Annex I List of Participants

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Annex II List of Presentations

Wednesday, 24 March 1999

09.00-09.10	Welcome and introduction to the meeting	Dr Lindsay J Martinez
09.10-09.20	Selection of Chair	
09.20-09.30	Goal of meeting and opening remarks from Secretary to the meeting	
09.30-09.45	Results of the Consultation on Reagents Meeting	Chair of Reagents Meeting
09.45-10.00	Questions	ALL

Epidemiology and projections

10.00-10.30	Extent of BSE exposure worldwide	Dr Raymond Bradley
10.30-11.00	Coffee break	
11.00-11.15	vCJD epidemiology	Dr Robert Will
11.15-11.30	Predictions of the epidemic of vCJD	Dr Peter Smith
11.30-12.00	Questions on BSE, vCJD, CJD epidemiology	ALL
12.00-13.00	Lunch break	

Identification of risk

13.00-13.15	Diagnosis of CJD (iatrogenic, familial, sporadic and vCJD)	Dr Martin Zeidler
13.15-13.30	Risk assessment and ethical issues	Dr Burleigh Trevor-Deutsch
13.30-13.45	Questions	ALL
13.45-14.15	Distribution of infectivity in CJD (iatrogenic, familial, sporadic)	Dr Paul Brown
14.15-14.30	Distribution of infectivity in vCJD	Dr James Ironside
14.30-14.45	Questions on tissue, blood and organ infectivity	ALL

Decontamination procedures

14.45-15.00	Decontamination procedures	Dr David Taylor
15.00-15.25	Instruments and environment; waste disposal	Dr R. Rohwer Ms Annette Pruess
15.25-15.45	Questions on decontamination	ALL
15.45-16.15	Coffee break	
16.15-17.00	Review of day's issues and conclusions	Chair, Working Group
17.30-19.30	Cocktail party	All

Thursday, 25 March 1999

Providing care to the ill

09.00-09.30	Care givers issues	CJD Support Network, CJD Voice, Human BSE Foundation
09.30-09.45	Nursing care in the home and hospital	Ms Blair Smith-Bathgate
09.45-10.00	Questions on provision of care	ALL

Protecting healthcare and allied workers: preventing iatrogenic transmission

10.00-10.15	Nursing practice in the hospital, long term care facility and nursing home	Miss Shirley Patton
10.15-10.30	Operating theatre	Dr Martinez-Lage
10.30-11.00	Coffee break	
11.00-11.15	New results from the Australian Case-Control Study	Dr Colin Masters
11.15-11.30	Post-exposure prophylaxis for prion diseases	Dr. Sebastian Brandner
11.30-12.00	Questions on protection of HCW and patients	ALL
12.00-13.00	Lunch break	
13.00-13.30	Clinical laboratory, pathology, and autopsy procedures Questions and comments	Dr Herbert Budka
13.30-14.00	Dentistry Questions and comments	Dr J. Cleveland
14.00-14.30	Mortuary Questions and comments	Mr George Lamb
14.30-14.45	Remarks of Chairs, table draft	Chair(s), Secretariat
14.45-15.30	Group discussion	All
15.30-16.00	Coffee	
16.00-17.00	Revisions of draft document	Chair(s), Secretariat, Rapporteur(s)

Friday, 26 March 1999

09.30-10.30	Summary of previous day and revisions
10.30-11.00	Coffee break
11.00-12.00	Revision of draft document
12.00-13.00	Lunch break
13.00-14.30	Final discussions
14.30-15.00	Final recommendations to secretariat
15.00-15.30	Coffee break
15.30-16.00	Meeting of Chairs, secretariat, speakers regarding revision of document
16.00	Close

Annex III Decontamination methods for Transmissible Spongiform Encephalopathies

The safest and most unambiguous method for ensuring that there is no risk of residual infectivity on contaminated instruments and other materials is to discard and destroy them by incineration. In some healthcare situations, as described in the guidance, one of the following less effective methods may be preferred. Wherever possible, instruments and other materials subject to re-use should be kept moist between the time of exposure to infectious materials and subsequent decontamination and cleaning. If it can be done safely, removal of adherent particles through mechanical cleaning will enhance the decontamination process.

