TECHNICAL REPORT

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Suggested citation: European Centre for Disease Prevention and Control. Review of guidelines for prevention of Creutzfeldt–Jakob disease transmission in medical settings in EU Member States and Norway. Stockholm: ECDC; 2011.

Stockholm, June 2011

ISBN 978-92-9193-295-5

doi:10.2900/54359

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Abbreviations

AT	Austria
BSE	Bovine spongiform encephalopathy
CIBERNED	Centro de Investigación Biomédica en Red sobre Enfermedades Neurodegenerativas
CJD	Creutzfeldt–Jakob disease
CNS	Central nervous system
CZ	Czech Republic
DE	Germany
DG	Directorate-General
DK	Denmark
ECDC	European Centre for Disease Prevention and Control
ES	Spain
EU	European Union
EUROCJD	European Creutzfeldt–Jakob Disease surveillance network
FFI	Fatal familial insomnia
FP	Framework Programme
FR	France
gCJD	Genetic Creutzfeldt–Jakob disease
GP	General practitioner
GSS	Gerstmann–Sträussler–Scheinker syndrome
gTSE	genetic transmissible spongiform encephalopathy
HU	Hungary
iCJD	Iatrogenic Creutzfeldt–Jakob disease
IT	Italy
LV	Latvia
NL	Netherlands
NO	Norway
NS	Not specified
PI	Population index
PL	Poland
PRNP	Prion protein gene
PrP	Prion protein
sCJD	Sporadic CJD
SE	Sweden
SI	Slovenia
SK	Slovakia
TSE	Transmissible spongiform encephalopathy
UK	United Kingdom
vCJD	Variant Creutzfeldt–Jakob disease
WHO	World Health Organization

Executive summary

Since 1996, following outbreaks of variant Creutzfeldt–Jakob disease (vCJD) in several Member States, both the European Union (EU) and individual countries have implemented special public health measures and renewed research efforts in the field of human and animal transmissible spongiform encephalopathies (TSEs). The purpose of this report is to provide a review of available national documents aimed at controlling the transmission of human TSE in medical settings, taking the epidemiological situation and recent research results into account. The ultimate goal was to identify potential needs and tools useful to Member States for drawing up recommendations suited to their specific needs.

This report consists of a descriptive and partly critical approach to existing guidelines in EU Member States, based on recent research results and information generated by data collection using a structured questionnaire that targeted members of the European Creutzfeldt–Jakob Disease Surveillance Network (EUROCJD). No information was collected by officially requesting data from the national health authorities. The questionnaire, which comprised 91 items, was based on a prior format[1] used by the EUROCJD to obtain information on public health policies and procedures, and exclusively addressed national documents. Questionnaire items were designed after examining existing official documents/guidelines, which were available on websites hosted by international organisations – and by health authorities in EU Member States and the United Kingdom, in particular – and focused on public health practices for human TSEs. The public health practices reflected in specific recommendations in reported national documents and examined by EUROCJD respondents focused on:

- blood;
- identification and follow-up of persons at risk;
- medical procedures; and
- medical device decontamination.

Responses were obtained from seventeen countries representing 87% of the EU population and Norway. Questionnaire answers were reviewed by a group of consultants and by EUROCJD members and their comments were taken into account in the final version of this report. The number of respondent countries and the percentage of the total population of the countries that they represent, here annotated as the population index (PI), were recorded for each question.

Fifteen countries (91% PI) reported having guidelines or official documents containing descriptions about TSE features, diagnosis, classification of entities, transmission mechanisms and distribution of infectivity in human tissues and body fluids, as well as patient categorisation by risk. Six countries possessed decision-making algorithms.

All respondent countries stated that they had official TSE documents that included measures to protect blood supplies from variant Creutzfeldt–Jakob disease (vCJD). Detailed recommendations varied widely among the respective countries.

The definition of 'person at risk' of CJD and the management of such patients varied among countries. Fourteen countries (91% PI) reported having guidelines on specific infection-prevention measures for surgery, such as single-use equipment and destruction of contaminated equipment by incineration. Ten countries (66% PI) reported having guidelines for quarantining surgical instruments used on possible CJD/vCJD patients, until confirmation of diagnosis. Instrument traceability was recommended in guidelines from seven countries (58% PI). Ten countries (61% PI) produced recommendations on specific decontamination procedures for flexible endoscopes. In general, recommendations for planning care based on tables or decision trees, allocated risk levels to certain invasive procedures on the basis of the infectivity ascribed to specific contacted tissues.

Fifteen countries (99% PI) had medical-device decontamination guidelines, including advice on the use of specific disinfectant chemicals or steam sterilisation parameters. Twelve countries (87% PI) had written recommendations on specific safety measures for labelling, packaging and transporting of TSE-infected materials.

There was a wide variation in responses to the questionnaire from the 17 respondent countries, with positive answers ranging from 12 to 79 of the 91 items. The limitations of this study thus include variation in the response rate and focusing on the content rather than the type or quality of the documents examined. Positive answers that proved difficult to interpret were likely to correspond to one of two fields:1) where the underlying concept of 'person at risk' used in the answer might have been unclear or different among respondents; and 2) where questions addressed an issue that covered both CJD and vCJD. In this latter case, direct perusal of documents in five languages showed, in general, that for 16 EU Member States and Norway, positive answers were determined solely for vCJD and should have been negative for other CJD forms.

[1] Ward H and Blystad H. Report on Public Health Inventory. Minutes of the Annual Meeting of the EUROCJD, 29 May 2008, Riga.

Guidelines account for only a small number of documents officially considered as representing TSE management policy. A considerable proportion of EU Member States (11/27) may lack guidance on control of TSE dissemination. Effective management and control of sporadic CJD, vCJD and other forms of TSE may benefit from more widespread adoption of an amalgam of policies and procedures based on the various approaches taken in EU Member States.

EU-wide guidance for prevention of transmission of CJD in healthcare settings must be based on sound scientific evidence and, should new risk factors be confirmed, further guidance will be needed. EU Member States could benefit from guidelines being drawn up at an EU level and their applicability being tailored to national circumstances.

1 Scope and purpose

Since 1996, the European Union (EU) has experienced a major public health threat in the field of transmissible spongiform encephalopathies (TSEs), as a consequence of outbreaks of variant Creutzfeldt–Jakob disease in several countries, the United Kingdom in particular. Public health measures and renewed research efforts have been undertaken at both a national and an EU level.

The purpose of this report is to provide a review of existing national documents aimed at controlling human TSE transmission in medical settings, taking the following into account: the epidemiological situation as regards the human TSE disease panorama in EU Member States; and recent research results. Furthermore, this report seeks to identify potential gaps and tools useful to Member States when it comes to drawing up recommendations to fit their specific needs.

2 Background – Epidemiological and public health update

In humans, transmissible spongiform encephalopathies (TSEs) are chronic, progressive disorders that prove lethal after a disease course, which generally ranges from a few months to up to two years [1]. The disease's presence cannot be identified before clinical manifestations occur. Accurate diagnosis requires post-mortem confirmation, since a characteristic neuropathological and immuno-histochemical profile of brain tissue is required. All TSEs are ascribed to similar pathophysiological mechanisms with intracellular neuronal and frequent extraneuronal deposits of an abnormal conformer of the PrP protein, causing neuronal death. For the purposes of this report, the terms TSE and CJD are deemed to encompass:

- genetic forms (gTSE), classified as gCJD, fatal familial insomnia (FFI) or Gerstmann–Sträussler–Scheinker syndrome (GSS), linked to mutations in the PRNP gene;
- sporadic CJD (sCJD) of unknown aetiology; and
- the three acquired forms.

The latter, in turn, correspond to: iatrogenic or accidentally transmitted disorders (iCJD), mainly linked to cadaveric dura mater implants or treatments with hormones of human origin (mostly growth hormone); variant vCJD, associated with dietary exposure to bovine spongiform encephalopathy (BSE), as well as being transmitted by blood transfusion, and Kuru, the form attributed to ritualistic cannibalism described among the Fore people in New Guinea. Viewed worldwide, all acquired forms are in the process of eradication, completely in the case of Kuru, and to a considerable degree in the case of iCJD and vCJD.

Epidemiological surveillance of CJD has been undertaken by the EUROCJD consortium in a small number of EU Member States since 1993. This consortium was generated as a set of Concerted Actions funded by the European Research Commission through DG XII calls for proposals. Surveillance in the remaining EU Member States has been implemented since 1998 within the framework of the NEUROCJD consortium. From 2003 onwards, human TSE surveillance in EU countries has been conducted in the form of an official network coordinated by the University of Edinburgh. The most accurate view of the epidemiological situation in the EU is to be had from surveillance reports. In Europe, TSE epidemiology has been summarised in a number of scientific reports [2,3,4,5]. Genetic forms of TSEs are particularly frequent in Slovakia and Italy, with some geographical clusters. Differences in reported sCJD might be attributable to methodology or diagnostic ascertainment. Since the 1990s, vCJD has been particularly frequent in the United Kingdom (UK) and France but has also been observed in other countries. Currently, the trend is decreasing or in some instances – such as Spain, Portugal and The Netherlands – the situation is unclear due to the low number of cases.

Prevention of CJD transmission in EU countries raised particular concern when vCJD was first described in the UK and France in 1996. Measures were implemented covering control of bovine meat, cattle exports and control of products containing bovine material. Food safety regulations, requiring measures to be taken in response to the crisis, initially in the UK and subsequently at an EU level, were introduced (Commission Decision 2000/418/EC, as amended by Decision 2001/233/EC). These included actions covering surveillance and the withdrawal of specified risk material from the food chain. Withdrawal of a medical product (Amerscam Pulmonate II) containing albumin from a donor who later developed vCJD was enforced in 1998. Other international organisations gave considerable attention to the vCJD epidemic in the early stages and provided guidance [6]..

The impact on public health measures of the strong support for TSE research in early 2000 – with special TSE calls linked to FP5, Theme 1, 'Quality of Life and Management of Living Resources' – has still to be evaluated. Research results already taken or to be taken into account when designing preventive measures in the field of blood and blood products are:

- the spread of vCJD by blood transfusion first identified in 2006 [7];
- the potential transmission of subclinical vCJD by blood products [8,9]; and
- the suggested potential risk factor of surgery-connected blood transfusion with more than 10 years latency in sCJD [10].

Concern about the spread of CJD by surgery has recently been raised by epidemiological evidence suggesting that sCJD may be linked to invasive medical procedures [11,12], particularly after a long latency.

3 Methods

In line with ECDC outsourcing policy, the Consortium for Biomedical Research in Neurodegenerative Diseases (Centro de Investigación Biomédica en Red sobre Enfermedades Neurodegenerativas – CIBERNED) at the Carlos III Institute in Madrid, created a panel made up of eight external experts to undertake the task of reviewing existing guidelines for prevention of transmission of TSEs in healthcare settings. A non-systematic search was made of web pages of official institutions worldwide, such as ministries of health, national CJD surveillance registries, national drug agencies and other national and international institutions (WHO, US Food and Drug Administration, European Medicines Agency), for documents containing TSE-related recommendations or rules governing the handling of patients or blood and blood products. Documents were not collected by officially requesting existing guidelines from the national health authorities. All original documents collected, plus a 30-item questionnaire used to compile individual, officially authorised opinions about national practices in countries belonging to the EUROCJD consortium [13], were made available to the panel and used to design a new questionnaire. Although all these international and national documents were examined by the authors with a view to designing questionnaire items, the documents were not used to complete national questionnaire responses.

The data collection procedure comprised two steps: firstly, in spring 2009, EUROCJD network coordinator, Professor RG Will (University of Edinburgh), invited all individuals in the network to identify national CJD guidelines from their Member States; and secondly, in April 2009, the questionnaire (Annex 1) was e-mailed to representatives of all countries in the EUROCJD network. The questionnaire included 91 yes/no questions focusing on national guideline content with respect to prevention of CJD transmission in healthcare settings. The questionnaire was tailored to the specific areas addressed in this project, namely:

- general questions;
- blood and blood products;
- identification and follow-up of persons 'at risk' of CJD for public health purposes;
- medical procedures; and
- medical device decontamination.

The questions covered areas observed in policies and procedures from countries with reported vCJD cases and those from the UK in particular. In addition, some new aspects were also included. In the study, questions were asked about information/recommendations contained in official documents, along with the title of and references to specific pages in such documents. Answers were tabulated and, in those cases where wide differences were seen among countries, the English, French, German, Italian, Spanish and Swedish documents cited were reviewed by one or more of the authors of this report. Documents sourcing the data available for each country are listed in Annex 3.

The proportion of positive, negative, and missing or unknown answers for the 91 items were tabulated and depicted in pie charts corresponding to the percentage of responding countries and a weighting coefficient (Annex 2). The rationale of weighting by population was an attempt to estimate the population coverage for each of the existing measures. Weights were obtained by dividing the country's population by the Slovenian population, and calculating the total representativeness of positive and negative answers for each question (see Table 1). The weighted proportion was denoted as a population index.

Variations between national document contents in cases where positive answers were given were initially examined in English, French, German, Italian, Spanish and Swedish documents. In addition, documents in other languages were read when a draft version of the report was reviewed by EUROCJD participants for possible additional specifications.

Table 1 National populations and weights by proportion of type of answer given by respondent countries

Country	Population*	Weighting coefficient
Austria	8 331 930	4.11
Belgium	10 666 866	5.27
Czech Republic	10 381 130	5.12
Denmark	5 475 791	2.70
France	61 875 822	30.54
Germany	82 217 837	40.58
Hungary	10 045 401	4.96
Italy	59 619 290	29.43
Latvia	2 270 894	1.12
Netherlands	16 405 399	8.10
Norway	4 737 171	2.34
Poland	38 115 641	18.81
Slovakia	5 400 998	2.67
Slovenia	2 025 866	1.00
Spain	45 283 259	22.35
Sweden	9 182 927	4.53
United Kingdom	61 175 586	30.20
TOTAL	**433 211 808**	**213.83**

**Source: http://epp.eurostat.ec.europa.eu/portal/page/portal/eurostat/home/*

4 Results

The following results are a summary of the guideline content reported in the completed questionnaires. Documents provided to the authors directly or cited in the answers are listed in Annex 3. Detailed tables and graphs drawn up to display the answers for each of the 91 items are shown in Annex 2.

By June 2010, EUROCJD members had submitted 17 completed questionnaires, 16 from EU Member States (accounting for 59% of the 27 EU Member States and 86% of the EU population) and one from a non-EU country, Norway. The respondent countries were Austria, Belgium, the Czech Republic, Denmark, France, Germany, Hungary, Italy, Latvia, the Netherlands, Norway, Poland, the Slovak Republic, Slovenia, Spain, Sweden and the United Kingdom.

4.1 General aspects

General aspects comprised questions relating to availability of national official policies or guidelines. The focus was on national recommendations for clinical decision-making with regard to:

- planning a broad set of diagnostic or invasive therapeutic procedures to prevent secondary transmission of CJD to other patients or healthcare workers; or
- management of incidents, i.e., events where transmission could potentially occur.

Fifteen countries (91% population index – PI) reported the availability of national policies or guidelines in which different TSE entities and diagnosis, classification and transmission mechanisms were described. Official documents addressing distribution of infectivity in human tissues and body fluids (item 1.4) were available for 12 of the respondent countries (87% PI).

Patient categorisation by risk (item 1.5) for the purpose of tailoring management recommendations was observed in documents from 13 countries. However, official TSE guidelines in only two countries, Sweden and the UK, included recommendations for the training of staff involved in blood extraction, biopsy, lumbar puncture, surgery and other invasive procedures (item 1.6). The question dealing with availability of classification frames or clinical decision matrices (item 1.7) in documents was answered positively by six countries (42% PI) and negatively by 10.

