project documents. Each week the working group met

Table 3: Map of the dangerous situations

General Situations	Specific Dangers	Dangerous events	Consultation	Operating Suite			Central sterilization										
			Completion of CJD questionnaire	Checking of CJD questionnaire	Double disinfection in specific vat	Filing of the documents in the patient file	Checking of CJD questionnaire	First rinse	Manual washing	Soaking in sodium hypochlorite 1N 1 hour	2nd rinse with distilled water	Repackaging in container	Sterilization at 134°C for 18 minutes	Quarantine	Destruction by incineration	End of quarantine	Filing of the documents
Operational (Ope)	Environments and equipment	No storage cupboard for equipment placed in quarantine												1			
		Chemical products out of stock			2				2	1							
		No management of waste			1			1	1	1	1				1		
	Data processing	Breakdown of data-processing network		2			2	2	2	2	2	2	2	1		2	2
	Procedures	Failure to comply with CJD procedures	1	1	1	2	1	2	2	1	2			1	1	1	1
		No CJD procedure	1	1	1	2	1	2	2	1	2			1	1	1	1
		Complexity of the documents	1	2		2	2			2	2			2	2	2	
		Non-identified containers			2			2	2	2	2	1		1	1	2	2
Management (Man)	Organization	Mix with non-contaminated instruments			2			2	2	2	2	1		1	1	2	2
		Absence of coordination group													1	1	
		Overwork	2	1	2	2	1	2	2	2	2	2	2	2	2	2	2
		No trained theater staff	1	1	2	2											
		No trained sterilization staff					1	2	2	2	2	2	2	2	2	2	2
	Communication	No communication with patient	1				1										
		Oral transmission		1		2	1								1	1	2
Legal (Jur)	Lawful	Failure to comply with NCTA circular	1	1	1	1	1	1	1	1	1	1		1	1	1	1
Economic (Eco)	Financial	Cost of repurchase of medical instruments													1		

and exchanged information on the results obtained. When all members were agreed on the items to be included in the risk mapping process, the risk manager collated the results in order to work out the preliminary risk analysis.

4.2. Preliminary risk analysis

The preliminary risk analysis (PRA) was based on the preliminary analysis of dangers (PAD). The PAD is a semi-quantitative analysis which makes it possible to identify all the risks and events which can lead to an accident, list the events identified according to their severity and identify actions for reducing and monitoring the risks (Krasnianski 2004, Ministry of Social Affairs and Labor 2001). The PRA takes into account the sedentary interfaces between various elements of the system including the operational, economic, management and legal constraints with the system. All the potential risks and events must be identified. It is important to consider all the parts of the system as operational modes. All the results are recorded. No risk is too insignificant to be recorded. To obtain a complete outline of all the possible risks, a checklist is drawn up and validated by the working group. The PRA is carried out in two stages: the PRA system and the PRA scenarios.

4.3. PRA System

The objectives of the PRA system are to determine the general and specific dangers and to map the situations posing a danger.

4.4. PRA Scenarios

The mapping process was based on the analysis of the scenarios corresponding to each situation posing a danger. The risk relating to a dangerous situation is a function of the frequency of the event and severity of its potential consequences. Thus, each dangerous situation is associated with a level of severity, probability, effort, and an acceptance of level of risk. The working group defined five levels of severity: from S1 (minor severity) to S5 (catastrophic severity) (Table 4). Probability must be related to the severity of each dangerous situation. The working group defined five levels of probability: from P1 (impossible) to P5 (very probable) (Table 1). The map drawn up highlighted the initial and residual risks. If the residual risks remained uncontrolled, then corrective measures must be planned to reduce the risks to a minimum.

Table 4: Severity, probability, effort and criticality

Severity	Index	Repercussions	Probability	Effort	Criticality
S1 (minor)	11	Without clinical consequence for the patient	P1 (impossible)	E0 (none)	C1 (acceptable)
	12	Dissatisfaction of the patient	P2 (improbable)	E1 (weak)	C2 (acceptable under control)
	13	Without consequence for the medical instrument	P3 (not very probable)	E2 (average)	C3 (unacceptable)
	14	No traceability of the treatment	P4 (probable)	E3 (significant)	
	15	Prolongation of quarantine	P5 (very probable)		
S2 (significant)	21	Without lengthening of the duration of stay			
	22	Cancellation of an operation without consequence for the patient			
	23	Destruction of the medical instrument			
	24	Negative impact on the image of the hospital			
S3 (serious)	31	Prolongation of the duration of stay			
	32	Serious consequences for the patient			
	33	Legal procedure			
S4 (critical)	41	Life prognosis jeopardized			
	42	Re-circulation of a contaminated MI			
	44	Surgical operation with a contaminated MI			
	41	Life prognosis jeopardized			
S5 (catastrophic)	51	Contamination of a patient by a NCTA			
	52	Declaration of CJD			
	53	Death			
	54	Total absence of traceability			

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