The following recommendations are based on the best available evidence at this time and are listed in order of more to less severe treatments. These recommendations may require revision if new data become available.

1. Incineration

1. Use for all disposable instruments, materials, and wastes.
2. Preferred method for all instruments exposed to high infectivity tissues.

2. Autoclave/chemical methods for heat-resistant instruments

1. Immerse in sodium hydroxide (NaOH)[20] and heat in a gravity displacement autoclave at 121°C for 30 min; clean; rinse in water and subject to routine sterilization.
2. Immerse in NaOH or sodium hypochlorite[21] for 1 hr; transfer instruments to water; heat in a gravity displacement autoclave at 121°C for 1 hr; clean and subject to routine sterilization.
3. Immerse in NaOH or sodium hypochlorite for 1 hr.; remove and rinse in water, then transfer to open pan and heat in a gravity displacement (121°C) or porous load (134°C) autoclave for 1 hr.; clean and subject to routine sterilization.
4. Immerse in NaOH and boil for 10 min at atmospheric pressure; clean, rinse in water and subject to routine sterilization.
5. Immerse in sodium hypochlorite (preferred) or NaOH (alternative) at ambient temperature for 1 hr; clean; rinse in water and subject to routine sterilization.
6. Autoclave at 134°C for 18 minutes.[22]

[20] Unless otherwise noted, the recommended concentration is 1N NaOH.
[21] Unless otherwise noted, the recommended concentration is 20 000 ppm available chlorine.
[22] In worse-case scenarios (brain tissue bake-dried on to surfaces) infectivity will be largely but not completely removed.

3. Chemical methods for surfaces and heat sensitive instruments

1. Flood with 2N NaOH or undiluted sodium hypochlorite; let stand for 1 hr.; mop up and rinse with water.
2. Where surfaces cannot tolerate NaOH or hypochlorite, thorough cleaning will remove most infectivity by dilution and some additional benefit may be derived from the use of one or another of the partially effective methods listed in Section 5.1 (Table 8).

4. Autoclave/chemical methods for dry goods

1. Small dry goods that can withstand either NaOH or sodium hypochlorite should first be immersed in one or the other solution (as described above) and then heated in a porous load autoclave at ≥ 121°C for 1 hr.
2. Bulky dry goods or dry goods of any size that cannot withstand exposure to NaOH or sodium hypochlorite should be heated in a porous load autoclave at 134°C for 1 hr.

5. Notes about autoclaving and chemicals

Gravity displacement autoclaves: Air is displaced by steam through a port in the bottom of the chamber. Gravity displacement autoclaves are designed for general decontamination and sterilization of solutions and instruments.

Porous load autoclaves: Air is exhausted by vacuum and replaced by steam. Porous load autoclaves are optimized for sterilization of clean instruments, gowns, drapes, towelling, and other dry materials required for surgery. They are not suitable for liquid sterilization.

Sodium Hydroxide (NaOH, or soda lye): Be familiar with and observe safety guidelines for working with NaOH. 1N NaOH is a solution of 40 g NaOH in 1 litre of water. 1 N NaOH readily reacts with CO_2 in air to form carbonates that neutralize NaOH and diminish its disinfective properties. 10 N NaOH solutions do not absorb CO_2, therefore, 1N NaOH working solutions should be prepared fresh for each use either from solid NaOH pellets, or by dilution of 10 N NaOH stock solutions.

Sodium hypochlorite (NaOCl solution, or bleach): Be familiar with and observe safety guidelines for working with sodium hypochlorite. Household or industrial strength bleach is sold at different concentrations in different countries, so that a standard dilution cannot be specified. Efficacy depends upon the concentration of available chlorine and should be 20 000 ppm available chlorine. One common commercial formulation is 5.25% bleach, for which a 1:2.5 dilution (1 part bleach plus 1.5 parts water) yields the desired working solution. Working solutions should be prepared fresh for each use.

6. Cautions regarding hazardous materials

In all cases, hazardous materials guidelines must be consulted.

1. Personnel

NaOH is caustic but relatively slow acting at room temperature, and can be removed from skin or clothing by thorough rinsing with water. Hot NaOH is aggressively caustic, and should not be handled until cool. The hazard posed by hot NaOH explains the need to limit boiling to 10 minutes, the shortest time known to be effective.
Hypochlorite solutions continuously evolve chlorine and so must be kept tightly sealed and away from light. The amount of chlorine released during inactivation may be sufficient to create a potential respiratory hazard unless the process is carried out in a well-ventilated or isolated location.