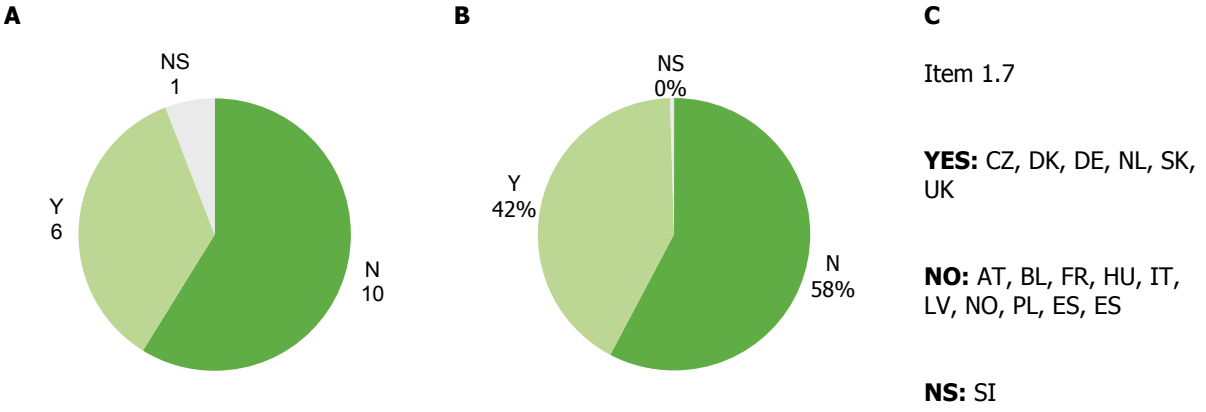
A detailed perusal of document content in selected languages showed that risk assessment for patients or individuals was available in France, Germany, Ireland, Italy, the Netherlands, Spain and the United Kingdom. Patient risk categories differed among countries but were generally built on criteria for the presence of specific symptoms, well-defined associated risk factors, such as family history, or potential risk factors, such as exposure to dura mater grafts, donor blood or potentially contaminated instruments, etc. Decision trees, based on patient risk category and the infectivity level of tissue with which the procedure was to come into contact, were described in documents from France, Italy and the United Kingdom. In general, documents focused on patients facing exposure to surgical procedures or endoscopy. Specific content varied considerably among countries, with regard to information about specific technologies or procedures, i.e., type of endoscope (fibroscope, gastroscope or arthroscope) and approach route (endonasal, oral, etc.).

Documents from 12 countries contained explicitly stated recommendations to minimise occupational exposure (item 1.8.1), with eight of these referring to existing reporting or registry systems (item 1.8.2). The absence of such documents was acknowledged by respondents from the Czech Republic, Belgium, France, Hungary, Italy, Latvia, Poland and Spain (item 1.8.2).

With respect to available recommendations for genetic counselling for persons or families with gTSE, a negative answer, representing 94% of the population (item 1.9), was obtained.

Recommendations for specific training of staff involved in invasive medical procedures was not addressed in existing TSE guidelines or documents from 13 of the respondent countries (70% PI), and only six (42% PI) included key matrices or algorithms for actions to be taken in case of possible risk of CJD transmission (Figure 1). Recommendations to minimise occupational exposure in healthcare settings were envisaged in 12 reporting countries (74% PI) and eight (45% PI) had defined systems in place for patient notification following adverse events, registration and incident follow-up.

Figure 1 Item 1.7 of the questionnaire: 'Do official guides/documents include key matrices, algorithms or decision trees for actions to be taken in case of possible risk of CJD transmission?' Responses shown by: A) country, B) population index, and C) answer category



NS = not specified

4.2 Blood and blood products

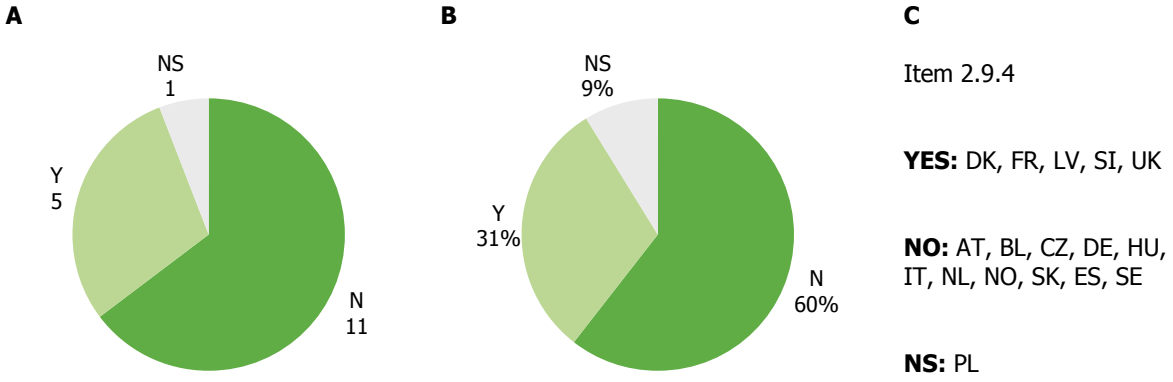
All countries recommended some blood supply protection measure in their CJD guidelines. Each respondent indicated that an official document or guideline including measures to protect blood supplies was available. The PIs for measures were as follows: for withdrawal or recall of blood or blood components, 88%; for import of plasma, 57%; and for leukodepletion, 60%.

Recommendations not to accept blood donations from persons with diverse UK-related histories varied among countries. While rejection of donations from former UK residents had a PI of 84%, in cases where the donor history was exclusively travel-related, this declined to 62%. Within categories, wide variation was in evidence, e.g., travel (item 2.5) remained unspecified in the majority of cases (except Austria) but residence was categorised by calendar time, for the most part 1980–1996, and by duration, generally more than six months.

All respondent countries recommended not accepting blood donations from any person having a family member diagnosed with CJD (item 2.7). Percentages varied little with type of CJD in donors' family history, with blood donations being rejected by 13 countries where the relative had gCJD and by 12 where the relative had vCJD and sCJD (items 2.7.1–2.7.3). However, specification of kinship showed a considerable variation, ranging from 'two or more blood relatives diagnosed with a prion-associated disease or persons informed that they are at risk following genetic counselling' in the UK, to 'all blood relatives' in Slovakia, 'close family members' in Sweden, 'all relatives' in Latvia, and undefined, i.e., 'individual decision', in Slovenia.

All countries rejected donations from recipients of hormones derived from human pituitary glands or of dura mater, and 16 countries (86% PI) rejected donations from corneal graft recipients (item 2.9.3). This proportion fell to five (31% PI) for countries having recommendations not to accept blood donations from persons at risk as a result of exposure to surgical instruments used on patients who were at risk of vCJD or later developed CJD/vCJD (item 2.9.4) (see Figure 2). Items 2.9.5 to 2.9.7 focused on 'persons at risk of vCJD due to reception of blood, plasma derivatives or tissue/organs, or donors of blood to persons who became vCJD patients', and here again there were few positive respondents, i.e., six and four countries, respectively. Only five countries (25% PI) – the Czech Republic, Denmark, Slovenia, Germany and Sweden – recommended a review of blood bank records to identify recipients of blood from CJD cases.

Figure 2 Countries not accepting blood donations from persons at risk of CJD/vCJD, owing to exposure to surgical instruments used on patients who later developed CJD/vCJD or were at risk of vCJD, broken down by: A) country, B) population index, and C) answer category



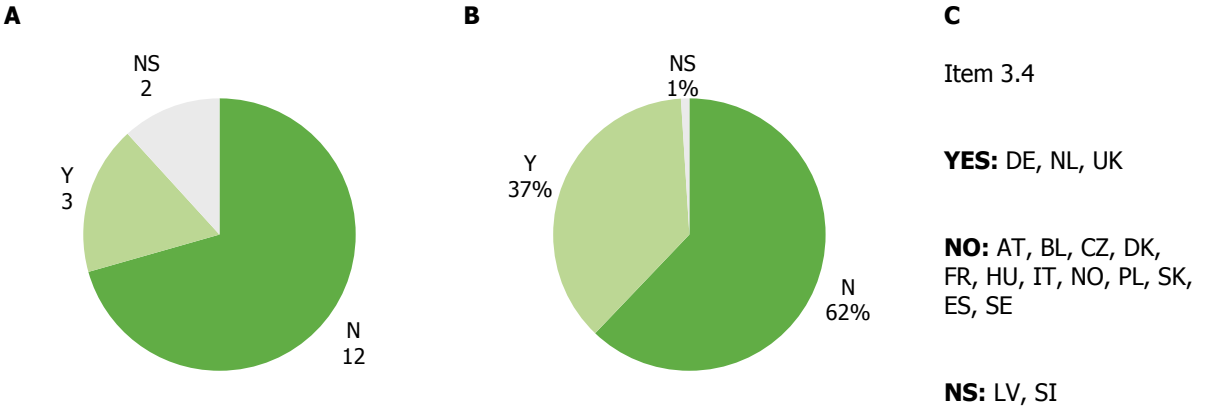
NS = not specified

4.3 Persons at higher risk for public health purposes

Items 3.1 and 3.2 enquired about the existence of documents defining asymptomatic patients deemed to be 'potentially at risk' of CJD. Twelve countries (74% PI) considered persons treated with hormones derived from human pituitary glands or cadaveric dura mater to be at risk of iCJD. Ten countries (46% PI) defined corneal graft recipients as being among such persons, and 10 countries (49% PI) also included any person who had been exposed to instruments used on a patient who later developed CJD/vCJD or was at risk of vCJD (item 3.2.1). Persons with a history of reception of blood components or plasma products from donors who later developed CJD were defined by eight countries (59% PI) as being 'at risk' of CJD. Seven and five countries (45% and 41% PI), respectively, defined the following individuals as 'persons at risk': (1) anyone who received tissue or organs from a donor that developed CJD (item 3.2.3); and (2) anyone who received blood from a donor that was subsequently diagnosed with vCJD (item 3.2.4). The latter countries included Germany, Hungary, the Netherlands, Sweden and the United Kingdom. Ten countries (71% PI) deemed a person to be at risk of gTSE where there was consanguinity with a case of probable or confirmed TSE.

Five countries (11% PI) had documented references to potential risk in cases where there was an occupational history of employment at a TSE laboratory. Three countries recommended follow-up of persons defined as 'at risk of CJD' (34% PI). Three countries reported having systems for notification and registration of persons at risk (items 3.2.6, 3.3, 3.4) (Figure 3). The national guidelines of five countries (52% PI) recommended offering specific advice to persons 'at risk of CJD' (item 3.5). Six countries in one case (26% PI) and three in another (20% PI) had policies, respectively, recommending retrospective investigation of: surgical interventions undertaken and blood donation by patients 'at risk of CJD'. For three countries, recommendations included the tracing of tissue/organ donations, and for two countries, these included the need for the general practitioner (GP) to alert the specialists to the patient's status if invasive procedures were to be conducted, and for the patient's family to be informed. For more than half the countries and more than 50% of the population, recommendations for tracing episodes, such as surgery, blood or other donations potentially transmitting the disease (items 3.7 and 3.8), were lacking. The negative or not-specified answers to items 3.8 to 3.11 were provided by the same 10–12 and 3–4 countries, with PI > 68% and < 7%, respectively.

Figure 3 Countries reporting the existence of guidelines/documents where systems for notification and registration of people at risk are defined, broken down by: A) country, B) population index, and C) answer category



NS = not specified

Negative answers may warrant separate description because, for a number of reasons, 40–56% of the population was not covered by guidelines defining patients 'at risk of vCJD'. There might be several reasons for this, including:

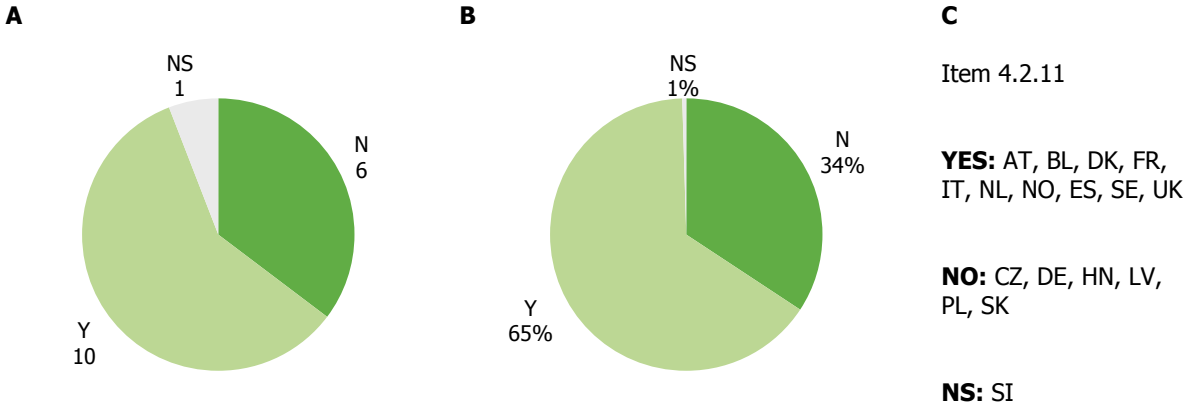
- the person could have been the source of infection for a patient transfused with blood who was later found to have vCJD, or
- the person could have been infected due to:
  - a corneal graft;
  - tissue/organs received from a donor who later developed CJD/vCJD; or
  - shared surgical instruments previously used on a patient who later developed CJD/vCJD.

Recommendations for follow-up of patients 'at risk of CJD' were lacking for 65% of the population covered, and excess risk due to occupational environmental exposure, such as staff working at a TSE laboratory, was not officially recognised in 10 countries (88% PI).

4.4 Medical procedures

A remarkably high number of countries, 14 (91% PI), had official guidelines that included specific preventive measures covering cases where symptomatic and asymptomatic CJD patients or persons 'at risk of CJD' had to undergo surgery (item 4.1). These included guidelines for single-use equipment (item 4.2.1), destruction of contaminated equipment by incineration (item 4.2.2) and decontamination of reusable instruments (item 4.2.3), as well as the use of protective clothing (item 4.2.7). Lower numbers, four to seven countries, recognised available organisational recommendations for planning operating-theatre time and personnel, or storing instruments (items 4.2.4–4.2.9). Ten countries confirmed guidelines for quarantining surgical instruments until confirmation/exclusion of CDJ/vCJD diagnosis (item 4.2.11).

Figure 4 Answers from countries with regard to existing recommendations for quarantining surgical instruments used on patients with possible CJD/vCJD, until confirmation of diagnosis, broken down by: A) country, B) population index, and C) answer category



NS = not specified

Questions regarding removal from use and quarantining endoscopes in specific situations (4.3 and 4.3.1–4.3.3), such as after contact with the central nervous system (CNS) or nasal cavity, elicited a high proportion of 'not specified' (two to six countries) and negative answers (five to eight countries). Ten countries reported having recommendations on specific procedures for decontamination of flexible endoscopes used on CJD patients, with an appendix being devoted to different endoscopes in the United Kingdom. Recommendations to remove endoscopes from use where these had come into contact with the CNS and nasal cavity were reported by four countries in each case (33% and 34% PI, respectively), with France, the Netherlands and the UK answering positively in both instances. Eight countries (50% PI) recommended quarantining endoscopes used on patients with possible CJD/vCJD, until confirmation of diagnosis. In general, countries in which vCJD has been described, such as France, the Netherlands and the UK, were represented in this group.

A similar predominance of negative or not-specified answers was observed where recommendations on prevention focused on:

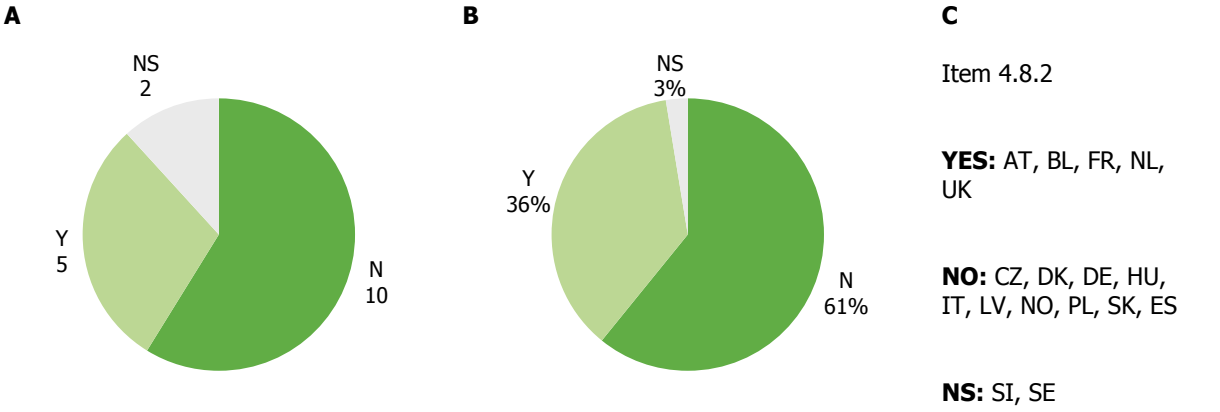
- maxillofacial and dental surgery in patients 'at risk of CJD' (item 4.5), 9/17 and 3/17, respectively;
- single use of endodontic reamers (item 4.5.1) 8/17 and 3/17, respectively;
- or destruction of other instruments in dental care (item 4.5.2), 8/17 and 3/17 respectively.

Nonetheless, population indices for recommending single-use endodontic reamers and files, and issuing instructions to decontaminate reusable instruments (item 4.5.3) were comparatively high, i.e., 65% and 77%, respectively. With regard to criteria for the destruction of other instruments used in dentistry (item 4.5.2), Austria, France and the Czech Republic furnished qualified answers of one kind or another, such as 'when difficulties to decontaminate appear', 'all instruments in contact', etc.

A different profile was seen for guideline content in terms of recommendations for the labelling, packaging and transport of TSE-infected materials (items 4.6.1–4.6.3), with a large majority of countries, 12 to 13/17, confirming their presence, and the same applied to guidance on autopsy procedures among patients with possible, probable or definite CJD/vCJD and those 'at risk of developing CJD/vCJD' (item 4.4), 13/17 countries (88% PI).

While recommendations for enabling sets of surgical instruments to be tracked through the process of decontamination so as to ensure that this had been effectively performed (item 4.8.1) featured in the guidelines of seven countries (58% PI), only five (37% PI), namely Austria, Belgium, France, the Netherlands and the United Kingdom, acknowledged having written recommendations in place to enable the identification of any given patient on whom a set of instruments had been used (item 4.8.2) (Figure 5).

Figure 5 Countries with or without existing guidelines/documents where traceability of surgical instruments enables the identification of patients on whom a given set of instruments has been used, broken down by: A) country, B) population index, and C) answer category



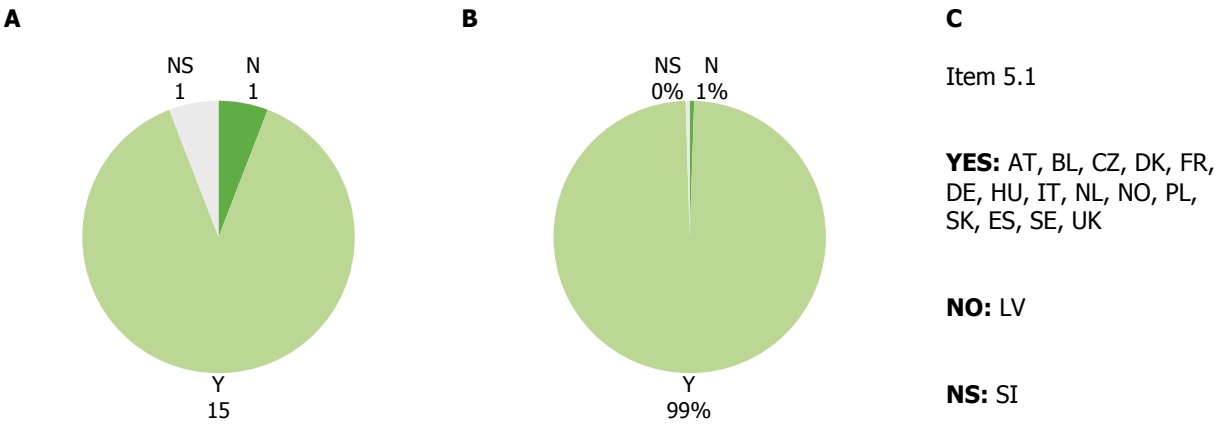
NS = not specified

Five to seven respondent countries had formal written recommendations for the single use of anaesthetic equipment (item 4.7), angioplasty catheters (item 4.9) and contact tonometers (item 4.10) in higher-risk patients. Five out of 17 countries (22% PI) had recommendations or preventive measures covering the care of TSE patients in the community.

4.5 Decontamination of medical devices

Fifteen countries (99% PI) had official documents that included guidelines on the decontamination of medical devices, and recommendations on the use of specific cleaning and chemical disinfectants or on steam-sterilisation parameters (items 5.1–5.3). See Figure 6 for the distribution pattern of medical device decontamination guidelines.

Figure 6 Mention of recommendations for decontamination of medical devices in official documents addressing CJD and other TSEs, broken down by: A) country, B) population index, and C) answer category



NS = not specified

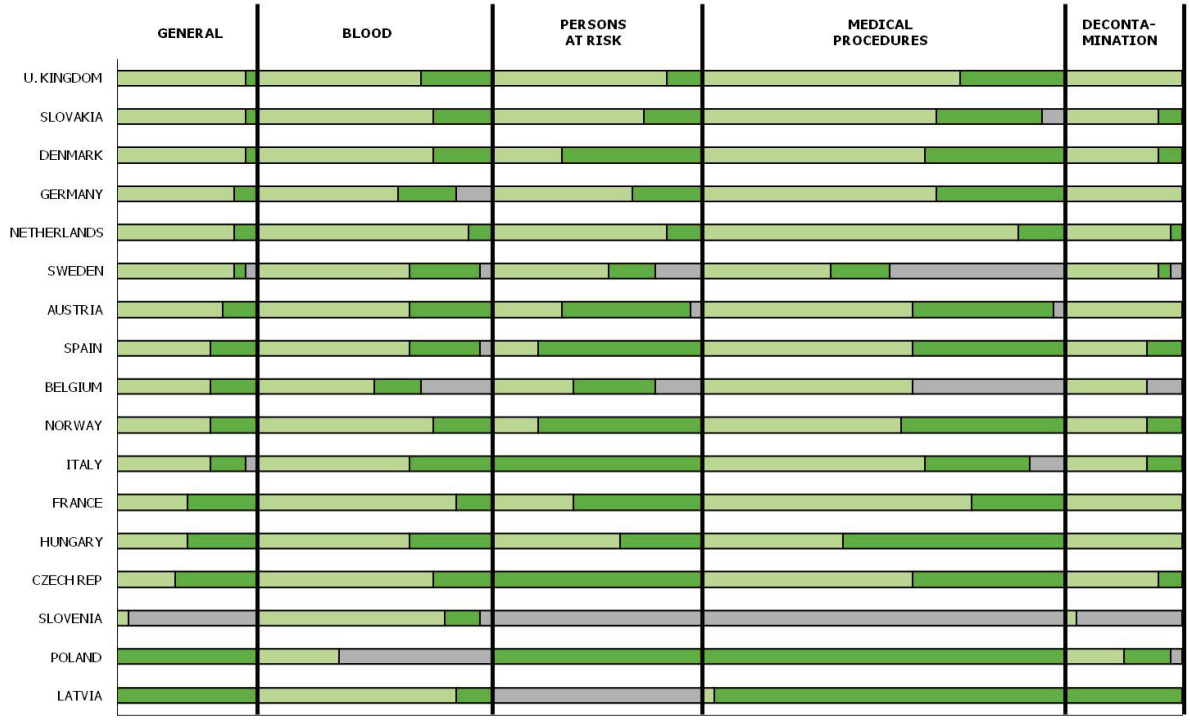
Proportions declined to 6/17 (54% PI) for recommendations on systems designed to track potentially infected reusable items of equipment (item 5.4). Specific recommendations for laboratories working with TSE agents or infective materials, such as sample tissue, appeared in 14 countries' guidelines (98% PI) (item 5.5). High proportions of positive respondents were also seen for recommendations on decontamination of work surfaces at laboratories (item 5.5.1) (91% PI), decontamination/incineration of waste from definite/probable/at-risk patients containing risk tissue (item 5.5.4) (89% PI), and decontamination of waste from post-mortem examination of patients at risk of CJD or probable/definite CJD patients (86% PI). Lower proportions were registered for recommendations on: inactivation of samples, 11/17 countries (75% PI); and decontamination of safety cabinets, seven countries (57% PI) (items 5.5.1–5.5.3).

4.6 National profiles

National profiles for 17 countries, i.e., the 16 responding EU Member States and Norway, are depicted in Figure 7. The most complete coverage would seem to be for recommendations on blood and decontamination of hospital environment/devices. Countries with the highest proportions of positive answers for existing documented recommendations were:

- the UK and Slovakia for general recommendations;
- the Netherlands and Latvia for blood-related items;
- the UK and the Netherlands for identification and follow-up of persons deemed to be at risk of TSE for public health purposes;
- the Netherlands and France for preventive measures linked to medical procedures; and
- Austria, France, Germany and the UK for decontamination of medical devices.

Figure 7 National guideline content profiles for 15 participant EU Member States and Norway. Scores correspond to the number of answers to each of the 91 questions



Legend:
Light green = positive;
Dark green = negative;
Grey = 'missing' or 'not specified.'

5 Comments

This report marks an attempt to provide an overview of the content and thrust of official policies/guidelines vis-à-vis recommendations for managing and preventing the spread of human TSEs in medical settings in the EU. Our results provide a varied and limited profile, obtained from a population in which epidemiological TSE conditions differ. Three major limitations should be borne in mind. Firstly, the data collected here were generated by TSE surveillance and TSE research experts that do not represent national health authorities, i.e., the information cannot be regarded as official policy. Secondly, the nature of the documents reviewed ranged from official guidelines to legal documents and regulations deemed by the respondents to warrant selection. Thirdly, this overview does not include an evaluation of the method of compiling official documents: these were accepted as sets of public health recommendations from each Member State, i.e., no attention was paid to the methodology of drawing up the documents, the nature of the stakeholders and the scientific evidence underlying or the expected effects of the preventive measures.

A number of the questionnaire's methodological limitations are listed below.

With respect to the general section:

- It is possible that the lists of documents provided by different respondents were based on different criteria. For instance, recall of existing documents by neurologists, haematologists and laboratory scientists may be different by virtue of their respective professional profiles. Caution is urged where negative answers are seen as a result of positive answers being missed. Whereas false negative answers could arise more easily due to early documents with the pertinent positive answers being overlooked, false positive answers, in contrast, are less plausible.
- There are regulations or statutory documents without any formal version existing as a guideline (e.g., for blood) and these may have been taken as the only documents available.
- Non-response affecting approximately 50% of Member States, rather than being random would appear to be linked to population size or to duration of time since the formal establishment of TSE surveillance.
- There are public health issues not covered by the questionnaire, since these may not directly pertain to prevention of TSE transmission in medical settings, e.g., genetic counselling or testing.

Negative answers to some questions in the general section may require interpretation, by taking positive answers to questions in the specific sections into account, e.g., a negative answer relating to the existence of documents addressing the distribution of infectivity in human tissues and body fluids was seen for countries with official documents available exclusively for blood (item 1.4). In brief, the questionnaire's ordinal item structure may possibly have rendered answering general questions somewhat difficult.

Some countries answering negatively to item 1.7, 'Do official guidelines/documents include key matrices, algorithms or decision trees for actions to be taken in case of possible risk of CJD transmission?', had decision-trees for surgical procedures, so that the answer was only negative 'in part'. The fact that the item was relevant for a varied spectrum of clinical or non-clinical situations, such as blood-donor selection, surgery and endoscopies, etc., means that specific wording in different sections might possibly have been called for.

The section on blood covered situations for blood sourcing and donation recall, which, though not exclusively, were nevertheless frequently and strongly linked to vCJD. The underlying rationale here was the higher risk posed by asymptomatic donors of presenting with gCJD, iCJD or vCJD, and international acceptance and concordance of recommendations was high. However, some items, such as 2.9.4 to 2.9.6, drew no distinction between CJD and vCJD, thereby arguably proving less informative than desired. In addition, albeit not mentioned, the section on blood overlaps with that for persons 'at risk for CJD' and public health. Some restrictions, e.g. as to blood donation in Sweden by UK visitors, may recently have changed.

The section on persons 'at risk of CJD' and public health was perhaps the most problematic from a linguistic standpoint. The concept of 'persons at risk of a specific TSE for public health purposes' was first shaped in the United Kingdom by applying statutory duties to potentially infective asymptomatic carriers of a rare disorder, as determined by an estimated 'risk of at least 1% of being infected with CJD through medical procedures'. The attack rate among exposed subjects may be high, as several persons went on to develop vCJD among a small group of recipients of non-filtered blood cells from donors who developed vCJD. Such donations have been classified as 'vCJD implicated' [9]. For other exposures, however, such as sCJD-implicated blood cells or surgical instruments used on a patient who later developed sCJD, the excess risk is debatable. As no instructions for questionnaire completion were given, it is possible that respondents' interpretation of items 3.1 to 3.11 was not similar and/or that the authors of official documents had no such concept in mind. Moreover, this concept may have been formulated in a way that was somewhat oversimplified. Indeed, since some questions (3.2.1 and 3.2.3) addressed both CJD and vCJD, answers may have lacked specificity.

The scant variation in positive answers to questions relating to non-acceptance of blood donations (2.9.4 and 2.9.6, 5/17 or 31% PI and 34% PI, respectively), when compared to identification of persons as being 'at risk' for

exposure to surgical instruments and for receipt of tissue/organs (3.2.1 and 3.2.3, 10/17 or 49% PI and 7/17 or 45% PI, respectively), may indicate that the questions were construed as being similar. However, since only approximately half the respondents answering positively to the first question answered positively to the second, in each case, the above interpretation appeared to be inappropriate.

Interesting contrasts exist between positive answers, 3/17, to item 3.4 focusing on an existing definition of notification and registries of persons 'at risk of CJD' and the higher proportion of positive respondents to item 3.7, 6/17 (2/17 concordant), when the recommendation was to check the surgical history of patients 'at risk of CJD', which was subsequently done without leaving a record in any auxiliary information system. This may suggest that the recommendation to follow up persons at risk is a step that precedes the formal setting-up of a registry or panel.

Items addressing the use of endoscopes elicited a proportion of 'not specified' responses higher than for other items. For instance, some items, such as item 4.3.1 and item 4.3.2 addressing the removal from use of any endoscope that had come into contact with the central nervous system or nasal cavity of a patient with possible CJD/vCJD, were not specifically answered by six and five countries, respectively, 22% and 20% PI. While positive respondents were countries with a history of vCJD – such as France, the Netherlands and the UK – patterns to explain the 'not specified' response by almost 1/3 of participant countries could not be identified.

A number of recommendations dealing with the definition of persons 'at risk of CJD' for public health purposes linked to CJD, apply to patients who, on the basis of their family or clinical histories, are judged to be at risk of gTSE and iTSE, respectively. Where clinical symptoms are present and CJD has not been ruled out, preventive measures may mainly apply to sCJD. In addition, recommendations for planning medical procedures or instrument management – such as quarantining, decontamination or disposal – are based on the estimated high-risk level of the procedure as suggested by tissue infectivity tables. What this means in practice is that they apply to neurosurgery or posterior eye surgery.