2. Material

In principle, NaOH does not corrode stainless steel, but in practice some formulations of stainless steel can be damaged (including some used for surgical instruments). It is advisable to test a sample or consult with the manufacturer before dedicating a large number of instruments to decontamination procedures. NaOH is known to be corrosive to glass and aluminum. Hypochlorite does not corrode glass or aluminum and has also been shown to be an effective sterilizing agent; it is, however, corrosive both to stainless steel and to autoclaves and (unlike NaOH) cannot be used as an instrument bath in the autoclave. If hypochlorite is used to clean or soak an instrument, it must be completely rinsed from the surfaces before autoclaving. Other decontamination methods may need testing, or consultation with the manufacturer to verify their effect on the instrument.

Annex IV Management of healthy 'at risk' individuals

Tissue recipients

The consultation felt that the risk from *recipients of dura mater, cornea transplants* and *human pituitary hormones,* and *from persons who have undergone neurosurgical procedures,* is no longer sufficient to warrant classifying this population as a risk for transmitting TSEs, except under conditions where there could be exposure to their high infectivity tissues (see Section 2.4.2). The consultants considered that appropriate control measures have immensely reduced or eliminated exposure to contaminated dura mater and pituitary hormones, and noted that there are only three reports of TSE transmission through cornea transplantation, and six reports (all before 1980) of transmission via neurosurgical instruments. In addition, it was recognized that recipients of dura mater are largely unaware of the fact, making identification of many of the dura mater recipients unlikely.

Countries not applying appropriate control measures cannot assume similarly low levels of current risk among tissue recipients.

Familial Transmissible Spongiform Encephalopathies

Consensus was not reached as to whether asymptomatic persons at risk for *familial TSE* should be classified as 'at risk' when determining appropriate infection control levels. It was argued that the identification of familial risk among asymptomatic people would confer a lifetime requirement for high-level infection control for a transmission risk that remains only hypothetical. Discrimination against such persons and legal implications regarding their access to insurance, employment and healthcare was described by several participants in the consultation, and it was proposed that such discrimination would inevitably lead to a harm which exceeded any evidence of risk posed by them to others.

Others argued that if a familial risk were identified, then more stringent levels of infection control could be adopted even in the absence of firm evidence of risk, particularly during procedures involving *high infectivity tissues*. All consultants agreed that persons 'at risk' for familial TSE should not be denied access to treatment or surgical procedures, particularly given the range of decontamination options available. Scientific resolution of these issues was impossible due to a lack of precise information about tissue infectivity during the pre-clinical phase of human disease, and the consultants emphasized the need to study any available tissues (including blood) from mutation-positive, but still asymptomatic, members of TSE families.

Annex V Management of individuals with confirmed or suspected variant Creutzfeldt-Jakob Disease

The TSE agent causing vCJD has shown certain differences from that of sporadic CJD, including the detection of prion protein (PrP) in a range of lymphoreticular tissues. Patients with vCJD might therefore pose a greater risk of transmitting iatrogenic infections than sporadic CJD. However, this hypothetical risk has to be balanced against the real danger of stigmatizing patients and causing distress and anxiety to the patient's relatives by the introduction of rigorous and possibly unnecessary infection control procedures in general patient care.

On current evidence, the infection control procedures in nursing care settings for sporadic CJD may be applied to cases of vCJD without the need for additional precautions, although a more conservative approach may be taken for interventions involving surgical procedures, or when handling tissues and body fluids in the laboratory. See Section 6.6 (Table 9) for measures that have been recommended for high infectivity tissues in patients with other forms of TSE, that could be applied to all tissues of persons with vCJD. It is noted that considerable safety is afforded through the measures described in Section 6 and Annex III, and that no person should be denied a diagnostic test given the efficacy of the recommended measures. Comparative tissue risks for vCJD and a case definition of possible vCJD cases will need to be redefined as further research findings emerge. If vCJD is suspected, consultation with persons expert in this disease, such as The Edinburgh CJD Surveillance Unit, Western General Hospital, United Kingdom, is recommended.