National patterns varied considerably. Our results may suggest that, rather than being related to cumulative incidence of vCJD since 1995, the reported positive proportion of recommendations was in fact related to the number of years of active TSE surveillance.

6 Conclusions

The results of this review confirm that there is a great degree of variation among the measures proposed to control CJD transmission in EU medical settings. Both the scope and purpose of this report would seem to be well founded.

Sixteen EU countries, representing 86% of the EU population, and Norway responded the questionnaire on existing guidelines for preventing the spread of CJD in medical settings. Ninety-one percent of countries reported having guidelines or official policies in which descriptions could be found of TSE features, diagnosis, classification, transmission mechanisms, distribution of infectivity in human tissues and body fluids, as well as patient categorisation by risk.

While all the respondents reported the existence of an official policy containing measures designed to protect blood supplies, recommendations nevertheless varied to a certain degree among the respective countries. The definition of 'person at risk for public health purposes' differed among countries and was often not explicitly mentioned. Of the respondent countries population:

- 91% is covered by guidelines on specific preventive measures for surgery, such as single-use equipment, where this is possible, or destruction of contaminated items of equipment by incineration;
- 66% is protected by measures recommending the quarantining of surgical instruments used on a possible CJD/vCJD, until confirmation of diagnosis; and
- 85% is also covered by recommendations on specific safety measures for the transport of TSE-infected materials.

Traceability of reprocessed medical devices is recommended by guidelines in seven countries (58% population).

Fifteen countries, covering 99% of the respondent population, had medical-device decontamination guidelines, including recommendations on the use of specific cleaning and disinfectant chemicals or on steam-sterilisation parameters. Ten of the countries that completed the questionnaire (61% of the population) mentioned recommendations on specific decontamination procedures for flexible endoscopes.

Positive answers that proved difficult to interpret were likely to correspond to one of two fields, namely**:** 1) where the underlying definition of 'person at risk of CJD' used in the answer might have been unclear; and, 2) where questions addressed an issue that covered both CJD and vCJD, the answer was determined solely by vCJD and should have been negative for other CJD forms.

Guidelines account for only a small number of documents officially considered as representing TSE-management policy. The following recommendations can be made for further guidance development: firstly, there is need for critical analysis of the vulnerability of research studies to bias with respect to specific hypotheses; secondly, new methodologically sound studies, as well as reanalysis of existing databases and identification of potential case-to-case transmission events, are called for; and thirdly, guidance to EU Member States should also incorporate an assessment of the scientific evidence specifically supporting the strength of each proposed recommendation or principle.

Because of the long latencies in human TSEs, identification and confirmation of new risk factors would have major implications for new strategies aimed at minimising the risks inherent in invasive procedures and treatments with blood/blood products. The availability of technical alternatives, the costs involved, and the expected benefits which may only be apparent after considerable delay and the immediate drawbacks in terms of blood donation and other policies, require careful weighting and tailoring to national circumstances.

There may be a place for guidance at an EU level.

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Annex 1: Country-specific questionnaire

This questionnaire is mainly based on the report by the Advisory Committee on Dangerous Pathogens' TSE Working Group (Health Department, UK) 'Transmissible spongiform encephalopathy agents: safe working and the prevention of infection'. Other guides on transmissible spongiform encephalopathies (TSE) have also been consulted.

A set of supporting guides and documents available in your country, obtained via EUROCJD and/or by other ways, has been attached to this questionnaire and listed at the end of the document. If you find any documents missing or invalid, please update the list introducing any new reference in the original, and in English language when applicable.

Whenever your answer to an item is 'yes', substantiate you response indicating at least one reference number and page interval of a supporting guide or document.

Country name:	
Information provided by:	

A. GENERAL		
1.	Are there official guides/documents on CJD and other human TSEs in your country that take into account the following issues?	☐ Yes ☐ No ref. _____ pp. _____
1.1	Diagnostic, definition and classification criteria for CJD and other TSEs?	☐ Yes ☐ No ref. _____ pp. _____
1.2	Sources of infection?	☐ Yes ☐ No ref. _____ pp. _____
1.3	Modes of transmission?	☐ Yes ☐ No ref. _____ pp. _____
1.4	Distribution of infectivity in human tissues and body fluids?	☐ Yes ☐ No ref. _____ pp. _____
1.5	Patients' categorisation by risk?	☐ Yes ☐ No ref. _____ pp. _____
1.6	Is it recommended to train staff involved in blood extraction, biopsy, lumbar puncture, surgery and other invasive procedures, in official TSEs guides?	☐ Yes ☐ No ref. _____ pp. _____
1.7	Do official guides/documents include key matrices or algorithms or decision trees for actions to be taken in case of possible risk of CJD transmission?	☐ Yes ☐ No ref. _____ pp. _____
1.8	Occupational exposure	☐ Yes ☐ No ref. _____ pp. _____

1.8.1	Are recommendations to minimise occupational exposure in heathcare settings considered in official guides/documents on TSEs?	☐ Yes ☐ No ref. _____ pp. _____
1.8.2	Do any official guide/document define systems for accident notification, registry and follow-up?	☐ Yes ☐ No ref. _____ pp. _____
1.9	Recommendations on available genetic counselling for persons/families with gTSEs	☐ Yes ☐ No ref. _____ pp. _____

B. BLOOD		
2.	Are there in your country official guides/documents on CJD and other human TSEs that include measures to protect blood supplies?	☐ Yes ☐ No ref. _____ pp. _____
2.1	Withdrawal and recall of any blood components, plasma products or tissues obtained from any individual who later develops vCJD	☐ Yes ☐ No ref. _____ pp. _____
2.2	Importing plasma for fractionation to manufacture plasma products	☐ Yes ☐ No ref. _____ pp. _____
2.3	Removal of white blood cells from all blood used for transfusion (leucodepletion)	☐ Yes ☐ No ref. _____ pp. _____
2.4	Not accepting blood donations from people who have received a blood transfusion in the UK since 1980	☐ Yes ☐ No ref. _____ pp. _____
2.5	Not accepting blood donations from people with history of travel to UK	☐ Yes ☐ No ref. _____ pp. _____
2.6	Not accepting blood donations from former UK residents	☐ Yes ☐ No ref. _____ pp. _____
2.6.1	If yes, indicate period of residence in the UK: _____	
2.7	Not accepting blood donations from a person with a family member diagnosed with CJD	☐ Yes ☐ No ref. _____ pp. _____
2.7.1	sCJD	☐ Yes ☐ No ref. _____ pp. _____
2.7.2	gCJD	☐ Yes ☐ No ref. _____ pp. _____
2.7.3	vCJD	☐ Yes ☐ No ref. _____ pp. _____

2.8	If yes, what degree of relative _____	
2.9	Not accepting blood donations from people at risk	☐ Yes ☐ No ref. _____ pp. _____
2.9.1	Recipients of hormone derived from human pituitary glands	☐ Yes ☐ No ref. _____ pp. _____
2.9.2	Dura mater recipients	☐ Yes ☐ No ref. _____ pp. _____
2.9.3	Corneal graft recipients	☐ Yes ☐ No ref. _____ pp. _____
2.9.4	Those at risk of CJD/vCJD due to exposure to surgical instruments used on patient who later developed CJD/vCJD or were at risk of vCJD	☐ Yes ☐ No ref. _____ pp. _____
2.9.5	Those at risk of vCJD due to receiving of blood components or plasma derivatives	☐ Yes ☐ No ref. _____ pp. _____
2.9.6	Those at risk of CJD/vCJD due to receiving tissues/organs	☐ Yes ☐ No ref. _____ pp. _____
2.9.7	Those at risk of vCJD for being the source of infection of some other vCJD patient to whom their blood was transfused	☐ Yes ☐ No ref. _____ pp. _____
2.10	Does any official guide/document on CJD and other TSEs recommend reviewing blood bank records to identify recipients of blood from CJD cases?	☐ Yes ☐ No ref. _____ pp. _____

C. People 'at risk' AND PUBLIC HEALTH		
3.1	According to official guides/documents, are asymptomatic patients considered to be potentially at risk due to iatrogenic exposure to CJD?	
3.1.1	Recipients of hormone derived from human pituitary glands	☐ Yes ☐ No ref. _____ pp. _____
3.1.2	Dura mater recipients	☐ Yes ☐ No ref. _____ pp. _____
3.1.3	Corneal graft recipients	☐ Yes ☐ No ref. _____ pp. _____
3.2	According to official guides/documents, are asymptomatic patients considered to be…	
3.2.1	…at risk of CJD/vCJD due to exposure to instruments used on a patient who later develop CJD/vCJD or was at risk of vCJD?	☐ Yes ☐ No ref. _____ pp. _____

3.2.2	…at risk of vCJD due to receipt of blood components or plasma derivatives of a donor that later develop CJD?	☐ Yes ☐ No ref. _____ pp. _____
3.2.3	…at risk of CJD/vCJD due to receipt of tissues/organs of a donor that later develop CJD ?	☐ Yes ☐ No ref. _____ pp. _____
3.2.4	…at risk of vCJD due to the probability they could have been the source of infection for a patient transfused with their blood who was later found to have vCJD?	☐ Yes ☐ No ref. _____ pp. _____
3.2.5	…at risk of gTSE due to consanguinity with a relative with probable or actual TSE?	☐ Yes ☐ No ref. _____ pp. _____
3.2.6	…at risk of TSE due to occupational environmental exposure as personnel working at a TSE laboratory.?	☐ Yes ☐ No ref. _____ pp. _____
3.3	Are there any official guide/document with recommendations on the follow up of 'at risk' people?	☐ Yes ☐ No ref. _____ pp. _____
3.4	Do these official guides/documents define systems for notification and registry of people at risk?	☐ Yes ☐ No ref. _____ pp. _____
3.5	Do these guides recommend offering patients specific advice?	☐ Yes ☐ No ref. _____ pp. _____
3.6	Do these guides recommend to advice to at risk patient's GP?	☐ Yes ☐ No ref. _____ pp. _____
3.7	Do these guides recommend checking if patient at risk has had surgery?	☐ Yes ☐ No ref. _____ pp. _____
3.8	Do these guides recommend checking if patients at risk have donated blood?	☐ Yes ☐ No ref. _____ pp. _____
3.9	Do these guides recommend checking if at risk patients have donated organs or tissues?	☐ Yes ☐ No ref. _____ pp. _____
3.10	Do these guides recommend that GP inform on the patient's risk status if surgery, dental surgery or any invasive diagnostic procedure is required?	☐ Yes ☐ No ref. _____ pp. _____
3.11	Do these guides recommend that patient's family need to be informed?	☐ Yes ☐ No ref. _____ pp. _____

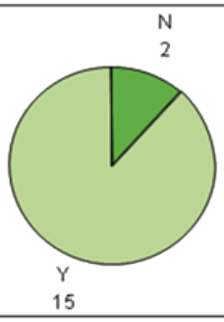
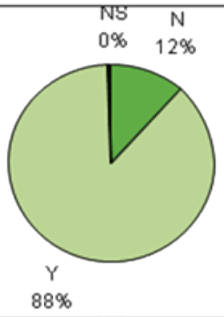
D. MEDICAL PROCEDURES		
4.1	Are there in your country official guides/documents on CJD and other TSEs that include specific preventative measures when symptomatic patients and asymptomatic patients at risk need to go through surgery?	☐ Yes ☐ No ref. _____ pp. _____
4.1	Do these official recommendations include:	
4.2.1	Single-use disposable equipment if possible	☐ Yes ☐ No ref. _____ pp. _____
4.2.2	To destroy by incineration contaminated items of equipment	☐ Yes ☐ No ref. _____ pp. _____
4.2.3	Special recommendations on decontamination of reusable instruments	☐ Yes ☐ No ref. _____ pp. _____
4.2.4	Intervention in a specific operating theatre	☐ Yes ☐ No ref. _____ pp. _____
4.2.5	Perform procedure at the end of the list	☐ Yes ☐ No ref. _____ pp. _____
4.2.6	Minimum number of healthcare personnel	☐ Yes ☐ No ref. _____ pp. _____
4.2.7	Single-use protective clothing (mask, gloves, etc.)	☐ Yes ☐ No ref. _____ pp. _____
4.2.8	If procedure is conducted at the bedside, environment specific cleaning	☐ Yes ☐ No ref. _____ pp. _____
4.2.9	Recommendations on storage of instruments for research purposes	☐ Yes ☐ No ref. _____ pp. _____
4.2.10	Specific guidance on safe use of lasers	☐ Yes ☐ No ref. _____ pp. _____
4.2.11	Quarantining surgical instrument used on a possible CJD/vCJD until the diagnosis is confirmed	☐ Yes ☐ No ref. _____ pp. _____
4.3	Do official guides/documents recommend specific procedures for the decontamination of flexible endoscopes used in patients with possible, probable or definite CJD/vCJD and those at risk of developing CJD/vCJD? What kind of endoscopes? _____	☐ Yes ☐ No ref. _____ pp. _____
4.3.1	Is it recommended to remove from use endoscopes in contact with CNS?	☐ Yes ☐ No ref. _____ pp. _____

4.3.2	Is it recommended to remove from use endoscopes in contact with nasal cavity?	☐ Yes ☐ No ref. _____ pp. _____
4.3.3	Is it recommended to quarantine endoscopes used on a possible CJD/vCJD until the diagnosis is confirmed?	☐ Yes ☐ No ref. _____ pp. _____
4.4	Do official guides/documents consider recommendations for autopsy procedures in patients with possible, probable or definite CJD/vCJD and those at risk of developing CJD/vCJD?	☐ Yes ☐ No ref. _____ pp. _____
4.5	Are there in your country official guides/documents on CJD and other TSEs that include specific precautions for maxillofacial surgery and endodontic procedures in symptomatic patients and asymptomatic patients at risk?	☐ Yes ☐ No ref. _____ pp. _____
4.5.1	Are single use endodontic reamers and files recommended?	☐ Yes ☐ No ref. _____ pp. _____
4.5.2	Is it recommended to destroy other instruments? Instruments: _____	☐ Yes ☐ No ref. _____ pp. _____
4.5.3	Are there special recommendations on decontamination of reusable instruments?	☐ Yes ☐ No ref. _____ pp. _____
4.6	Are there in your country official guides/documents on CJD and other TSEs that include specific safety measures in the transport of TSE infected materials?	☐ Yes ☐ No ref. _____ pp. _____
4.6.1	Recommendations on packaging	☐ Yes ☐ No ref. _____ pp. _____
4.6.2	Recommendations on labelling	☐ Yes ☐ No ref. _____ pp. _____
4.6.3	Recommendations on transporting	☐ Yes ☐ No ref. _____ pp. _____
4.7	Are there in your country official guides/documents on CJD and other TSEs that recommend single-use anaesthetic equipment, including tubing and masks that have been in direct mucosal contact with high-risk patients?	☐ Yes ☐ No ref. _____ pp. _____
4.8	In those guides is traceability recommended to allow sets of surgical instruments:	
4.8.1	To be tracked through decontamination processes to ensure they have been carried out effectively?	☐ Yes ☐ No ref. _____ pp. _____
4.8.2	To enable the identification of a patient with whom a set of instruments have been used?	☐ Yes ☐ No ref. _____ pp. _____

4.9	Are there in your country official guides/documents on CJD and other TSEs that recommend single-use of devices such as angioplasty catheters to be used with higher-risk patients?	☐ Yes ☐ No ref. _____ pp. _____
4.10	Are there in your country official guides/documents on CJD and other TSEs that include specific precautions for use of contact tonometers in ophthalmic care of symptomatic patients and asymptomatic patients at risk?	☐ Yes ☐ No ref. _____ pp. _____
4.11	Are there in your country official guides/documents on CJD and other TSEs that recommend specific preventative measures for nursing care of CJD and other TSEs patients in the community?	☐ Yes ☐ No ref. _____ pp. _____

E. Decontamination		
5.1	Are there in your country official documents on CJD and other TSEs that include guidelines on cleaning and sterilisation of medical devices?	☐ Yes ☐ No ref. _____ pp. _____
5.2	Are there in those guides/documents official recommendations on the use of specific chemical disinfectants?	☐ Yes ☐ No ref. _____ pp. _____
5.3	Are there in those guides/documents official recommendations on autoclaving?	☐ Yes ☐ No ref. _____ pp. _____
5.4	Are there in those guides/documents official recommendations on systems to track reusable items of equipment used on potentially infected sites?	☐ Yes ☐ No ref. _____ pp. _____
5.5	Do those guides make specific recommendations for laboratories working with TSE agents or infective materials?	☐ Yes ☐ No ref. _____ pp. _____
5.5.1	Do those guides make specific recommendations for laboratories on decontamination of work surfaces?	☐ Yes ☐ No ref. _____ pp. _____
5.5.2	Inactivation of samples	☐ Yes ☐ No ref. _____ pp. _____
5.5.3	Decontamination of safety cabinets	☐ Yes ☐ No ref. _____ pp. _____
5.5.4	Decontamination of wastes including incineration of waste from definite/probable/ at risk patients containing risk tissue	☐ Yes ☐ No ref. _____ pp. _____
5.5.5	Decontamination of waste from post-mortem examination of definite/probable/ at risk patients	☐ Yes ☐ No ref. _____ pp. _____

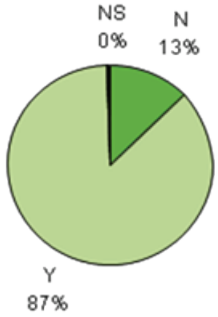
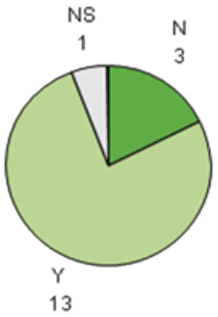
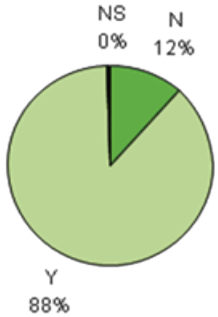
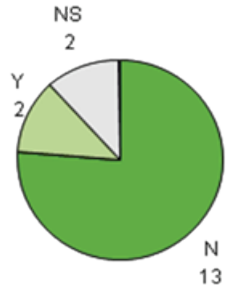
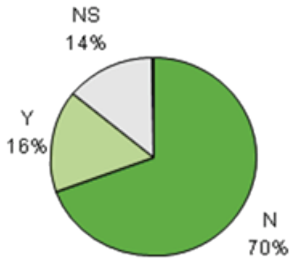
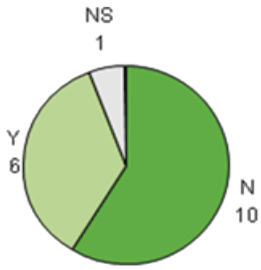
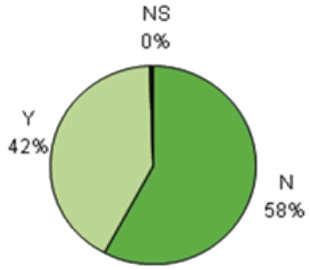
Annex 2: Questionnaire responses

GENERAL	A	B
1. Are there official guides/documents on CJD and other human TSEs in your country? **Yes:** AT, BL, CZ, DK, FR, DE, HU, IT, NL, NO, SK, SI, ES, SE, UK **No:** LV, PL		
Do they take into account the following issues?		
1.1 Diagnostic, definition and classification criteria for CJD and other TSEs? **Yes:** AT, BL, DK, FR, DE, HU, IT, NL, NO, SK, ES, SE, UK **No:** LV, PL , CZ **NS:** SI		
1.2 Sources of infection? **Yes:** AT, BL, DK, FR, DE, HU, IT, NL, NO, SK, ES, SE, UK **No:** LV, PL , CZ **NS:** SI		
1.3 Modes of transmission? **Yes:** AT, BL, CZ, DK, FR, DE, HU, IT, NL, NO, SK, ES, SE, UK **No:** LV, PL **NS:** SI		

Yes
No
Not specified

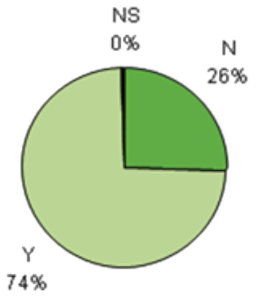
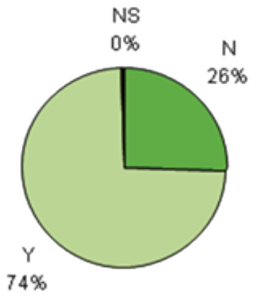
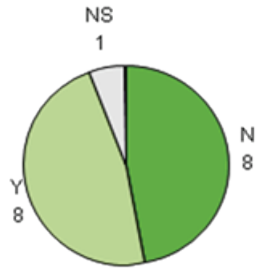
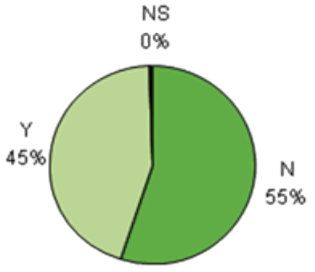
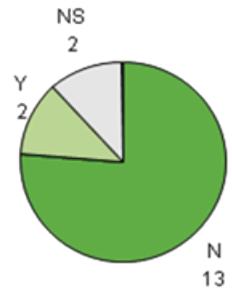
A = Crude (number of respondant countries)
B = Percent respondant countries' population

AT: Austria, BL: Belgium, CZ: Czech Rep., DE: Germany, DK: Denmark, ES: Spain, FR: France, HU: Hungary, IT: Italy, LV: Latvia, NL: The Netherlands, NO: Norway, PL: Poland, SE: Sweden, SI: Slovenia, SK: Slovakia, UK: United Kingdom

	A	B
1.4 Distribution of infectivity in human tissues and body fluids? **Yes:** AT, BL, DK, FR, DE, HU, IT, NL, SK, ES, SE, UK **No:** LV, NO, PL, CZ **NS:** SI		
1.5 Patients' categorisation by risk? **Yes:** AT, BL, DK, FR, DE, HU, IT, NL, NO, SK, ES, SE, UK **No:** CZ, LV, PL **NS:** SI		
1.6 Is it recommended to train staff involved in blood extraction, biopsy, lumbar puncture, surgery and other invasive procedures, in official TSEs guides? **Yes:** SE, UK **No:** AT, BL, CZ, DK, FR, DE, HU, LV, NL, NO, PL, SK, ES **NS:** IT, SI		
1.7 Do official guides/documents include key matrices or algorithms or decision trees for actions to be taken in case of possible risk of CJD transmission? **Yes:** CZ, DK, DE, NL, SK, UK **No:** AT, BL, FR, HU, IT, LV, NO, PL, ES, SE **NS:** SI		

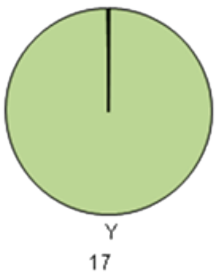
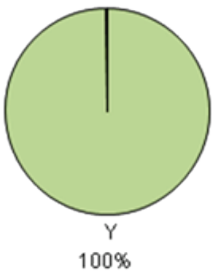
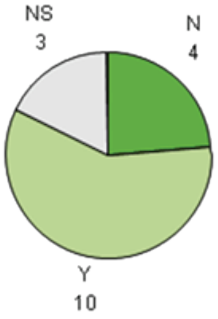
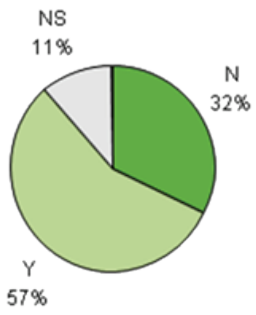
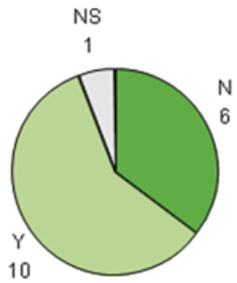
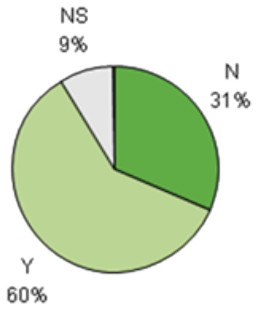
Yes
No
Not specified

A = Crude (number of respondant countries)
B = Percent respondant countries' population

	A	B
1.8 Occupational exposure **Yes:** AT, BL, CZ, DK, DE, IT, NL, NO, SK, ES, SE, UK **No:** FR, HU, LV, PL **NS:** SI		
1.8.1 Are recommendations to minimize occupational exposure in heath care settings considered in official guides/documents on TSEs? **Yes:** AT, BL, CZ, DK, DE, IT, NL, NO, SK, ES, SE, UK **No:** FR, HU, LV, PL **NS:** SI		
1.8.2 Do any official guide/document define systems for accident notification, registry and follow up? **Yes:** AT, DK, DE, NL, NO, SK, SE, UK **No**: BL, CZ, FR, HU, IT, LV, PL , ES **NS:** SI		
1.9 Recommendations on available genetic counselling for persons/families with gTSEs **Yes:** DK, SK **No:** AT, BL, CZ, FR, DE, HU, IT, LV, NL, NO, PL, ES, UK **NS:** SI, SE		

Yes
No
Not specified

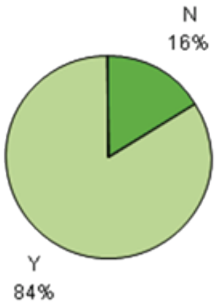
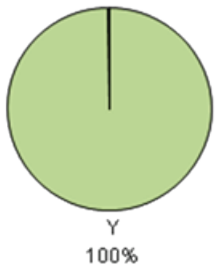
A = Crude (number of respondant countries)
B = Percent respondant countries' population

BLOOD	A	B
2. Are there in your country official guides/documents on CJD and other human TSEs that include measures to protect blood supplies? **Yes:** AT, BL, CZ, DK, FR, DE, HU, IT, LV, NL, NO, PL, SK, SI, ES, SE, UK		
2.1 Withdrawal and recall of any blood components, plasma products or tissues obtained from any individual who later develops vCJD. **Yes:** BL, CZ, DK, FR, DE, HU, IT, LV, NL, NO, SI, ES, SE, UK **No:** AT, SK **NS:** PL		
2.2 Importing plasma for fractionation to manufacture plasma products **Yes:** BL, CZ, DK, DE, LV, NL, NO, SK, ES, UK **No:** AT, FR, HU, IT **NS:** PL, SI, SE		
2.3 Removal of white blood cells from all blood used for transfusion (leucodepletion) **Yes:** AT, BL, FR, DE, LV, NL, NO, SI, SE, UK **No:** CZ, DK, HU, IT, SK, ES **NS:** PL		

Yes
No
Not specified

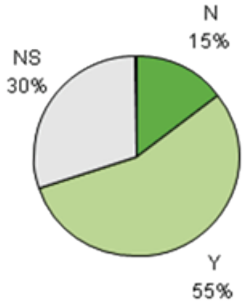
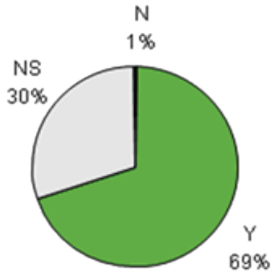
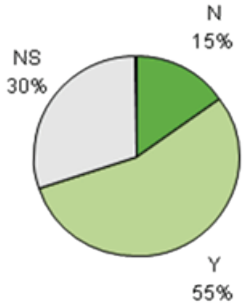
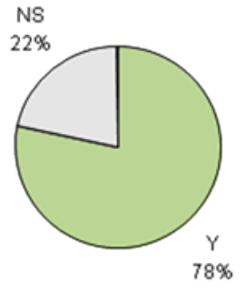
A = Crude (number of respondant countries)
B = Percent respondant countries' population

32

	A	B
2.4 Not accepting blood donations from people who have received a blood transfusion in the UK since 1980 **Yes:** AT, BL, CZ, FR, DE, HU, IT, LV, NL, NO, SK, SI, ES, UK **No:** DK, SE **NS:** PL		
2.5 Not accepting blood donations from people with history of travel to UK **Yes:** AT, CZ, DK, FR, HU, IT, LV, NL, NO, PL, SK, SI, ES **No:** BL, DE, SE, UK		
2.6 Not accepting blood donations from former UK residents **Yes:** AT, BL, CZ, DK, DE, FR, HU, IT, LV, NL, NO, PL, SK, SI, ES **No:** SE, UK		
2.7 Not accepting blood donations from a person with a family member diagnosed with CJD **Yes:** AT, BL, CZ, DK, FR, DE, HU, IT, LV, NL, NO, PL, SK, SI, ES, SE, UK		

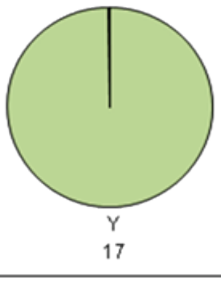
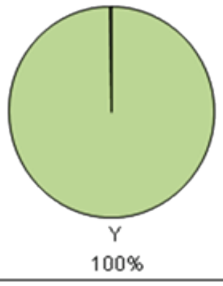
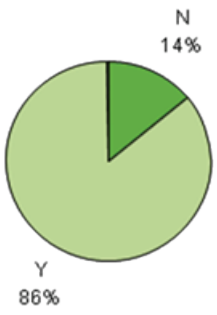
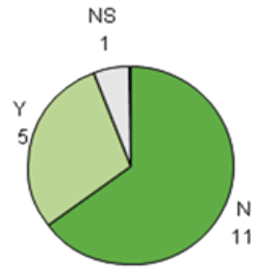
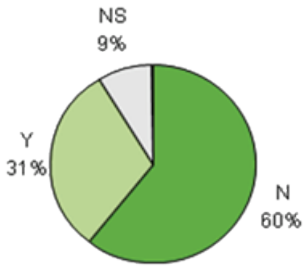
Yes
No
Not specified

A = Crude (number of respondant countries)
B = Percent respondant countries' population

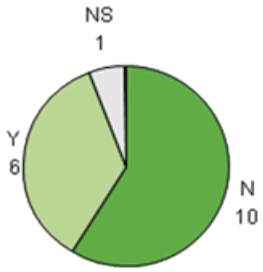
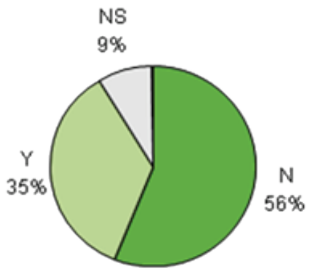
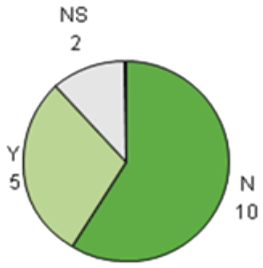
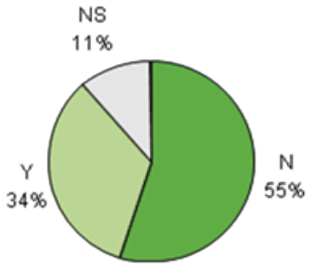
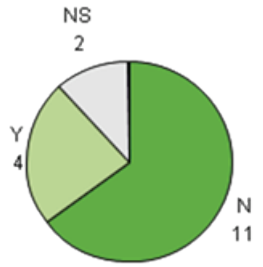
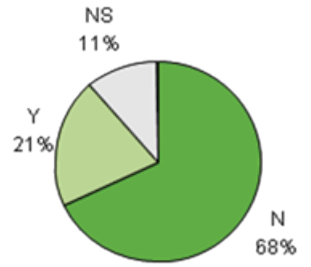
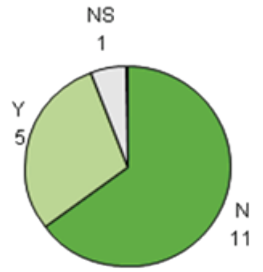
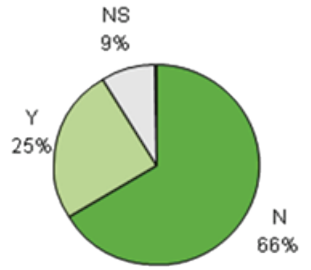
	A	B
2.7.1 sCJD **Yes:** AT, CZ, DK, FR, HU, IT, NL, NO, SK, SI, ES, SE **No:** LV, UK **NS:** BL, DE, PL		
2.7.2 gCJD **Yes:** AT, CZ, DK, FR, HU, IT, NL, NO, SK, SI, ES, SE, UK **No:** LV **NS:** BL, DE, PL		
2.7.3 vCJD **Yes:** AT, CZ, FR, HU, IT, LV, NL, NO, SK, SI, ES, SE **No:** DK, UK **NS:** BL, DE, PL		
2.9 Not accepting blood donations from people at risk **Yes:** AT, CZ, DK, FR, DE, HU, IT, LV, NL, NO, SK, SI, SE, UK **NS:** BL, PL, ES		

Yes
No
Not specified

A = Crude (number of respondant countries)
B = Percent respondant countries' population

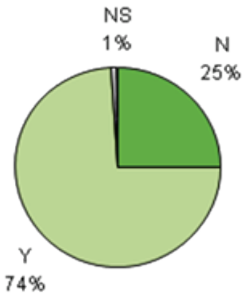
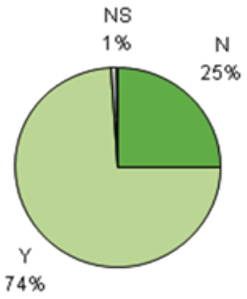
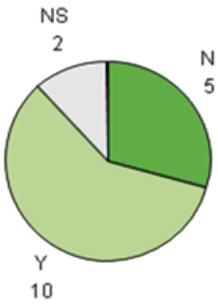
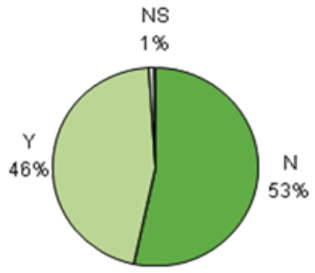
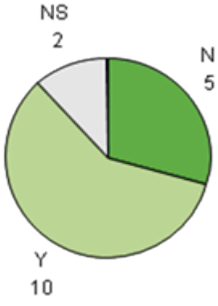
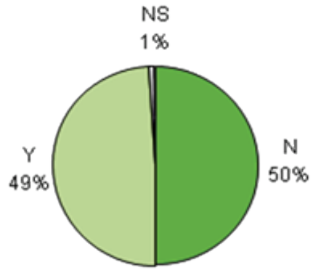
	A	B
2.9.1 Recipients of hormone derived from human pituitary glands **Yes:** AT, BL, CZ, DK, FR, DE, HU, IT, LV, NL, NO, PL, SK, SI, ES, SE, UK		
2.9.2 Duramater recipients **Yes:** AT, BL, CZ, DK, FR, DE, HU, IT, LV, NL, NO, PL, SK, SI, ES, SE, UK		
2.9.3 Corneal graft recipients **Yes:** AT, BL, CZ, DK, FR, DE, HU, IT, LV, NL, NO, PL, SK, SI, ES, SE **No:** UK		
2.9.4 Those at risk of CJD/vCJD due to exposure to surgical instruments used on patient who later developed CJD/vCJD or were at risk of vCJD **Yes:** DK, FR, LV, SI, UK **No:** AT, BL, CZ, DE, HU, IT, NL, NO, SK, ES, SE **NS:** PL		

A = Crude (number of respondant countries)
B = Percent respondant countries' population

	A	B
2.9.5 Those at risk of vCJD due to receiving of blood components or plasma derivatives **Yes:** DK, FR, LV, NL, SK, UK **No:** AT, BL, CZ, DE, HU, IT, NO, SI, ES, SE **NS:** PL		
2.9.6 Those at risk of CJD/vCJD due to receiving tissues/organs **Yes**: FR, LV, NL, SK, UK **No:** AT, CZ, DK, DE, HU, IT, NO, SI, ES, SE **NS:** BL, PL		
2.9.7 Those at risk of vCJD for being the source of infection of some other vCJD patient to whom their blood was transfused **Yes:** LV, NL, SE, UK **No:** AT, CZ, DK, FR, DE, HU, IT, NO, SK, SI, ES **NS:** BL, PL		
2.10 Does any official guide/document on CJD and other TSEs recommend reviewing blood bank records to identify recipients of blood from CJD cases? **Yes:** CZ, DK, DE, SI, SE **No:** AT, BL, FR, HU, IT, LV, NL, NO, SK, ES, UK **NS:** PL		

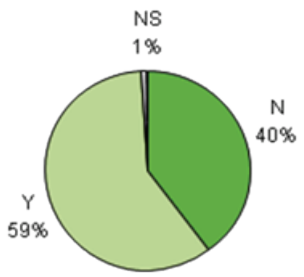
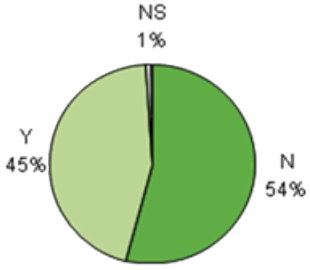
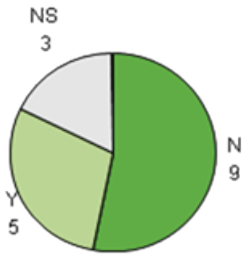
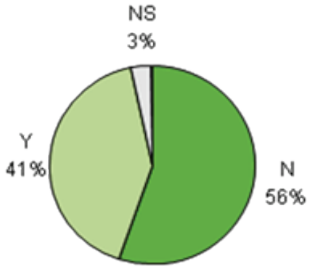
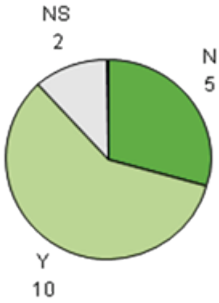
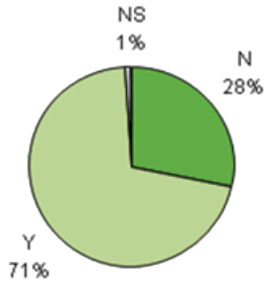
Yes
No
Not specified

A = Crude (number of respondant countries)
B = Percent respondant countries' population

PEOPLE "AT RISK" FOR PUBLIC HEALTH	A	B
3.1 According to official guides/documents, are asymptomatic patients considered to be potentially at risk due to iatrogenic exposure to CJD? **3.1.1** Recipients of hormone derived from human pituitary glands **Yes:** AT, BL, DK, FR, DE, HU, NL, NO, SK, ES, SE, UK **No:** CZ, IT, PL **NS:** LV, SI		
3.1.2 Duramater recipients **Yes:** AT, BL, DK, FR, DE, HU, NL, NO, SK, ES, SE, UK **No:** CZ, IT, PL **NS:** LV, SI		
3.1.3 Corneal graft recipients **Yes:** AT, BL, DK, DE, HU, NL, NO, SK, ES, SE **No:** CZ, FR, IT, PL , UK **NS:** LV, SI		
3.2 According to official guides/documents, are asymptomatic patients considered to be… **3.2.1** at risk of CJD/vCJD due to exposure to instruments used on a patient who later develop CJD/vCJD or was at risk of vCJD? **Yes:** AT, BL, DK, DE, HU, NL, NO, SK, SE, UK **No:** CZ, FR, IT, PL, ES **NS:** LV, SI		

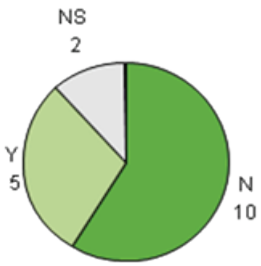
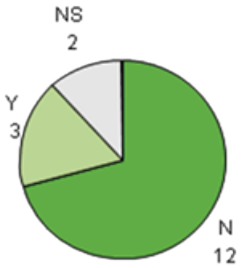
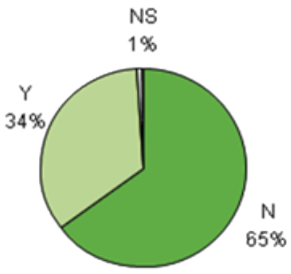
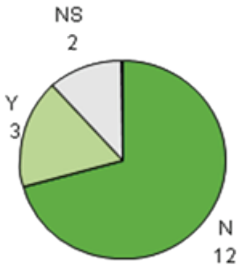
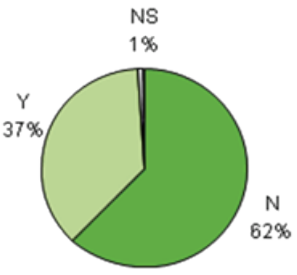
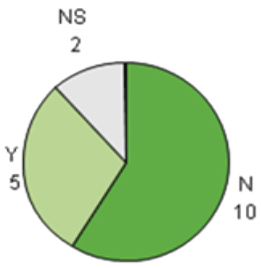
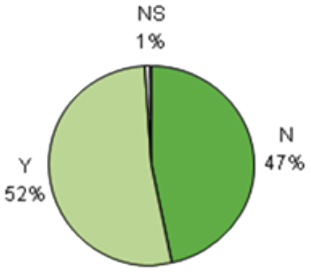
Yes
No
Not specified

A = Crude (number of respondant countries)
B = Percent respondant countries' population

	A	B
3.2.2 at risk of vCJD due to receipt of blood components or plasma derivatives of a donor that later develop CJD? **Yes:** BL, DE, FR, HU, NL, SK, SE, UK **No:** AT, CZ, DK, IT, NO, PL, ES **NS:** LV, SI		
3.2.3 at risk of CJD/vCJD due to receipt of tissues/organs of a donor that later develop CJD ? **Yes**: BL, DE, HU, NL, SK, SE, UK **No:** AT, CZ, DK, IT, FR, NO, PL, ES **NS:** LV, SI		
3.2.4 at risk of vCJD due to the probability they could have been the source of infection for a patient transfused with their blood who was later found to have vCJD? **Yes:** DE, HU, NL, SE, UK **No:** AT, CZ, DK, IT, FR, NO, PL, SK, ES **NS:** BL, LV, SI		
3.2.5 at risk of gTSE due to consanguinity with a relative with probable or actual TSE? **Yes:** AT, BL, DK, FR, DE, NL, SK, ES, SE, UK **No:** CZ, HU, IT, NO, PL **NS:** LV, SI		

Yes
No
Not specified

A = Crude (number of respondant countries)
B = Percent respondant countries' population

	A	B
3.2.6 at risk of TSE due to occupational environmental exposure as personnel working at a TSE laboratory? **Yes:** DK, HU, NL, SK, SE **No:** AT, BL, CZ, IT, FR, DE, NO, PL, ES, UK **NS:** LV, SI		
3.3 Are there any official guide/document with recommendations on the follow up of "at risk" people? **Yes:** DE, SK, UK **No:** AT, BL, CZ, DK, FR, HU, IT, NL, NO, PL, ES, SE **NS:** LV, SI		
3.4 Do these official guides/documents define systems for notification and registry of people at risk? **Yes:** DE, NL, UK **No:** AT, BL, CZ, DK, FR, HU, IT, NO, PL, SK, ES, SE **NS:** LV, SI		
3.5 Do these guides recommend offering patients specific advice? **Yes:** DE, FR, NL, SK, UK **No:** AT, BL, CZ, DK, HU, IT, NO, PL, ES, SE **NS:** LV, SI		

Yes
No
Not specified

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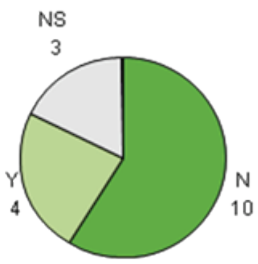
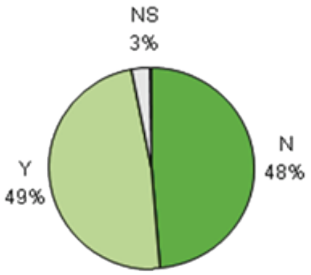
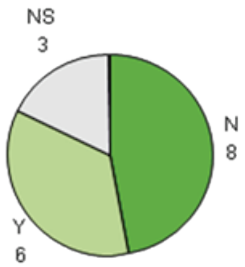
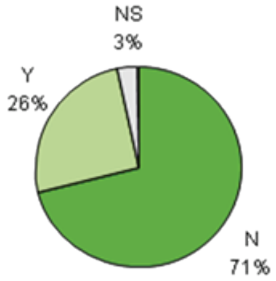
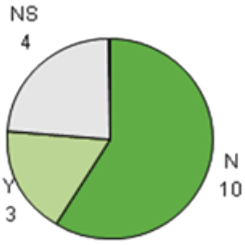
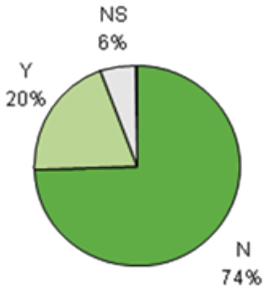
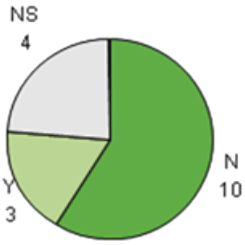
	A	B
3.6 Do these guides recommend to advice to at risk patient's GP? **Yes:** DE, FR, SK, UK **No:** BL, CZ, DK, HU, IT, NL, NO, PL, ES, SE **NS:** AT, LV, SI		
3.7 Do these guides recommend checking if patient at risk has had surgery? **Yes:** AT, HU, NL, SK, SE, UK **No:** CZ, DK, FR, DE, IT, NO, PL, ES **NS:** BL, LV, SI		
3.8 Do these guides recommend checking if patients at risk have donated blood? **Yes:** HU, NL, UK **No:** AT, CZ, DK, FR, DE, IT, NO, PL, SK, ES **NS:** BL, LV, SI, SE		
3.9 Do these guides recommend checking if at risk patients have donated organs or tissues? **Yes:** HU, NL, SK **No:** AT, CZ, DK, FR, DE, IT, NO, PL, ES, UK **NS:** BL, LV, SI, SE		

Yes
No
Not specified

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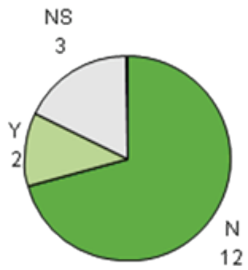
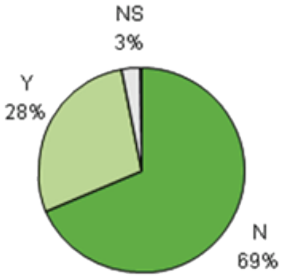
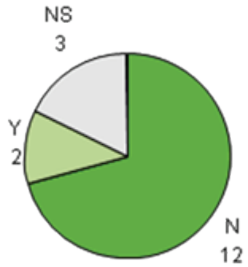
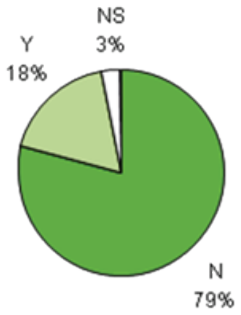
B = Percent respondant countries' population

	A	B
3.10 Do these guides recommend that GP inform on the patient's risk status if surgery, dental surgery or any invasive diagnostic procedure is required? **Yes**: FR, UK **No:** AT, BL, CZ, DK, DE, HU, IT, NL, NO, PL, SK, ES **NS:** LV, SI, SE		
3.11 Do these guides recommend that patient's family need to be informed? **Yes:** NL, UK **No:** AT, BL, CZ, DK, FR, HU, IT, DE, NO, PL, SK, ES **NS:** LV, SI, SE		

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B = Percent respondant countries' population

MEDICAL PROCEDURES	A	B
4.1 Are there in your country official guides/documents on CJD and other TSEs that include specific preventative measures when symptomatic patients and asymptomatic patients at risk need to go through surgery? **Yes:** AT, BL, CZ, DK, FR, DE, HU, IT, NL, NO, SK, ES, SE, UK **No:** LV, PL **NS:** SI		
4.2 Do these official recommendations include: **4.2.1** Single-use disposable equipment if possible **Yes:** AT, BL, CZ, DK, FR, DE, HU, IT, NL, NO, SK, ES, SE, UK **No:** LV, PL **NS:** SI		
4.2.2 To destroy by incineration contaminated items of equipment **Yes**: AT, BL, CZ, DK, FR, DE, HU, IT, NL, NO, SK, ES, SE, UK **No:** LV, PL **NS:** SI		
4.2.3 Special recommendations on decontamination of reusable instruments **Yes:** AT, BL, CZ, DK, FR, DE, HU, IT, NL, NO, SK, ES, SE, UK **No:** LV, PL **NS:** SI		

Yes
No
Not specified

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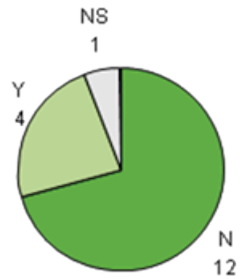
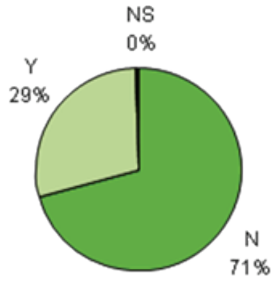
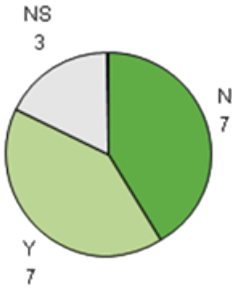
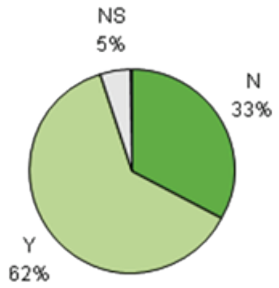
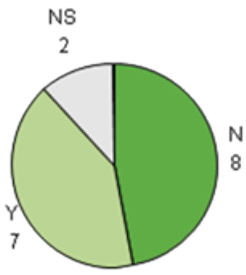
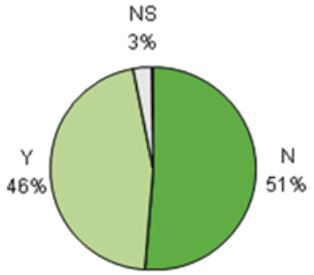
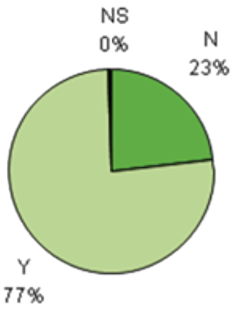
	A	B
4.2.4 Intervention in a specific operating theatre **Yes:** BL, HU, IT, ES **No:** AT, CZ, DK, FR, DE, LV, PL, NL, NO, SK, SE, UK **NS:** SI		
4.2.5 Perform procedure at the end of the list **Yes:** DK, DE, HU, IT, SK, ES, UK **No:** AT, CZ, FR, LV, PL, NL, NO, **NS:** BL, SI, SE		
4.2.6 Minimum number of health care personnel **Yes:** DK, IT, NL, NO, SK, ES, UK **No:** AT, CZ, FR, DE, HU, LV, PL, SE **NS:** BL, SI		
4.2.7 Single-use protective clothing (mask, gloves, etc.) **Yes:** AT, BL, CZ, DK, DE, HU, IT, LV, NL, NO, SK, ES, SE, UK **No:** FR, PL **NS:** SI		

Yes
No
Not specified

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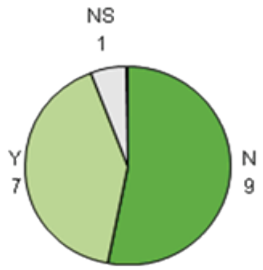
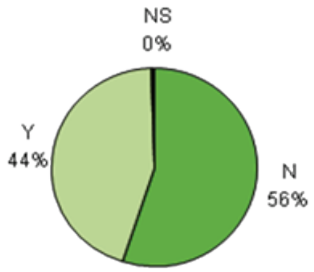
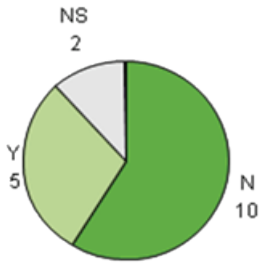
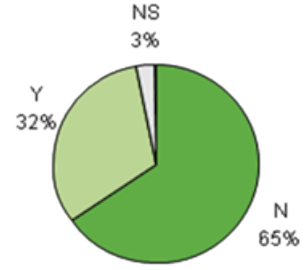
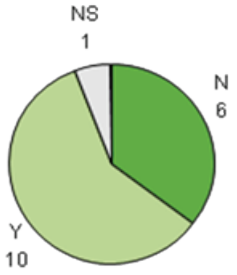
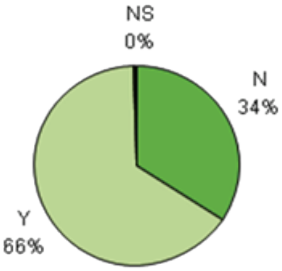
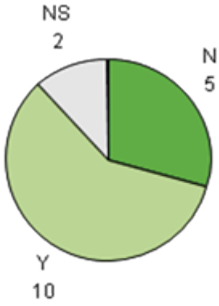
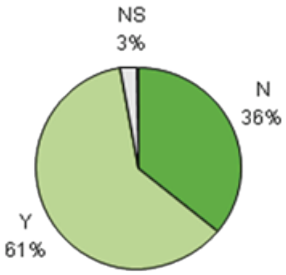
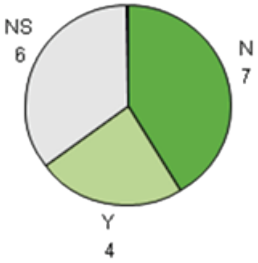
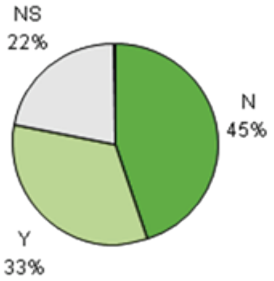
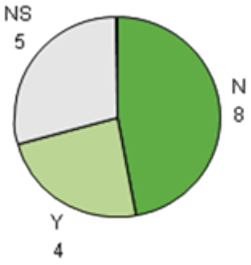
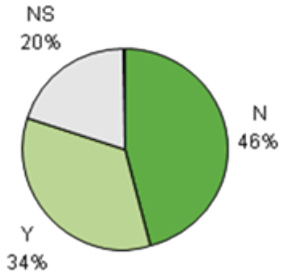
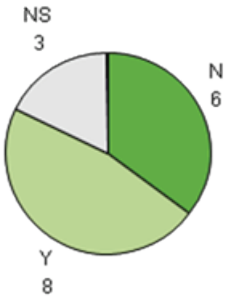
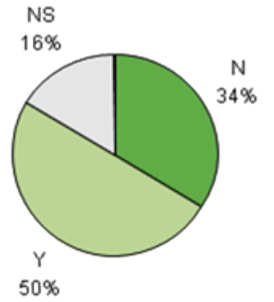
B = Percent respondant countries' population

	A	B
4.2.8 If procedure is conducted at the bedside, environment specific cleaning **Yes:** AT, BL, DE, HU, IT, NL, SK **No:** CZ, DK, FR, LV, NO, PL, ES, SE, UK **NS:** SI		
4.2.9 Recommendations on storage of instruments for research purposes **Yes:** HU, NL, SK, ES, UK **No:** AT, CZ, DK, FR, DE, IT, LV, NO, PL, SE **NS**: BL, SI		
4.2.10 Specific guidance on safe use of lasers **No:** AT, CZ, DK, FR, DE, HU, IT, LV, NL, NO, PL, SK, ES, SE, UK **NS:** BL, SI		
4.2.11 Quarantining surgical instrument used on a possible CJD/vCJD until the diagnosis is confirmed **Yes:** AT, BL, DK, FR, IT, NL, NO, ES, SE, UK **No:** CZ, DE, HU, LV, PL, SK **NS:** SI		

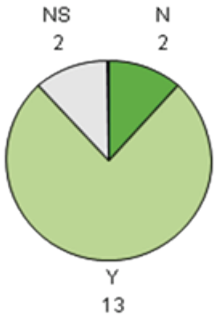
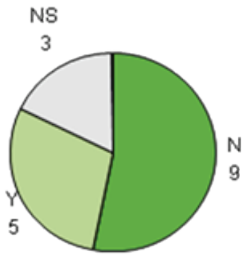
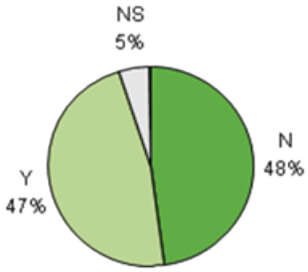
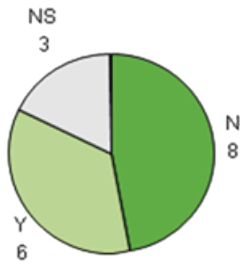
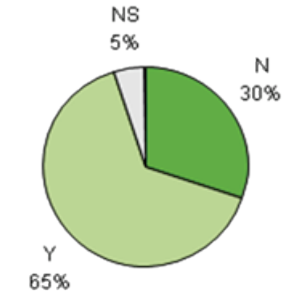
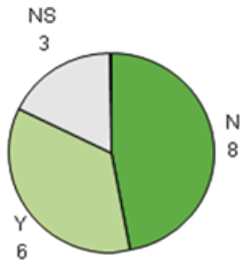
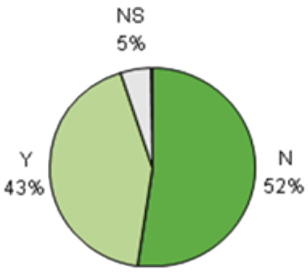
Yes
No
Not specified

A = Crude (number of respondant countries)
B = Percent respondant countries' population

	A	B
4.3 Do official guides/documents recommend specific procedures for the decontamination of flexible endoscopes used in patients with possible, probable or definite CJD/vCJD and those at risk of developing CJD/vCJD? **Yes:** AT, BL, CZ, DK, DE, FR, NL, NO, SK, UK **No:** HU, IT, LV, PL, ES **NS:** SI, SE		
4.3.1 Is it recommended to remove from use endoscopes in contact with CNS? **Yes:** FR, NL, NO, UK **No:** CZ, DK, DE, HU, LV, PL, ES **NS:** AT, BL, IT, SK, SI, SE		
4.3.2 Is it recommended to remove from use endoscopes in contact with nasal cavity? **Yes:** AT, FR, NL, UK **No:** CZ, DK, DE, HU, LV, NO, PL, ES **NS:** BL, IT, SK, SI, SE		
4.3.3 Is it recommended to quarantine endoscopes used on a possible CJD/vCJD until the diagnosis is confirmed? **Yes:** BL, DK, FR, HU, NL, NO, ES, UK **No:** AT, CZ, DE, LV, PL, SK **NS:** IT, SI, SE		

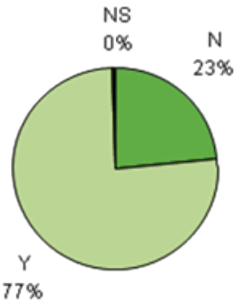
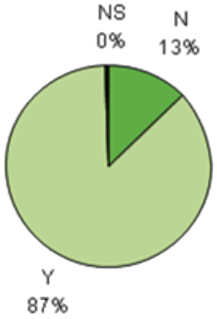
Yes
No
Not specified

A = Crude (number of respondant countries)
B = Percent respondant countries' population

	A	B
4.4 Do official guides/documents consider recommendations for autopsy procedures in patients with possible, probable or definite CJD/vCJD and those at risk of developing CJD/vCJD? **Yes:** AT, BL, CZ, DK, FR, DE, HU, IT, NL, NO, SK, ES, UK **No:** LV, PL **NS:** SI, SE		
4.5 Are there in your country official guides/documents on CJD and other TSEs that include specific precautions for maxillofacial surgery and endodontic procedures in symptomatic patients and asymptomatic patients at risk? **Yes:** DK, FR, IT, NL, UK **No:** AT, CZ, DE, HU, LV, NO, PL, SK, ES **NS:** BL, SI, SE		
4.5.1 Are single use endodontic reamers and files recommended? **Yes:** CZ, DK, FR, DE, IT, UK **No:** AT, HU, LV, NL, NO, PL, SK, ES **NS:** BL, SI, SE		
4.5.2 Is it recommended to destroy other instruments? **Yes:** AT, CZ, DK, FR, DE, NL **No:** HU, IT, LV, NO, PL, SK, ES, UK **NS:** BL, SI, SE		

Yes
No
Not specified

A = Crude (number of respondant countries)
B = Percent respondant countries' population

	A	B
4.5.3 Are there special recommendations on decontamination of reusable instruments? **Yes:** AT, BL, CZ, DK, FR, DE, HU, IT, NL, NO, SK, ES , SE **No:** LV, PL, UK **NS:** SI		
4.6 Are there in your country official guides/documents on CJD and other TSEs that include specific safety measures in the transport of TSE infected materials? **Yes:** AT, CZ, DK, FR, DE, IT, NL, NO, SK, ES , SE, UK **No:** HU, LV, PL **NS**: BL, SI		
4.6.1 Recommendations on packaging **Yes:** AT, BL, CZ, FR, DE, IT, NL, NO, SK, ES , SE, UK **No:** DK, HU, LV, PL **NS:** SI		
4.6.2 Recommendations on labelling **Yes:** AT, BL, CZ, DK, FR, DE, IT, NL, NO, SK, ES , SE, UK **No:** HU, LV, PL **NS:** SI		

Yes
No
Not specified

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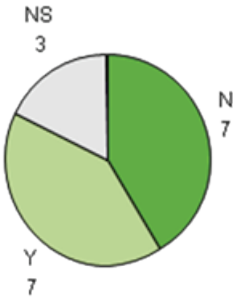
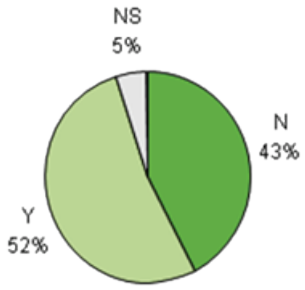
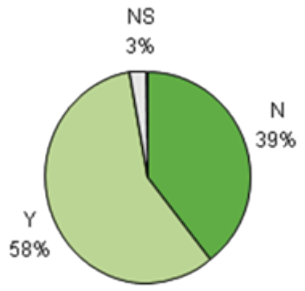
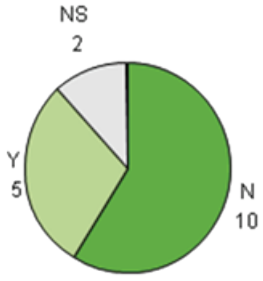
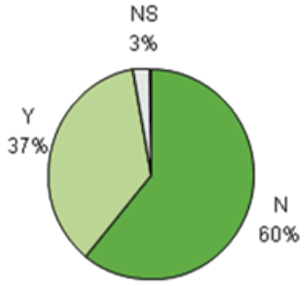
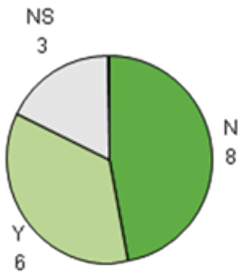
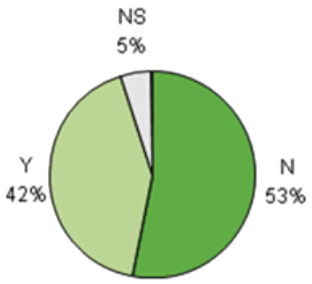
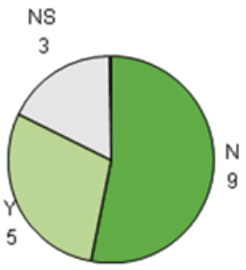
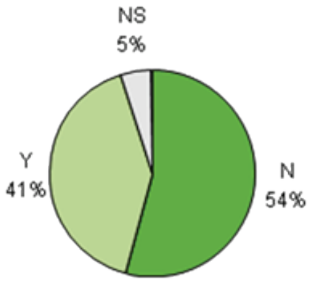
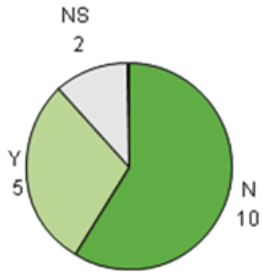
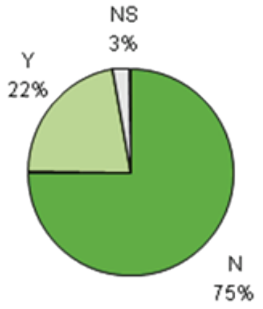
B = Percent respondant countries' population

	A	B
4.6.3 Recommendations on transporting **Yes:** AT, BL, CZ, FR, DE, IT, NL, NO, SK, ES , SE, UK **No:** DK, HU, LV, PL **NS:** SI		
4.7 Are there in your country official guides/documents on CJD and other TSEs that recommend single-use anaesthetic equipment, including tubing and masks that have been in direct mucosal contact with high-risk patients? **Yes:** CZ, DK, FR, DE, NL, SK, ES **No:** AT, HU, IT, LV, NO, PL, UK **NS:** BL, SI, SE		
4.8 In those guides is traceability recommended to allow sets of surgical instruments: **4.8.1** To be tracked through decontamination processes to ensure they have been carried out effectively? **Yes:** AT, BL, CZ, FR, DE, NL, UK **No:** DK, HU, IT, LV, NO, PL, SK, ES **NS:** SI, SE		
4.8.2 To enable the identification of a patient with whom a set of instruments have been used? **Yes:** AT, BL, FR, NL, UK **No:** CZ, DK, DE, HU, IT, LV, NO, PL, SK, ES **NS:** SI, SE		

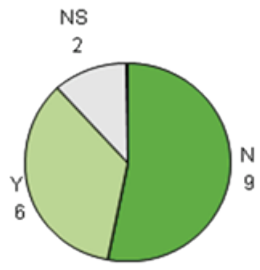
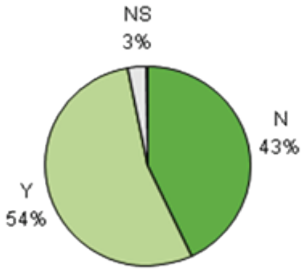
Yes
No
Not specified

A = Crude (number of respondant countries)
B = Percent respondant countries' population

	A	B
4.9 Are there in your country official guides/documents on CJD and other TSEs that recommend single-use of devices such as angioplasty catheters to be used with higher-risk patients? **Yes:** CZ, DK, FR, DE, NL, SK **No:** AT, HU, IT, LV, NO, PL, ES, UK **NS:** BL, SI, SE		
4.10 Are there in your country official guides/documents on CJD and other TSEs that include specific precautions for use of contact tonometers in ophthalmic care of symptomatic patients and asymptomatic patients at risk? **Yes:** CZ, FR, DE, NL, SK **No:** AT, DK, IT, HU, LV, NO, PL, ES, UK **NS:** BL, SI, SE		
4.11 Are there in your country official guides/documents on CJD and other TSEs that recommend specific preventative measures for nursing care of CJD and other TSEs patients in the community? **Yes:** BL, IT, NL, NO, SK **No:** AT, CZ, DK, FR, DE, HU, LV, PL, ES, UK **NS:** SI, SE		

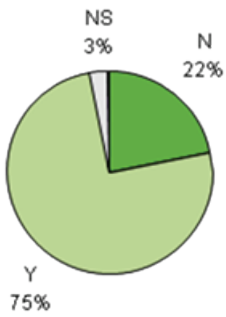
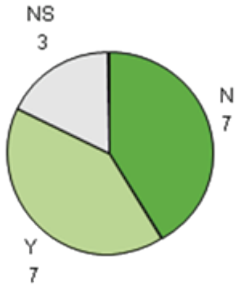
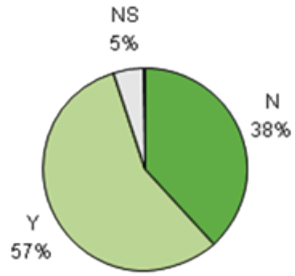
Yes
No
Not specified

A = Crude (number of respondant countries)
B = Percent respondant countries' population

DECONTAMINATION	A	B
5.1 Are there in your country official documents on CJD and other TSEs that include guidelines on cleaning and sterilization of medical devices? **Yes:** AT, BL, CZ, DK, FR, DE, HU, IT, NL, NO, PL, SK, ES, SE, UK **No:** LV **NS:** SI		
5.2 Are there in those guides/documents official recommendations on the use of specific chemical disinfectants? **Yes:** AT, BL, CZ, DK, FR, DE, HU, IT, NL, NO, PL, SK, ES, SE, UK **No:** LV **NS:** SI		
5.3 Are there in those guides/documents official recommendations on autoclaving? **Yes:** AT, BL, CZ, DK, FR, DE, HU, IT, NL, NO, PL, SK, ES, SE, UK **No:** LV **NS:** SI		
5.4 Are there in those guides/documents official recommendations on systems to track reusable items of equipment used on potentially infected sites? **Yes:** AT, CZ, FR, DE, HU, UK **No:** DK, IT, LV, NL, NO, PL, SK, ES, SE **NS:** BL, SI		

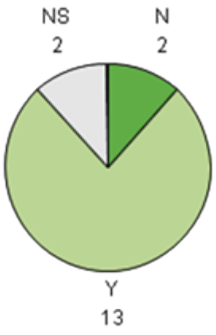
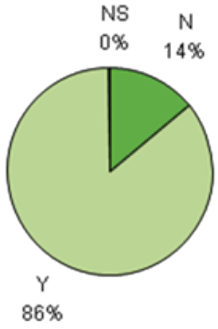
Yes
No
Not specified

A = Crude (number of respondant countries)
B = Percent respondant countries' population

	A	B
5.5 Do those guides make specific recommendations for laboratories working with TSE agents or infective materials? **Yes:** AT, BL, CZ, DK, FR, DE, HU, IT, NL, PL, SK, ES, SE, UK **No:** LV, NO **NS:** SI		
5.5.1 Do those guides make specific recommendations for laboratories on decontamination of work surfaces? **Yes:** AT, BL, CZ, DK, FR, DE, HU, IT, NL, NO, SK, ES, SE, UK **No:** LV, PL **NS:** SI		
5.5.2 Inactivation of samples **Yes:** AT, DK, FR, DE, HU, IT, NL, NO, SK, SE, UK **No:** CZ, LV, PL, ES **NS:** BL, SI		
5.5.3 Decontamination of safety cabinets **Yes:** AT, DK, FR, DE, HU, NL, UK **No:** CZ, IT, LV, NO, PL, SK, ES **NS:** BL, SI, SE		

Yes
No
Not specified

A = Crude (number of respondant countries)
B = Percent respondant countries' population

	A	B
5.5.4 Decontamination of wastes including incineration of waste from definite/probable/ at risk patients containing risk tissue **Yes:** AT, BL, CZ, FR, DE, HU, IT, NL, NO, SK, ES, SE, UK **No:** DK, LV **NS:** PL, SI		
5.5.5 Decontamination of waste from post-mortem examination of definite/probable/ at risk patients **Yes:** AT, BL, CZ, DK, FR, DE, HU, NL, NO, PL, SK, SI, ES, SE, UK **No:** IT, LV		

Yes
No
Not specified

A = Crude (number of respondant countries)
B = Percent respondant countries' population

Annex 3: List of national documents examined

When titles or rubrics are available in non-original English, the translation was provided by questionnaire respondents and its nature, or origin, was not indicated.

Austria

1. Richtlinie für den Schutz vor einer Übertragung der Creutzfeldt–Jakob-Krankheit bei invasiven Eingriffen. (Erstellt vom Arbeitskreis CJK des BMGFJ; Fassung: 10. Oktober 2007).

2. 44. Bundesgesetz: Blutsicherheitsgesetz 1999 – BSG 1999.

3. Erlass des Bundesministeriums für Gesundheit, GZ 21.700/41-II/D/2 96.

4. Verpackung, Kennzeichnung und Beförderung von biologischen und ansteckungsgefährlichen Stoffen. Arbeitskreis für Hygiene in Gesundheitseinrichtungen des Magistrats der Stadt Wien MA15, Stand 26. März 2009.

Belgium

1. Inactivation and security of tissues and cells. Part I: Creutzfeldt–Jakob diseases and tissue transplantation: risk and prevention (July 2008) (CSS 8143).

2. Recommendation of brain autopsy in case of transcranial removal of ossicles of the internal ear and technical recommendations for brain autopsy (February 2008) (CSS 8340).

3. Considering risk transmission of CJD, could medical examination be mandatory in a public health approach (November 2007) (CSS 8153).

4. Information to give in case of risk to transmit Creutzfeldt–Jakob Diseases (October 2007) (CSS 8152).

5. Recommendations for prevention of TSE transmission in hospitals (Creutzfeldt–Jakob Diseases) (Revision May 2006) (CSH 7276-2).

6. Opinion on vCJD transmission risk through transfusion of human plasma products (November 2005) (CSH 8097).

7. Opinion on vCJD transmission risk through blood transfusion (June 2005) (CSH 8048-4).

8. Recommendations for professionals potentially exposed to TSE in the process of animal products elimination. (February 2002) (CSH 5932).

9. Recommendations for professionals potentially exposed to TSE in slaughterhouses, cutting workshops and butcheries (May 2001) (CSH 7795-13).

Czech Republic

1.Zajištění hlášení, diagnostiky a léčení creutzfeld-jakobovy nemoci (cjn) a nové varianty této nemoci (nvcjn) – Vyhláška ministerstva zdarvotnictví Zn.: HEM-370-22.1.01/3238. [Measures to assure the report, diagnostics and treatment of the Creutzfeld–Jakobs disease (CJD) and the new variant of the Creutzfeld–Jakobs disease (nvCJD). Promulgation of Ministery for Public Health. No.: HEM-370-22.1.01/3238].

2. Vyhláška č. 195/2005 Sb., kterou se upravují podmínky předcházení vzniku a šíření infekčních onemocnění a hygienické požadavky na provoz zdravotnických zařízení a ústavů sociální péče – příloha č. 3. [Excerpt form promulgation No.: 195/2005 sb. to adjust conditions to prevent infectious diseases emergence and propagation and hygienic requirements to regulate the operation in public health and social care institutions, supplement No. 3].

3. Vyhláška MZ ČR 143 / 2008 Sb. (vyhláška o lidské krvi) §10 a příloha 3.

4. Zákon 378/2007 Sb. (zákon o léčivu), §24.

Denmark

1. Prionsygdomme. Hygiejniske forholdsregler til forebyggelse af smitte I sundhedssektoren. Retningslinier. Statens Serum Institut, 2001. (Prion diseases. Infection control guidelines to prevent transmission in the healthcare sector. Statens Serum Institut, 2001). To be updated (2011).

2. Transfusionsmedicinske Standarder. (Medical transfusion standards, Danish Society for Clinical Immunology, 2008, 343 pp).

3. Bortskaffelse af klinisk risikoaffald (Vejledning Miljøstyrelsen 4/1998). (Handling of healthcare risk waste, Danish Environmental Protection Agency, 1998).

4. Vejledning om lægers anmeldelse af Creutzfeldt–Jakob sygdom og beslægtede spongiforme encefalopatier. No. 54/1997. (Notification procedure of CJD and other spongiform encephalopathies. Ministry of Health/Danish Medical Board, No. 54, May 7, 1997).

5. Specialevejledning for neurologi. Sundhedsstyrelsen 26. februar 2010. (Neurology. Danish Medical Board, 2010).

France

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There are also Scottish guidance & standards not listed here, available upon request.

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This report, along with those relating to the CIBERNED-ECDC 1250 project, took material shape thanks to unstinting and efficient support for the web SharePoint interface, data and document management and graphic display received from the staff of the Spanish CJD Registry and Department of Applied Epidemiology-CIBERNED, and from Javier Almazán, Enrique Alcalde and Fuencisla Avellanal, in particular.

Acknowledgements

The authors would like to thank the following:

- all the EUROCJD Surveillance Network members and officials who reviewed and/or furnished documents constituting the basis of this study, and particularly: H Budka, R Höftberger and GG Kovacs, Austria; M Radoslav, Czech Republic; JP Brandel, France; K Schenkel and I Zerr, Germany; A Ladogana, Italy; I Lucenko, Latvia; CM van Duijn and M Schuur, the Netherlands; H Blystad, Norway; B Sikorska, Poland; E Mitrova, Slovakia; N Caks, A Kraigher and M Popovic, Slovenia; E Alcalde and F Avellanal, Spain; AL Hammarin and S Ivarsson, Sweden; and T Lindsay and HT Ward, United Kingdom;
- Dr Martin Mengel, ECDC EPIET fellow at the Carlos III Institute of Health, Madrid, and Alberto Rábano, neuropathologist and member of the Consultant Group, for their careful perusal of the documents in German;
- Alberto Jiménez, at the Support Data Unit, for his help with communications;
- Isabel Iribarren, Carlos III University, for her support in the documents search;
- Julian Pérez Gil, María Ángeles Pérez, Almudena Flores, Almudena Olivares and Ana María Cochón, from the Fundación CIEN and CIBERNED, for providing administrative support;
- the following members of the Consultant Group for their invaluable comments and criticisms:
  - Elias Sanz, Carlos III University, Madrid;
  - Outi Lyytikainen, Finnish Institute of Public Health, Helsinki;
  - Alberto Rábano, Fundacion CIEN, Madrid;
  - Rosario Arrieta Gallástegui, La Paz University Teaching Hospital, Madrid;
  - Odorina Tello Anchuela, National Centre for Epidemiology, Carlos III Institute, Madrid;
  - Pablo Martínez Martín, Carlos III Institute, Madrid;
  - Pascual Sánchez-Juan, Marqués de Valdecilla University Teaching Hospital, Santander;
  - Åke Siden, Huddinge University Teaching Hospital, Stockholm;
  - Nicky Connor, UK Incidents Panel, London;
  - Sophie Quolin, CJD Registry, Brussels;
  - Hans Blystad, National Institute of Infectious Diseases, Oslo;
  - Juan Martinez Lage, Virgen Arriaxaca Hospital, Murcia;
  - Mabel Cruz, Karolinska Institute, Stockholm;
  - Paul Brown, USA;
  - Margarita Ramírez de Santa Pau, Madrid; and
- Ana-Belén Escriva, Johanna Takkinen and Frode Forland at ECDC, Stockholm, for their stimulating cooperation.